ASX Announcement
30 January 2023

Neurotech International

Quarterly Activities Report
for the period ending 31 December 2022

Neurotech International Limited (ASX: NTI) ('**Neurotech**', '**NTI**' or '**the Company**') is pleased to present its activities report for the quarter ended 31 December 2022, together with its Appendix 4C Quarterly Cash Flow Report.

The Company will host an investor conference call at 11.00am AEDT today with Dr Thomas Duthy, Executive Director. Details below

CLINICAL UPDATES

First Patient Treated in Phase II/III Clinical Trial In ASD

On 17 November 2022, the Company received Human Research Ethics Committee (HREC) Approval and Clinical Trial Notification (CTN) scheme clearance by the Therapeutic Goods Administration (TGA) to commence the Phase II/III Clinical Trial in Children with Autism Spectrum Disorder (ASD)[1]. Subsequently, on the 19 December 2022, the Company announced that the first patient had been randomised and treated as part of this larger, randomised, double-blind, placebo-controlled clinical trial, titled 'NTIASD2'[2].

NTIASD2 aims to evaluate the effectiveness and safety of lead drug candidate, NTI164 compared to placebo in paediatric patients with ASD. Up to 54 patients will be enrolled in the trial through the Paediatric Neurology Unit at Monash Medical Centre in Melbourne, Victoria.

The trial will take 16 weeks, comprising of an 8-week treatment period, followed by an 8-week open-label maintenance period, and a 2-week wash-out period. Participants who wish to continue receiving NTI164 after the trial will have the option to do so for an additional 38 weeks, with a 2-week down-titration phase at the end.

The primary outcome of the trial is the Clinical Global Impression-Severity (CGI-S) which is a measurement of illness severity on a 7-point scale. Secondary endpoints include changes in adaptive behaviour, social responsiveness, improvement, anxiety, depression and mood, and safety as measured by blood, liver, and kidney tests at specific intervals.

Completion of recruitment is expected to occur in 2H CY2023.

20 Week Data from Phase I/II Clinical Trial in ASD[3]

On 26 October 2022, the Company announced that the twelve (n=12) ASD patients participating in the Phase I/II extension study showed significant improvements across all gold-standard ASD measures after 20 weeks of daily treatment with NTI164.

The study found significant improvements in various measures of ASD, including severity of illness, anxiety, social responsiveness, and adaptive behaviour. Notably, the study showed that 40% of patients were markedly/severely ill at the start of the study, however this reduced to 0% from weeks

[1] ASX Announcement 17 November 2022 – Neurotech Receives HREC/TGA Approval for Phase II/III ASD Trial
[2] ASX Announcement 19 December 2022 – Commencement of Phase II/III ASD Clinical Trial and Patient Randomisation
[3] ASX Announcement 26 October 2022 - Neurotech Reports Further Significant Clinical Improvement at 20 Weeks for Paediatric Autism Patients Treated with NTI164

4 onwards. The data also showed that NTI164 was safe and well-tolerated with no serious adverse effects.

The study concluded that NTI164 was effective at improving the symptoms of ASD after 20 weeks of daily treatment, with statistically significant results. The side effects reported were mild and did not significantly impact the patients' ability to function.

32 Week Data from Phase I/II Clinical Trial in ASD[4]

On 30 November 2022, it was announced that the twelve (n=12) paediatric ASD patients participating in the Phase I/II extension study had shown continued improvements in terms of their Severity of Illness scale (CGI-S) at 32 weeks. Specifically, the mean CGI-S of the children continued to shift in a positive direction from moderate at baseline towards the intersection between borderline/mild.

NTI164 continued to be safe and well tolerated at the maximum tolerated dose for each patient over the 32 week period, with no serious adverse events recorded and no changes to blood analysis or liver function tests.

In line with the study protocol and HREC approval, all 12 patients will be followed-up for additional safety and efficacy analysis up-to 54 weeks, with further results to be reported in due course.

