

Quarterly Activities Report for the period ending 30 September 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 30 September 2023 (Q1 FY24), together with its Appendix 4C Quarterly Cash Flow Report.

The Company will host an investor conference call at 12.00pm AEDT today with Dr Thomas Duthy, Executive Director. Details below

CLINICAL UPDATES

PANDAS/PANS

On 31 August 2023, Neurotech announced the Last patient last visit (LPLV) successfully completed NTI164 treatment under the auspices of Professor Russell Dale, Co-Principal Investigator for the NTI164 clinical trial in PANDAS/PANS and Professor of Paediatric Neurology, University of Sydney and Children's Hospital at Westmead. All 15 patients completed 12 weeks of treatment under the trial protocol and elected to continue to receive daily oral treatment with NTI164. Three patients turned 18 years of age while continuing on treatment, which was approved under a revised HREC approval granted 30 May 2023.

On 11 September 2023, the Company hosted an investor webinar with Professor Russell Dale. Professor Dale is an internationally recognised clinician and researcher in PANDAS/PANS research.

Professor Dale introduced this challenging neurological disorder to investors, how PANDAS/PANS is diagnosed, along with treatment options and a discussion of the Phase I/II NTIPANS1 clinical trial sponsored by Neurotech.

A recent scientific publication¹ provided an estimate of the incidence of PANDAS and PANS in three primary care populations in the United States (US), which indicated within the US the estimated annual incidence of PANDAS/PANS was 8.5 cases per 100,000 children between 3 and 12 years of age with considerable place-to-place variation. The authors concluded PANDAS/PANS is a rare disorder with substantial heterogeneity across geography and time. In Europe, an Orphan Drug Designation (ODD) applies to diseases where the annual incidence is less than 5 in 10,000 patients and in the US a disease affecting less than 200,000 patients. The Company continued to advance its planned ODD filings for NTI164 in PANDAS/PANS in the US and Europe during the quarter.

Rett Syndrome

On 10 July 2023, Neurotech announced written 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 investigating the use of NTI164 in female Rett Syndrome patients.

On 1 August 2023, the Company announced the first patient enrolled and treated in the Company's Phase I/II clinical trial. This followed a presentation at the 2023 International Rett Syndrome Foundation

¹ Wald ER et al. Estimate of the incidence of PANDAS and PANS in 3 primary care populations. Front Pediatr. 2023 Sep 21;11:1170379.

(IRSF) Rett Syndrome Scientific Meeting in Nashville, Tennessee on 5-7 June by Associate Professor Carolyn Ellaway, the Principal Investigator of Neurotech's clinical trial in Rett Syndrome.

On 26 September 2023, Neurotech announced the completion of patient recruitment in the Company's Phase I/II clinical trial investigating the use of NTI164 in female Rett Syndrome patients.

The NTIRTT1 Phase I/II clinical trial will examine the effects of daily oral treatment of NTI164 in 14 Rett Syndrome patients. The trial will be an open-label, exploratory study over 16 weeks of treatment with NTI164 at the maximum tolerated dose of 20mg/kg/day. The Company believes the neuroprotection shown by NTI164, with improvements in neuronal function and strong anti-inflammatory effects in brain-derived neuronal and microglial cells could translate to improved clinical outcomes in Rett Syndrome patients.

The results of the Phase I/II clinical trial are expected in early Q1 CY2024. 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 a rare genetic neurological and developmental disorder and is almost exclusively the result of a mutation(s) in the methyl CpG binding protein 2 (MECP2) gene located on the X chromosome, which is required for normal brain development and function. Rett Syndrome occurs almost exclusively in girls, with incidence of one in 10,000 female live births. The prevalence is approximately 15,000 girls and women in the US and 350,000 globally. Rett Syndrome is an orphan disease with no cure and an annual market opportunity estimated at over US\$2 billion.

Autism Spectrum Disorder²

The Company continued to recruit patients in the Phase II/III clinical trial. The target recruitment is 54 pediatric patients. The Company is on track to complete recruitment during Q2 FY24. The recruitment was slowed somewhat by the allocation of NTI164 drug product to rapidly complete recruitment in the Rett Syndrome Phase I/II trial.

Subsequent Event – PANDAS/PANS Phase I/II Clinical Trial Results

The Company was very pleased to report strong safety and efficacy effects for the PANDAS/PANS Phase I/II clinical trial on 6 October. Professor Dale commented *"I am very pleased with the clinical results reported to date and wish to thank all patients and their families for participating in this novel clinical trial. I have observed quite profound improvements in a number of my patients with NTI164, making it the first trial of its kind with a broad-spectrum cannabinoid therapy showing initial clinical utility like this with excellent safety. In addition, we await further evidence of genomic molecular changes from baseline measures and after 12 weeks of treatment to correlate this meaningful clinical response we have seen with biological evidence of effect. This would be a major step-forward for PANDAS/PANS patients and assist in identifying relevant biomarkers of the disease."*

There are no regulatory approved treatments for PANDAS/PANS and NTI164 is the first ever broad spectrum cannabinoid drug therapy to show a significant benefit in these moderate to severely ill children. The NTIPANS1 clinical trial was designed to examine safety, and gold standard measures of clinical symptoms associated with PANDAS/PANS, relating to the severity of their condition, important measures relating to anxiety, depression, obsessive compulsive disorders and physical tic movements at 12 weeks compared to baseline measures. NTI164 showed clinically significant and meaningful improvements in clinical function, with excellent safety and tolerability over 12 weeks of daily oral treatment.

