ASX Announcement

29 January 2025

Quarterly Activities Report

for the period ending 31 December 2024

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 December 2024 (Q2 FY2025), together with its Appendix 4C Quarterly Cash Flow Report.

CLINICAL UPDATES

Rett Syndrome

Rett Syndrome is the second leading cause of intellectual disability in girls, with an urgent medical need to develop safe and effective therapies to treat this progressive neurological disease. Rett Syndrome is an orphan disease with no cure and an annual market opportunity estimated at over US$2 billion[1].

On 4 October 2024, Associate Professor Carolyn Ellaway, Principal Investigator of the Neurotech Phase I/II Rett Syndrome Clinical Trial, Senior Staff Specialist, The Children's Hospital at Westmead, Sydney Children's Hospital Network presented at the 9th World Rett Syndrome Congress on the Gold Coast. The presentation titled *"A novel full-spectrum medicinal cannabis-derived clinical trial in Rett syndrome"* highlighted the Phase I/II clinical trial data for her patients receiving daily NTI164.

On 26 November 2024, Neurotech announced the US Food and Drug Administration (FDA) has granted the Company orphan drug designation (ODD) for the use of NTI164 in children and adults diagnosed with Rett Syndrome. Rett Syndrome remains a difficult to treat rare neurological disorder where safe and effective treatments are needed. Neurotech's Phase I/II clinical trial demonstrated significant clinical effects in these patients with an excellent safety profile extending beyond the initial 12 weeks of the trial.

The ODD qualifies Neurotech for incentives including: (a) tax credits for qualified clinical trials (b) exemption from user fees and (c) potential seven years of market exclusivity after approval. The Orphan Drug Act defines a rare disease as a disease or condition that affects less than 200,000 people in the United States.

In October, Neurotech filed an orphan designation request for NTI164 in Rett Syndrome with the European Medicines Agency (EMA). The orphan designation response from the EMA is expected in Q1 CY2025. Sponsors who obtain orphan designation benefit from protocol assistance, a type of scientific advice specific for designated orphan medicines, and ten years' market exclusivity once the medicine is on the market. Regulatory fee reductions are also available.

PANDAS/PANS

Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS) (PANDAS/PANS) is a clinical diagnosis given to children who have a dramatic (typically within one day) onset of neuropsychiatric symptoms including Obsessive-Compulsive Disorder (OCD) and/or restrictive eating. On 4 October 2024, Neurotech announced it was unsuccessful with the Orphan Drug Designation (ODD) request

[1] https://www.livewiremarkets.com/wires/a-de-risked-biotech-with-4x-upside

from the FDA. The FDA granted Neurotech a 12-month abeyance. The FDA had no objections to Neurotech's submitted non-clinical and clinical evidence supporting the scientific rationale for the ODD, NTI164's mechanism of action, efficacy in pre-clinical and human clinical trials to date and relevance of NTI164 to PANDAS/PANS.

Neurotech's development plans for PANDAS/PANS remain unaffected by the FDA's decision, given the strength of the clinical data to date, excellent safety and new data showing NTI164 reverses immune dysregulation seen in these patients. All 15 children remain on active treatment (representing over 88 weeks of daily treatment). In light of the FDA response, the Company has postponed a planned European ODD application for PANDAS/PANS until further supportive data becomes available.

On 15 November 2024, the Company announced primary results of a genomic analysis undertaken by Professor Russell Dale's group on Neurotech study patients. The genomic analysis followed on from a set of proteomic data from the same patients reported on 9 September 2024 which showed NTI164 reversed the immune dysregulation observed in PANDAS/PANS children via immune cell function and gene translation.

