ASX Announcement
31 October 2022

Quarterly Activities Report
for the period ending 30 September 2022

Neurotech International Limited (ASX: NTI) ('**Neurotech**', '**NTI**' or '**the Company**'), a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders, is pleased to present its activities report for the quarter ended 30 September 2022, together with its Appendix 4C Quarterly Cash Flow Report.

PHASE I/II PAEDIATRIC ASD CLINICAL TRIAL RESULTS

Breakthrough Results with NTI164 in Paediatric ASD[1]

In July 2022, Neurotech announced breakthrough results from its paediatric Phase I/II open label clinical study evaluating the safety and efficacy of the Companies' lead drug candidate, NTI164 in children with ASD.

The landmark study demonstrated 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.

SEVERITY OF ILLNESS

- The average rating for the severity of illness score was reduced to 3.6 from a baseline of 4.4 (out of a score of 7 meaning "extremely ill" and 1 meaning, "not ill").

The study was subsequently granted HREC approval to continue for a further 52 weeks due to the positive therapeutic effects of NTI164, combined with feedback from parents and clinicians who requested children remain on treatment and that the "washout" period be eliminated.

[1] ASX Announcement 8 July 2022 – Breakthrough Results with NTI164 in Paediatric ASD

Further Significant Clinical Improvement at 20 Weeks[2]

Post quarter end on 26 October 2022, Neurotech released 20 week data from 12 paediatric ASD patients who continued to receive daily treatment of NTI164 (noting that two patients discontinued treatment for reasons not related to drug effects of NTI164). The data at 20 weeks was compared to the same patients' data at baseline and 28 days. The observations from this data include:

- Significant improvements across all gold-standard ASD measures at 20 weeks vs. baseline, specifically including; severity of illness (p=0.005), anxiety (p=0.001), social responsiveness (p=0.012) and adaptive behaviour (p=0.0005). These measures are all considered clinically important and primary goals in the treatment of children with ASD.
- Significant, positive effects on severity of illness, with children re-diagnosed from "moderately ill" (CGI-S: 4.3) at baseline to "mildly ill" (CGI-S: 3.2) at 20 weeks, representing a 26% improvement (p=0.005) with 40% of patients markedly/severely ill at baseline to 0% from weeks 4 onwards
- NTI164 continued to be safe and well tolerated at the maximum dose for each patient, with no serious adverse events recorded and no changes to blood analysis or liver function tests over the 20 week period
- Strong efficacy and safety results at 20 weeks warrant progression to a Phase II/III randomised, double-blind, placebo-controlled clinical trial – HREC submission completed

All 12 patients will be followed-up for additional safety and efficacy analysis up-to 54 weeks, as per protocol revisions and HREC approval, with further results to be reported in due course.

NEW PHASE I/II CLINICAL TRIAL FOR NTI164 IN CHILDREN WITH PANDAS/PANS[3]

In October 2022, the Company announced the initiation of a new Phase I/II Clinical trial of NTI164 in children diagnosed with Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), designated 'NTIPAN1'.

PANDAS/PANS is a clinical diagnosis given to children who have a dramatic (typically within one day) onset of neuropsychiatric symptoms including intense anxiety, Obsessive-Compulsive Disorder (OCD) and/or severely restrictive eating. Children may exhibit repetitive tic movements, become moody, irritable/aggressive, and anxious. The cause of PANS is unknown in most cases; however, the disorder is hypothesised to be triggered by infections, metabolic disturbances, and other inflammatory reactions.

During the quarter, the Company filed additional provisional patent applications around this novel application of NTI164 in PANDAS/PANS and prepared applications for HREC approval and Clinical Trial Notification (CTN) scheme clearance by the Therapeutic Goods Administration (TGA).

NTIPAN1 is proposed to be a single-arm, open-label, Phase I/II clinical trial that will recruit up to 15 paediatric patients with a clinical diagnosis of moderate to severe PANDAS/PANS to determine the safety and efficacy of orally administered NTI164 in these patients.

Subject to regulatory approvals, NTI expects to commence the Phase I/II trial prior to the end of CY2022, with patient recruitment to commence in 1H CY2023 and results anticipated in 2H CY2023.

