ASX Announcement
27 April 2023

Quarterly Activities Report
for the period ending 31 March 2023

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 31 March 2023, together with its Appendix 4C Quarterly Cash Flow Report.

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

CLINICAL UPDATES

Launch of Phase II Clinical Trial in Rett Syndrome[1]

On 20 March 2023, the Company announced the launch of a new clinical program in Rett Syndrome, with plans to conduct a Phase II clinical trial of daily oral NTI164 in females aged 5-20. The trial will be conducted at two centres within Australia, the Royal Children's Hospital and Monash Children's Hospital in Melbourne. Human Research Ethics Committee (HREC) approval and Clinical Trial Notification (CTN) scheme clearance are expected for Q2 CY2023, with patient recruitment to commence in 2H CY2023. In April 2023, the Company added an additional site to the trial, led by Associate Professor Carolyn Ellaway, Senior Staff Specialist NSW Genetic Metabolic Disorders Service, the Sydney Children's Hospital Network and Metabolic Genetics at The Children's Hospital at Westmead.

Rett Syndrome is a rare genetic neurological and developmental disorder with no cure. Subsequently, this indication is in line with Neurotech's strategic focus on rare neurological disorders in children that are characterised by persistent neuroinflammation. The trial's proposed primary endpoints at 12 weeks of treatment include the Rett Syndrome Behaviour Questionnaire, Clinical Global Impression Scale-Improvement, and severity of illness. Key secondary endpoints include safety, adverse events, and measures associated with hand function, motor skills, communication, and quality of life. If successful, the Company will follow with a 14-week double-blind, randomised, placebo-controlled Phase II in 34 participants to determine further efficacy and safety.

52 Week Results from Phase I/II Clinical Trial in ASD[2]

On 17 March 2023, the Company announced the full results from 52 weeks of daily treatment with NTI164 in the Phase I/II clinical trial in paediatric Autism Spectrum Disorder (ASD). The results showed strong safety and efficacy effects of daily oral treatment, with significant improvements in severity of illness, social responsiveness, and adaptive behaviour. These results will inform Investigational New Drug (IND) enabling clinical trials in the US.

The Company has been encouraged by the recent attention ASD has been receiving in government and the media with particular focus around the costs to the National Disability Insurance Scheme (NDIS) in Australia[3]. A new study out of Western Australia has highlighted the potential cost savings to be made from early intervention in ASD, together with improved outcomes for the individual.

[1] ASX Announcement 20 March 2022 – Neurotech to Launch Phase II Clinical Trial in Rett Syndrome
[2] ASX Announcement 17 March 2022 – Significant Clinical Improvement at 52 Weeks for Paediatric Autism Patients Treated with NTI164
[3] https://www.theaustralian.com.au/nation/politics/act-early-on-autism-for-ndis-savings/news-story/6b39bb81d41bc6f66ce4e344cf62aae8

Neurotech looks forward to collaborating with researchers, clinicians, and advocates to further advance the collective efforts in this area and to improve the lives of those affected by autism.

Further Extension of Phase I/II Clinical Trial in ASD[4]

On 14 February 2023, the Company received approval from the Monash HREC to extend the Phase I/II ASD clinical trial beyond the 54-week period of daily oral treatment with NTI164 for an additional six months on a patient-specific basis. Individual patients can now continue to receive NTI164 for a total of 80 weeks or 1.5 years of daily treatment. This extension will generate additional safety data for Neurotech and enhance future regulatory submissions for additional trials in ASD or other paediatric neurological disorders.

Pre-IND Meeting with the US Food and Drug Administration (FDA)[5]

On 19 January 2023 Neurotech announced the US FDA had granted the Company a virtual Face-to-Face Pre-IND (PIND) meeting set for 15 March 2023. The purpose of this meeting was to discuss the development plans for the Neurotech's lead drug candidate, NTI164 with the agency in relation to the proposed clinical development program in ASD. The Company obtained valuable information on the chemistry/manufacture/control package, non-clinical requirements, and proposed clinical developmental program for NTI164 in ASD.

PANDAS/PANS[6],[7]

On 27 January 2023 Neurotech announced Human Research Ethics Committee (HREC) approval and Clinical Trial Notification (CTN) scheme clearance by the Therapeutic Goods Administration (TGA) to commence the Phase I/II clinical trial of NTI164 in Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS.

On 16 February 2023, the Company announced commencement of the Phase I/II trial at two centres within Australia; the Children's Hospital at Westmead and the Paediatric Neurology Unit at Monash Medical Centre.

The trial will recruit 15 paediatric patients with a clinical diagnosis of moderate to severe PANDAS/PANS to determine the efficacy and safety of orally administered NTI164 in these patients with results anticipated in 2H CY2023. The Company intends to progress the development of NTI164 in PANDAS/PANS using available regulatory mechanisms, including orphan drug designations where applicable.

Outlook

Neurotech has made excellent progress to date in accelerating the use of NTI164 in a number of paediatric neurological disorders, where there is a significant unmet medical need for new safe and effective therapies.