Pre-IND Acknowledgement and Meeting Request Granted

The Company filed for a Pre-IND (PIND) meeting with the US Food and Drug Administration (FDA) and received acknowledgment and subsequent to the end of the quarter, a meeting request was granted with a date set for 15 March 2023. The purpose of this virtual Face-to-Face meeting will be to discuss the development plans for the Neurotech's lead drug candidate, NTI164 with the agency and provide an opportunity for the Company to receive feedback on the proposed study design and any potential regulatory issues that may need to be addressed.

The PIND meeting is an important milestone for the Company as it can help to expedite the overall drug development process.

PANDAS/PANS[5]

In October 2022, the Company announced the initiation of a new clinical trial designated 'NTIPAN1', which will investigate the safety and efficacy of NTI164 in treating patients with Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS)(PANDAS/PANS). The Phase I/II trial is single-arm, open-label, and will enrol up to fifteen (n=15) paediatric patients with moderate to severe PANS/PANDAS.

The primary endpoint of the trial is to evaluate the change from baseline for Clinical Global Impression Scales (CGI: severity, global improvement and therapeutic response) and the Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS)(OCD severity). Secondary endpoints will examine the safety and tolerability of the drug.

The trial will be conducted at two centres in Australia, the Children's Hospital at Westmead and the Paediatric Neurology Unit at Monash Medical Centre.

On 27 January 2023 Neurotech announced receipt of written Human Research Ethics Committee (HREC) approval and Clinical Trial Notification (CTN) scheme clearance by the Therapeutic Goods

[4] ASX Announcement 30 November 2022 – 2022 Annual General Meeting Presentation
[5] ASX Announcement 17 October 2022 – Neurotech to Initiate New Phase I/II Clinical Trial for NTI164 in Children with PANDAS/PANS

Administration (TGA) to commence the Phase I/II clinical trial of NTI164 in PANDAS/PANS. The Company expects to commence the Phase I/II trial in Q1 CY2023 and results are anticipated in 2H CY2023.

Cerebral Palsy

Neurotech continues to refine a study protocol for Cerebral Palsy examining the efficacy and safety of daily oral treatment with NTI164. The Company expects to complete this process and obtain the necessary HREC clearance during 1H CY2023.

CORPORATE ACTIVITY

Appendix 4C Commentary

During the quarter, the Company recorded gross total operating expenses (excluding revenue sources) of $2,671,000 which was comprised of research and development ($2,152,000), advertising and marketing ($42,000), staff costs ($85,000) and administrative, corporate costs and interest of ($392,000). Total operating cash outflows for the quarter were $1,354,000.

R&D costs during the quarter were directed towards the completion/reporting and ongoing treatment costs of the Phase I/II Autism Spectrum Disorder (ASD) trial, commencement of the Phase II/III ASD clinical trial, preparations for the Company's PIND Application package submitted to the FDA in late December, and drug product manufacturing and testing.

In addition, the Company received $423,000 from the exercise of share options. The Company closed the quarter with cash and cash equivalents of $8,094,000. During the quarter the Company completed a $9,000,000 share placement to institutional, professional and sophisticated Australian and overseas investors.

Further, payments to related parties and their associates as detailed in Section 6 of the Appendix 4C relate to director fees ($91,000) and corporate services, accounting and company secretarial fees ($38,000).

Completion of $9M Placement

On 28 October 2022, the Company announced that it had received binding commitments for an equity placement with institutional and sophisticated investors totalling $9,000,000 at an issue price of $0.10 per share. PAC Partners and Peloton Capital acted as Joint Lead Managers for the Placement. As part of the Placement, each Placement participant was entitled to subscribe for 1 free attaching option for every 2 New Shares subscribed for under the Placement.

Funds raised under the placement will be applied to the Company's paediatric clinical trials program, including multiple Phase I/II trials in PANDAS/PANS and cerebral palsy, the Phase II/III clinical trial in Autism Spectrum Disorder (ASD), drug product manufacturing and scale-up, lead-in pre-clinical work associated with the Company's planned submissions to the US Food and Drug Administration (FDA) to undertake future US trials for NTI164 and general working capital.