Key points of the recent genomic analysis were:

- Genomic analysis in PANDAS/PANS patients who participated in Neurotech Phase I/II clinical trial shows reversal of immune system dysregulation – consistent with prior protein expression results
- NTI164 shown to modulate the immune system, protein translation, and epigenetic factors at both a gene expression (genomic) level and protein (proteomic) level in PANDAS/PANS children
- Data reinforces that administration of NTI164 is safe and effective under the inflammatory conditions experienced by PANDAS/PANS children (no activation of potentially damaging cellular pathways)

Autism Spectrum Disorder (ASD)

During the quarter, the Company continued to provide NTI164 to a total of 54 level II and level III ASD patients who previously participated in Neurotech's two clinical trials. All patients who initially participated in the Phase II/III clinical trial and have entered the extension phase of treatment (n=43) have now crossed over 52 weeks of daily oral treatment (first patient over two years of daily treatment). There have been no reportable safety or toxicity events noted. Similarly, the Company's original Phase I/II trial participants continue to receive NTI164 therapy, with total treatment duration of approximately 2.7 years.

As the Company has previously reported, no ASD patient has dropped out of either Neurotech clinical studies through any safety concerns or symptomatic reversal while on treatment. Patient compliance has been excellent, and clinician engagement high.

Neurotech is committed to the regulatory and commercial development of NTI164 in Australia noting the continued upward growth trend of ASD patients, which now exceeds >250k as at 30 September 2024 currently enrolled on the National Disability Insurance Scheme (NDIS), representing 38% of all NDIS participants and annual growth of 13%.[2] This represents a total cost for the 12 months to 30 September 2024 of $8.6 billion, up 20%. Neurotech believes a cost-effective intervention with an excellent safety profile and demonstrated clinical evidence of benefit such as NTI164, would represent a significant commercial opportunity in Australia if ultimately approved for ASD by the Therapeutic Goods Administration (TGA). Further regulatory engagement is anticipated following the results of the FDA IND-enabling studies discussed below.

[2] https://dataresearch.ndis.gov.au/reports-and-analyses/participant-dashboards/autism

During the quarter, a scientific publication on NTI164 from Dr Bobbi Fleiss, School of Health & Biomedical Sciences, RMIT University, Victoria, Australia was published in the peer-reviewed journal *Biomolecules*. The findings suggest that the anti-inflammatory and neuroprotective effect of NTI164 is likely due to the synergistic interaction of the highly purified and reproducibly manufactured cannabinoids comprising NTI164 rather than isolated CBD supporting the entourage effect of NTI164.

FDA IND-Enabling Studies

During the quarter, Neurotech continued to progress its animal pharmacology and toxicology studies across two species in certified laboratories in the United States. As previously indicated, this important pre-clinical research generates the necessary data per the safety and toxicity requirement from the FDA prior to the approval of an Investigational New Drug (IND). Such studies are also a requirement for the Therapeutic Goods Administration (TGA) in assessing provisional product registrations.

On 25 November 2024, Neurotech announced the receipt of Human Research Ethics Committee (HREC) approval for the Company's pharmacokinetic (PK) study in healthy human adult participants to be conducted at CMAX Clinical Research, Adelaide, South Australia. The study is examining the effects of a single ascending dose (SAD) of NTI164 (Part A) followed by multiple ascending doses (MAD) of NTI164 (Part B) in healthy adults.

The Company expects to complete the necessary pre-clinical toxicology and human PK trial in line with FDA, TGA and EMA standards for NTI164 before the end of Q1 CY2025.

Outlook

Neurotech has developed a significant clinical portfolio across three paediatric neurological disorders. These patients continue to receive daily NTI164 therapy and over time these patients have seen further improvement, or their disorder has stabilised. The Company aims to complete its necessary IND-enabling studies before the end of Q1 CY2025 and secure an additional orphan drug designation in Rett Syndrome.

Neurotech holds cash and cash equivalents of $5.9 million (as at 31 December 2024) which is sufficient to deliver on current pre-clinical toxicology studies and the human PK trial, alongside current regulatory initiatives which include preparation for a provisional determination filing with the TGA and completion of an IND with the US FDA. In addition, the Company anticipates the FY24 R&D tax incentive rebate of approximately $2.4 million to be received in Q1 CY2025.