[2] ASX Announcement 26 October 2022 – 20 Week Data Shows Significant Improvement For ASD Children
[3] ASX Announcement 17 October 2022 – New Phase I/II Clinical Trail in Children with PANDAS/PANS

CORPORATE ACTIVITY

Board Changes

During the quarter, NTI announced several changes to the composition and roles of the Board and management team, noting:

- The appointment of experienced biotech executive, Dr Thomas Duthy as Executive Director
- The transition of Dr Alexandra Andrews to the role of Chief Operating Officer
- The appointment of non-executive director, Mr Mark Davies, as Chairman of the Board following the resignation of former chairman, Brian Leedman
- The appointment of Mr Gerald Quigley as Non-Executive Director and Director of Public Relations, following the resignation of former non-executive director, Krista Bates; and
- The appointment of non-executive director, Professor Allan Cripps, as Chief Scientist.

$9.0M Placement

Following the success of its Phase I/II Paediatric ASD study and the recent release of the Company's 20 week clinical trial data, the Company announced a $9.0 million placement to institutional, professional and sophisticated Australian and overseas investors.

PAC Partners and Peloton Capital were joint leaded managers to the capital raise.

Funds raised under the placement will be applied to fully fund the Company's paediatric clinical trial programs, including the Phase II/III clinical trial in ASD and Phase I/II trials in PANDAS/PANS and Cerebral Palsy. The Funds will also be applied to drug product manufacturing, scale-up, and non-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.

Appendix 4C Commentary

During the quarter, the Company recorded gross total operating expenses (excluding revenue sources) of $1,641,000 which was comprised of research and development ($1,097,000), product manufacturing ($3,000), advertising and marketing ($55,000), staff costs ($86,000) and administrative, corporate costs and interest of ($400,000).

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, preparations for the Phase II/III ASD clinical trial, preparations for the Company's pre-Investigational New Drug Application (pre-IND) package to be submitted to the US Food and Drug Administration (FDA), and drug product manufacturing and testing.

In addition, the Company received $315,000 from the exercise of share options. The Company closed the quarter with cash and cash equivalents of $650,000. In October, the Company announced a $9.0 million 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 ($137,000) and corporate services, accounting and company secretarial fees ($61,000).

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 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	30 September 2022

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	1	1
1.2	Payments for		
	(a) research and development	(1097)	(1,097)
	(b) product manufacturing and operating costs	(3)	(3)
	(c) advertising and marketing	(55)	(55)
	(d) leased assets	0	0
	(e) staff costs	(86)	(86)
	(f) administration and corporate costs	(398)	(398)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	1	1
1.5	Interest and other costs of finance paid	(2)	(2)
1.6	Income taxes paid	0	0
1.7	Government grants and tax incentives (R&D Rebate)	0	0
1.8	Other (VAT and GST Refunds)	89	89
1.9	**Net cash from / (used in) operating activities**	**(1,550)**	**(1,550)**

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 (3 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)	0	0
3.2	Proceeds from issue of convertible debt securities	0	0
3.3	Proceeds from exercise of options	315	315
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**	**315**	**315**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	1,891	1,891
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,550)	(1,550)
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)	315	315
4.5	Effect of movement in exchange rates on cash held	(2)	(2)
4.6	**Cash and cash equivalents at end of period**	**654**	**654**

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	1,891
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**	**1,891**

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	198
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 ($137,000) and corporate services, accounting and company secretarial fees ($61,000).

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	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 0.6618.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,550)
8.2	Cash and cash equivalents at quarter end (item 4.6)	654
8.3	Unused finance facilities available at quarter end (item 7.5)	91
8.4	Total available funding (item 8.2 + item 8.3)	745
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	0.48

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?

The Company anticipates a continued net operating deficit as it continues its research and development activities.

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?

Yes – The Company announced a $9 million share placement to existing and new institutional, professional and sophisticated investors on 28 October 2022, with settlement of placement proceeds expected on 4 November 2022.

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?
	Yes – Refer above

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 October 2022
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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.