

Quarterly Activities Report for the period ending 30 June 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 June 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

Autism Spectrum Disorder¹

On 31 May 2023, the Company announced it has obtained clearance from the Human Research Ethics Committee (HREC) to extend the Phase I/II trial of NTI164 in children with Autism Spectrum Disorder (ASD). This extension allows for an additional two years of daily oral treatment with NTI164 for ASD patients who have already participated in the trial for a total of 1.5 years. During this extension, the Company will continue to collect periodic safety information under the HREC approval, providing valuable long-term data.

The extension allows these 11 ASD patients to transition to a compassionate use program, specifically the Special Access Scheme (SAS) Category B, through Monash Medical Centre. The SAS B program will be applicable only to NTI164 and for the 11 ASD patients under the care of Professor Michael Fahey, the treating clinician. Neurotech will also benefit from reduced charges associated with pharmacy, clinician, and pathology costs for supplying the drug to these patients.

Neurotech remains committed to the clinical development of NTI164 in paediatric patients with various neurological disorders and continues to recruit patients for the Phase II/III ASD trial at Monash Medical Centre.

PANDAS/PANS^{2,3}

On 3 May 2023, the Company announced the successful completion of patient recruitment for the 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).

A total of 15 paediatric patients have commenced treatment with NTI164 and the study aims to provide valuable insights into the clinical efficacy and safety of NTI164 in these patients over the 12-week study period. The Company congratulates Co-Principal Investigators; Professor Russell Dale and Professor Michael Fahey and their respective clinical teams on the rapid enrolment and anticipates releasing top-line results of the NTIPANS1 trial in Q3 CY2023.

¹ ASX Announcement 31 May 2023 – Neurotech Granted Two Year Extension of NTI164 Treatment for Autism Trial Participants to Facilitate Commencement of Compassionate Use

² ASX Announcement 3 May 2023 – Neurotech Completes Recruitment in Phase I/II PANDAS/PANS Clinical Trial

³ ASX Announcement 30 May 2023 – Neurotech Granted HREC Approval for PANDAS/PANS Trial Extension

On 30 May 2023, the Company announced Human Research Ethics Committee (HREC) approval to extend the current Phase I/II clinical trial of NTI164 in children diagnosed with PANDAS/ PANS to allow children to continue to receive treatment after they turn 18 years of age. This decision by the HREC was granted based on requests from investigators and parents so that a patient who turns 18 years of age while on NTI164 treatment may elect to continue daily oral NTI164 dosing beyond their 12-week treatment phase and into the fifty-four (54) week extension phase of the trial. This HREC approval gives the Company upmost flexibility and will provide valuable data with respect to regulatory submissions.

Rett Syndrome⁴

On 5 June 2023, Associate Professor Carolyn Ellaway presented at the 2023 International Rett Syndrome Foundation (IRSF) Rett Syndrome Scientific Meeting in Nashville, Tennessee on the subject of “NTI164: A Novel, Full-Spectrum Medicinal Cannabis-Derived Treatment for Rett Syndrome”. This esteemed event served as a global platform to share knowledge and engage with the Rett Syndrome community regarding the promising progress in the development of NTI164. The Company was delighted to have the opportunity to share this information with clinicians and researchers, representing academia, industry, and governmental agencies from around the world.

Subsequent Events

Subsequent to the end of the quarter, on 10 July 2023, the Company announced Human Research Ethics Committee (HREC) approval and Clinical Trial Notification (CTN) scheme clearance by the Therapeutic Goods Administration (TGA) to initiate its planned Phase I/II clinical trial of NTI164 in female patients with Rett Syndrome⁵. The study will be conducted across three centres in Australia with Principal Investigator 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 and Associate Principal Investigators Professor Michael Fahey, Head of the Paediatric Neurology Unit at Monash Medical Centre, Director of Neurogenetics and Dr Giuliana Antolovich, Department of Neurodevelopment & Disability, Royal Children's Hospital Melbourne.

Investors

Neurotech has developed and released a new corporate video outlining a patient experience, clinician advocacy and the various paediatric neurological clinical trials in development across four disorders (ASD, Rett, PANDAS/PANS and cerebral palsy), two of which are considered rare or 'orphan diseases' potentially opening up new regulatory levers such as orphan drug designation(s). To watch the video, please navigate to <https://neurotechinternational.com/corporate-videos/>.