Received $1.2M R&D Tax Rebate[6]

On 31 October 2022, the Company received $1.2 million R&D Tax incentive rebate. This significantly strengthens the Companies capital position and, together with the $9 million capital raise, fully funds

[6] ASX Announcement 31October 2022 – Neurotech Receives $1.2M R&D Tax Rebate

the clinical trial programs in ASD (Phase II/III),the planned PANDAS/PANS and Cerebral Palsy trials, while also supporting the existing ASD patients who continue to receive NTI164 as part of the extension to the Phase I/II program.

Passing of Professor Allan Cripps AO, Non-Executive Director[7]

In December, the Company was deeply saddened to announce the passing of Emeritus Professor Allan Cripps AO, Non-Executive Director and Chief Scientist of the Company. Allan was an eminent scientist, internationally recognised expert in the field of mucosal immunology and a leading public health administrator. Since his appointment in May 2021, Allan was instrumental in shaping the pre-clinical and clinical programs as well as building upon the Company's intellectual property.

AGM Held[8]

On 30 November 2022, the Company held its Annual General Meeting at the Perth offices of BDO Australia. All resolutions were passed as determined by a poll.

Quarterly Conference Call Details

The Company will host an investor conference call at 11.00am AEDT today - Monday, 30 January 2023 with Dr Thomas Duthy, Executive Director.

Details of the call are set out below.

In order to pre-register for the conference call and avoid a queue when calling, please follow the link below. You will be given a unique pin number to enter when you call which will bypass the operator and give you immediate access to the event.

https://s1.c-conf.com/diamondpass/10028298-fj84y1.html

Alternatively, you may dial in with the following details, approximately five minutes before the scheduled start time and provide the Conference ID to an operator.

Conference ID: **10028298**

Participant Dial-in Numbers:

Australia Toll Free: 1800 908299
Australia Local: +61 2 9007 8048
New Zealand: 0800 452 795
Canada/USA: 1855 624 0077
Hong Kong: 800 968 273
Japan: 006 633 868 000
China: 108 001 401 776
Singapore: 800 101 2702
United Kingdom: 0800 0511 453

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

[7] ASX Announcement 21 December 2022 – Passing of Professor Allan Cripps AO, Non-Executive Director
[8] ASX Announcement 30 November 2022 – Results of Annual General Meeting

Further Information
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About Neurotech

Neurotech International Limited (ASX:NTI) is a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders. Neurotech is currently conducting a world-first clinical trial to assess the potential application of NTI164 for the treatment of Autism Spectrum Disorder (ASD). Results of the Phase I/II clinical trial 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 a Phase II/III clinical trial to further assess the long-term safety and efficacy of NTI164, with the potential to lead to drug registration. 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 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	31 December 2022

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	2	3
1.2	Payments for		
	(a) research and development	(2,152)	(3,249)
	(b) product manufacturing and operating costs	-	(3)
	(c) advertising and marketing	(42)	(97)
	(d) leased assets	0	0
	(e) staff costs	(85)	(171)
	(f) administration and corporate costs	(389)	(787)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	9	10
1.5	Interest and other costs of finance paid	(3)	(5)
1.6	Income taxes paid	0	0
1.7	Government grants and tax incentives (R&D Rebate)	1,189	1,189
1.8	Other (VAT and GST Refunds)	117	206
1.9	**Net cash from / (used in) operating activities**	**(1,354)**	**(2,904)**

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

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 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**	**0**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	9,000	9,000
3.2	Proceeds from issue of convertible debt securities	0	0
3.3	Proceeds from exercise of options	423	738
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(626)	(626)
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**	**8,797**	**9,112**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	654	1,891
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,354)	(2,904)
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 (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	8,797	9,112
4.5	Effect of movement in exchange rates on cash held	(3)	(5)
4.6	**Cash and cash equivalents at end of period**	**8,094**	**8,094**

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	8,079	639
5.2	Call deposits	15	15
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)**	**8,094**	**654**

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	129
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 ($91,000) and corporate services, accounting and company secretarial fees ($38,000).

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 0.6359.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,354)
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,094
8.3	Unused finance facilities available at quarter end (item 7.5)	94
8.4	Total available funding (item 8.2 + item 8.3)	8,188
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	6.05

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?

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?

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?

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 January 2023
.....

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.