For the first half of the 2025 calendar year, Neurotech anticipates:

- Orphan Drug Designation in Europe for Rett Syndrome
- Completion of FDA IND / EMA enabling toxicology program
- Completion of the Phase I human PK trial

CORPORATE ACTIVITY

Dr Anthony Filippis Appointed Managing Director &CEO

During the quarter, the Company was pleased to announce the appointment of Dr Anthony Filippis as Managing Director and CEO of Neurotech, following an extensive search of potential candidates for the role. With 25 years' biotech experience, Anthony is an internationally proven senior business leader with a deep understanding and knowledge of the biotech industry and capital markets. Anthony is a transaction-focused deal maker, having led and completed several partnering (in and out-licensing),

M&A transactions with pharmaceutical and biotech companies. Anthony commences with Neurotech on 1 February 2025.

Appendix 4C Commentary

During the quarter, the Company recorded total cash operating expenses (excluding revenue sources) of $2.8 million (Q1 FY2025: $3.5 million), consisting of research and development costs of $2.4 million (Q1 FY2025: $2.9 million), along with advertising, marketing, staff, administrative, and corporate costs of $0.4 million (Q1 FY2025: $0.6 million).

Total operating cash outflows for the quarter were $2.7 million (Q1 FY2025: $3.4 million). R&D expenditure during the quarter reflected investment into the IND enabling pre-clinical toxicology work required to support an FDA IND and TGA provisional application, along with extension phase costs of the Phase II/III ASD clinical trial, and Phase I/II clinical trials in Rett Syndrome, maintenance costs associated with children migrating to extension phases of previous clinical trials, along with drug product manufacturing costs and regulatory development.

The Company closed the quarter with cash and cash equivalents of $5.9 million (Q1 FY25: $8.7 million). The Company anticipates receiving approximately $2.45 million relating to the FY2024 R&D tax incentive rebate in February 2025.

Further, payments to related parties and their associates as detailed in Section 6 of the Appendix 4C totalled $111,000.

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 with a broad-spectrum oral cannabinoid drug therapy called NTI164. Neurotech has completed a Phase II/III randomised, double-blind, placebo-controlled clinical trial in Autism Spectrum Disorder (ASD) with clinically meaningful and statistically significant benefits reported across a number of clinically-validated measures and excellent safety. In addition, Neurotech has completed and reported statistically significant and clinically meaningful Phase I/II trials in ASD and Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS along with Rett Syndrome. Neurotech has received human ethics committee clearance for a Phase I/II clinical trial in spastic cerebral palsy.

For more information about Neurotech 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	**Quarter ended ("current quarter")**
73 610 205 402	31 December 2024

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	0	0
1.2	Payments for		
	(a) research and development	(2,422)	(5,602)
	(b) product manufacturing and operating costs	0	0
	(c) advertising and marketing	(47)	(90)
	(d) leased assets	0	0
	(e) staff costs	(31)	(88)
	(f) administration and corporate costs	(316)	(515)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	68	193
1.5	Interest and other costs of finance paid	0	0
1.6	Income taxes paid	0	0
1.7	Government grants and tax incentives (R&D Rebate)	0	0
1.8	Other (GST refunds)	0	3
1.9	**Net cash from / (used in) operating activities**	**(2,748)**	**(6,099)**

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)	0	0
3.2	Proceeds from issue of convertible debt securities	0	0
3.3	Proceeds from exercise of options	0	434
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**	**434**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	8,704	11,623
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,748)	(6,099)
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)	0	434
4.5	Effect of movement in exchange rates on cash held	1	(1)
4.6	**Cash and cash equivalents at end of period**	**5,957**	**5,957**

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	5,942	4,189
5.2	Call deposits	15	4,515
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)**	**5,957**	**8,704**

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	111
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 ($111,000).

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	67	0
7.2	Credit standby arrangements	0	0
7.3	Other (please specify)	0	0
7.4	**Total financing facilities**	67	0

7.5	**Unused financing facilities available at quarter end**	67

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 0.612.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,748)
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,957
8.3	Unused finance facilities available at quarter end (item 7.5)	67
8.4	Total available funding (item 8.2 + item 8.3)	6,024
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.19

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: 29 January 2025
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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.