In Q2 CY2023 the Company anticipates:

- Securing HREC/TGA Approval for the Rett Syndrome Phase II Clinical Trial
- Securing HREC/TGA Approval for the Cerebral Palsy Phase I/II Clinical Trial
- Completion of Patient Recruitment for the PANDAS/ PANS Phase I/II Clinical Trial

[4] ASX Announcement 14 February 2022 – Approval for Additional Phase I/II ASD Trial Extension
[5] ASX Announcement 19 January 2023 – Neurotech Granted FDA Pre-IND Meeting for NTI164 in Autism Spectrum Disorder
[6] ASX Announcement 27 January 2023 – Neurotech Receives HREC Approval for Phase I/II PANDAS/PANS Clinical Trial
[7] ASX Announcement 16 February 2023 – First Patient Treated in Phase I/II PANDAS/PANS Clinical Trial

In the second half of CY2023 Neurotech expects:

- The results of PANDAS/PANS Phase I/II Clinical Trial
- Commence the Phase II Clinical Trial in Rett Syndrome
- Commencement of Patient Recruitment for the Cerebral Palsy Phase I/II Clinical Trial
- Completion of Patient Recruitment ASD Phase II/III Clinical Trial
- Completion of initial recruitment of Rett Syndrome Phase II Clinical Trial
- US FDA IND submission

The Company remains fully funded to complete these important clinical trials through to top-line results.

CORPORATE ACTIVITY

Appendix 4C Commentary

During the quarter, the Company recorded gross total operating expenses (excluding revenue sources) of $2,273,000 which was comprised of research and development ($1,843,000), advertising and marketing ($33,000), staff costs ($65,000) and administrative, corporate costs and interest of ($332,000). Total operating cash outflows for the quarter were $2,253,000. 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. The Company closed the quarter with cash and cash equivalents of $6,141,000. Further, payments to related parties and their associates as detailed in Section 6 of the Appendix 4C relate to director fees ($92,000) and corporate services, accounting and company secretarial fees ($96,000).

Quarterly Conference Call Details

The Company will host an investor conference call at 11.00am AEST today 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/10030381-tfye7v.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: **10030381**

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.

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 has completed a Phase I/II clinical trial in Autism Spectrum Disorder (ASD), which demonstrated excellent safety and efficacy results at 28 days, 20 weeks and 52 weeks of treatment with NTI164. The Company commenced Phase II/III randomised, double-blind, placebo-controlled clinical trial in ASD in Q4 CY2022. Neurotech is also conducting additional Phase I/II trials in Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS, along with Rett Syndrome and Cerebral Palsy during CY2023. 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 March 2023

CONSOLIDATED STATEMENT OF CASH FLOWS		Current quarter $A'000	Year to date (9 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	2	5
1.2	Payments for		
	(a) research and development	(1,843)	(5,092)
	(b) product manufacturing and operating costs	-	(3)
	(c) advertising and marketing	(33)	(130)
	(d) leased assets	0	0
	(e) staff costs	(65)	(236)
	(f) administration and corporate costs	(332)	(1,119)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	18	28
1.5	Interest and other costs of finance paid	(2)	(7)
1.6	Income taxes paid	0	0
1.7	Government grants and tax incentives (R&D Rebate)	0	1,189
1.8	Other (VAT refunds)	2	208
1.9	**Net cash from / (used in) operating activities**	**(2,253)**	**(5,157)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	0	0
	(b) businesses	0	0

CONSOLIDATED STATEMENT OF CASH FLOWS		Current quarter $A'000	Year to date (9 months) $A'000
	(c) property, plant and equipment	0	0
	(d) investments	0	0
	(e) intellectual property	0	0
	(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	9,000
3.2	Proceeds from issue of convertible debt securities	0	0
3.3	Proceeds from exercise of options	413	1,151
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(111)	(737)
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**	**302**	**9,414**

CONSOLIDATED STATEMENT OF CASH FLOWS		Current quarter $A'000	Year to date (9 months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	8,094	1,891
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,253)	(5,157)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	0	0
4.4	Net cash from / (used in) financing activities (item 3.10 above)	302	9,414
4.5	Effect of movement in exchange rates on cash held	(2)	(7)
4.6	**Cash and cash equivalents at end of period**	**6,141**	**6,141**

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	4,126	8,079
5.2	Call deposits	2,015	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)**	**6,141**	**8,094**

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	188
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 ($92,000) and corporate services, accounting and company secretarial fees ($96,000).

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	65	0
7.2	Credit standby arrangements	0	0
7.3	Other (please specify)	0	0
7.4	**Total financing facilities**	65	0

7.5	**Unused financing facilities available at quarter end**	65

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 40,000. 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 0.6156.

8.	ESTIMATED CASH AVAILABLE FOR FUTURE OPERATING ACTIVITIES	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,253)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,141
8.3	Unused finance facilities available at quarter end (item 7.5)	65
8.4	Total available funding (item 8.2 + item 8.3)	6,206
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.75

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: 27 April 2023
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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.