In addition, the Company has developed six informative fact sheets that explain the value proposition in Neurotech, our lead therapeutic candidate NTI164 and additional information on ASD, Rett Syndrome, PANDAS/PANS and cerebral palsy. To read these fact sheets please visit <https://neurotechinternational.com/fact-sheets/>

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 the second half of CY2023 Neurotech expects:

- Securing HREC/TGA approval for the Rett Syndrome Phase I/II clinical trial – **Achieved 10 July**

⁴ ASX Announcement 5 June 2023 – Neurotech to Present at the International Rett Syndrome Foundation Scientific Meeting

⁵ ASX Announcement 10 July 2023 – Neurotech Receives HREC Approval for Phase I/II Clinical Trial in Rett Syndrome

- Commencement of the Phase I/II clinical trial in Rett Syndrome
- Results of PANDAS/PANS Phase I/II clinical trial
- Completion of initial recruitment of Rett syndrome Phase I/II clinical trial
- Completion of patient recruitment ASD Phase II/III clinical trial
- Securing HREC/TGA approval for the Cerebral Palsy Phase I/II clinical trial

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 \$1,589,000 which was comprised of research and development (\$1,254,000), advertising and marketing (\$22,000), staff costs (\$88,000) and administrative, corporate costs and interest of (\$225,000). The Company received a \$460,000 GST refund for the quarter. Total operating cash outflows for the quarter were \$1,118,000.

The Company closed the quarter with cash and cash equivalents of \$5,022,000. Further, payments to related parties and their associates as detailed in Section 6 of the Appendix 4C relate to director fees (\$82,000) and corporate services, accounting and company secretarial fees (\$37,000).

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/10032388-qvb5az.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: **10032388**

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

Dr Thomas Duthy
Executive Director
td@neurotechinternational.com
+61 (0) 402 493 727

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 June 2023

CONSOLIDATED STATEMENT OF CASH FLOWS		Current quarter \$A'000	Year to date (12 months) \$A'000
1. Cash flows from operating activities			
1.1 Receipts from customers	1	6	
1.2 Payments for			
(a) research and development	(1,254)	(6,346)	
(b) product manufacturing and operating costs	-	(3)	
(c) advertising and marketing	(22)	(152)	
(d) leased assets	0	0	
(e) staff costs	(88)	(324)	
(f) administration and corporate costs	(223)	(1,342)	
1.3 Dividends received (see note 3)	0	0	
1.4 Interest received	11	39	
1.5 Interest and other costs of finance paid	(2)	(9)	
1.6 Income taxes paid	0	0	
1.7 Government grants and tax incentives (R&D Rebate)	0	1,189	
1.8 Other (GST refunds)	459	667	
1.9 Net cash from / (used in) operating activities	(1,118)	(6,275)	
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 (12 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:		
	(g) entities	0	0
	(h) businesses	0	0
	(i) property, plant and equipment	0	0
	(j) investments	0	0
	(k) intellectual property	0	0
	(l) 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	0	1,151
3.4	Transaction costs related to issues of equity securities or convertible debt securities	0	(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	0	9,414

CONSOLIDATED STATEMENT OF CASH FLOWS		Current quarter \$A'000	Year to date (12 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	6,141	1,891
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,118)	(6,275)
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)	0	9,414
4.5	Effect of movement in exchange rates on cash held	(1)	(8)
4.6	Cash and cash equivalents at end of period	5,022	5,022

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	3,007	4,126
5.2	Call deposits	2,015	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)	5,022	6,141

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	119
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 (\$82,000) and corporate services, accounting and company secretarial fees (\$37,000).		

7. FINANCING FACILITIES		Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
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.			
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 0.6099.		

8. ESTIMATED CASH AVAILABLE FOR FUTURE OPERATING ACTIVITIES	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,118)
8.2 Cash and cash equivalents at quarter end (item 4.6)	5,022
8.3 Unused finance facilities available at quarter end (item 7.5)	66
8.4 Total available funding (item 8.2 + item 8.3)	5,088
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.55
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: 26 July 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.