² ASX Announcement 31 May 2023 – Neurotech Granted Two Year Extension of NTI164 Treatment for Autism Trial Participants to Facilitate Commencement of Compassionate Use

The key outcomes included:

- Statistically significant and clinically meaningful improvements shown across a range of gold standard, clinically validated assessments over 12 weeks of NTI164 treatment
- Primary endpoint of anxiety and depression (RCADS-P) met ($p=0.016$) with a 30% improvement in overall symptoms from high severity at baseline to low severity from week 4 onwards
- Primary endpoint of severity of illness: Children re-classified from markedly ill at baseline (CGI-S: 5.0) to moderately ill at 12 weeks (CGI-S: 4.1), an 18% improvement ($p=0.0005$)

All patients have entered the 54-week extension phase of the trial.

In conclusion, NTI164 has shown to be safe and well tolerated up to doses of 20/mg/kg/day. The side effects reported were not serious or severe and did not significantly interfere with patients' functioning. No clinically significant abnormal laboratory values were reported.

NTI164 has shown statistically significant efficacy in improving the symptoms associated with PANDAS/PANS after 12 weeks of daily therapy, with the trial meeting the key primary endpoints of anxiety and depression (RCADS-P) with a 30% improvement overall and severity of illness displaying an 18% improvement. Other efficacy measures also showed improvements over 12 weeks of treatment.

Given these results, NTI will look towards developing an orphan drug pathway and will progress with applications for an Orphan Drug Designation (ODD) for NTI164 associated with the treatment of PANDAS/PANS in the US and Europe.

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 FY24 Neurotech anticipates:

- Completion of recruitment in the Phase II/III clinical trial in ASD (Q2 FY24)
- Human Research Ethics Committee (HREC) approval for a Phase I/II clinical trial in paediatric spastic cerebral palsy (Q2 FY24)
- Results of the Phase I/II Rett Syndrome clinical trial (Q3 FY24)
- Results of the Phase II/III ASD clinical trial (Q3 FY24)
- Submitting of application for Orphan Drug Designation (ODD) for NTI164 in PANDAS/PANS with US and EU regulatory bodies

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

CORPORATE ACTIVITY

Appendix 4C Commentary

During the quarter, the Company recorded total cash operating expenses (excluding revenue sources) of \$2.4 million (Q4 FY2023: \$1.6 million), consisting of research and development \$1.9 million (Q4 FY23: \$1.25 million), along with advertising, marketing, staff costs, administrative, and corporate costs of \$0.48 million (Q4 FY23: \$0.33 million). The Company received a \$0.23 million GST refund for the quarter (Q4 FY23: \$0.46 million). Total operating cash outflows for the quarter were \$2.1 million (Q4

FY23: \$1.11 million), up 91% on Q4 FY23, reflecting a significant increase in R&D (up 55% on Q4 FY23) attributable to the expanded Phase II/III ASD trial, and Phase I/II clinical trials in Rett Syndrome and PANDAS/PANS.

The Company closed the quarter with cash and cash equivalents of \$2.9 million (Q4 FY23: \$5.0 million). Neurotech anticipates a \$3.2 million R&D tax incentive rebate to be paid during the current quarter (Q2 FY24), resulting in a pro-forma cash balance of \$6.1 million, which is sufficient to fund the Company's operations through FY24 and complete all active clinical trials as previously indicated to the market.

Further, payments to related parties and their associates as detailed in Section 6 of the Appendix 4C relate to director fees (\$96,000) and corporate services, accounting and company secretarial fees (\$39,000).

Quarterly Conference Call Details

The Company will host an investor conference call at 12.00pm AEDT 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/10034608-3n2pgt.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: **10034608**

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

73 610 205 402

Quarter ended ("current quarter")

30 September 2023

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	(1,939)	(1,939)
(b) product manufacturing and operating costs	0	0
(c) advertising and marketing	(98)	(98)
(d) leased assets	0	0
(e) staff costs	(72)	(72)
(f) administration and corporate costs	(311)	(311)
1.3 Dividends received (see note 3)	0	0
1.4 Interest received	42	42
1.5 Interest and other costs of finance paid	(1)	(1)
1.6 Income taxes paid	0	0
1.7 Government grants and tax incentives (R&D Rebate)	0	0
1.8 Other (GST refunds)	234	234
1.9 Net cash from / (used in) operating activities	(2,144)	(2,144)

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	0	0
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	0

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	5,022	5,022
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,144)	(2,144)
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)	0	0
4.5	Effect of movement in exchange rates on cash held	(2)	(2)
4.6	Cash and cash equivalents at end of period	2,876	2,876

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	2,861	3,007
5.2	Call deposits	15	2,015
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)	2,876	5,022

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	135
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 (\$96,000) and corporate services, accounting and company secretarial fees (\$39,000).		

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	66	0
7.2	Credit standby arrangements	0	0
7.3	Other (please specify)	0	0
7.4	Total financing facilities	66	0
7.5	Unused financing facilities available at quarter end		66
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 0.6106.		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,144)
8.2	Cash and cash equivalents at quarter end (item 4.6)	2,879
8.3	Unused finance facilities available at quarter end (item 7.5)	66
8.4	Total available funding (item 8.2 + item 8.3)	2,945
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.37
	<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?	
	Yes	
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 has applied for an R&D Tax Incentive Refund for qualifying expenditures for the year ended 30 June 2023, which Neurotech anticipates receiving in the coming weeks. The quantum of the rebate is anticipated to be approximately \$3.2 million.	

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: 27 October 2023

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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.