



## Quarterly report for the period ending 30 June 2018

### KEY HIGHLIGHTS

- **US clinical trial results confirm positive impact of Mente Autism for children with autism spectrum disorder**
- **Study demonstrated reduction in autistic behaviours as well as improved social and communication skills and changes in brain activity**
- **Neurotech receives CE acceptance for improvements to the Mente Autism device, which are being incorporated into the devices currently in production**
- **Neuroscience expert Dr David Cantor joins Neurotech board**
- **Business development and marketing activities a focus for H2 2018**

**Perth, Australia & Malta – 31 July 2018** – Neurotech International Limited (ASX: NTI) (“Neurotech” or “the Company”) is pleased to present its quarterly report for the period ending 30 June 2018.

Following provisional acceptance of the US clinical trial for Mente Autism by leading medical journal *Frontiers in Neurology* in June, Neurotech announced in July that full results of the trial had been published. The results showed significant positive changes in the active treatment group including:

- **Significant reductions in the brain wave frequency bands** of interest, delta, beta and high beta, which are typically abnormally high in children with autism
- **Improved balance** with eyes open rather than closed, which is the opposite effect experienced by autistic children
- **Positive effects and a reduction of autistic behaviors** across questionnaires used globally as validated tools in clinical applications
- **Parents indicating significant improvements in social skills and communication** of their children

The clinical trial, carried out by Florida’s Carrick Institute, was a randomised-controlled, double-blind investigation that compared Mente Autism with a control (or sham) device over 12 weeks. The trial was designed to ascertain the consequences of the Mente Autism neurofeedback treatment, with a variety of outcome measurements examined to assess the effectiveness of the device. This included analysis of brain activity, balance and behavior. Evaluations were completed at enrolment and again after the 12-week therapy concluded.

More than 700 potential subjects applied to participate in the trial, with 83 recruited and 34 participants completing the trial. The participants ranged from 5 to 17 years of age.

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### Neurotech International Ltd

ABN 73 610 205 402

Level 14, 191 St Georges Terrace

Perth, Western Australia 6060

[www.neurotechinternational.com](http://www.neurotechinternational.com)

Positive results of the trial suggest Mente Autism is uniquely placed to target autism as a home-based neurofeedback tool, and clinical evidence from the trial will be used to support the Company's submission to the US Food and Drug Administration (FDA), which is targeted for Q3 CY2018.

Neurotech held a webinar to discuss the US clinical trial on 12 July 2018 which is available at: <https://attendee.gotowebinar.com/register/6810929568269084674>

In June, Neurotech also announced CE acceptance of considerable improvements to Mente Autism, allowing the Company to move ahead with production. These design improvements include improvements to wi-fi connectivity, synchronisation and usability linked to the firmware and the Mente Autism application.

## **CORPORATE**

### **Board Changes**

In July, Neurotech announced the appointment of neuroscience expert Dr David Cantor to its Board as a Non-Executive Director.

Dr Cantor is a highly distinguished clinician, neuroscientist, program developer and a member of the Company's Scientific Advisory Board with a career spanning more than 40 years in the academic and clinical neuroscience sector.

He is the CEO and Clinical Director of Mind and Motion Developmental Centers of Georgia, a multidisciplinary treatment facility providing a range of diagnostic and treatment services to children and adults seeking help with neurological disorders such as autism, ADHD, traumatic brain injury and sensory processing disorders. He is also the CEO and Managing Partner of BrainDx, an international software company that produces functional brain analytic software through computer assisted quantitative EEG (QEEG) reports and big database measures of brain development.

Dr Cantor's appointment followed the retirement of Neurotech founder Dr Adrian Attard Trevisan as a Non-Executive Director of the Company in June.

## **OUTLOOK**

With the positive US clinical trial results now in hand, the Company's next regulatory milestone will be obtaining the US FDA clearance for the Mente Autism device using a de-novo application process. Documents pertaining to the technical aspects of the product are being prepared. Neurotech expects to complete these elements and provide its submission to the FDA before the end of Q3 2018. Depending on several factors, including the FDA's current backlog, benchmarks indicate the approval would take 9 - 12 months.

Initial units of the next batch of Mente Autism devices are expected to be available this month, with the first shipment of devices expected in August. Pre-orders have been received from several of Neurotech's existing distributors, who are initiating various marketing activities to coincide with the release of the Mente Autism clinical trial results. This has included direct mailouts to contacts, outreach to media targets, social media activity targeting potential customers, autism group events and dedicated Mente Autism pages via the distributor websites. Promosalute, Neurotech's Italian distribution partner, has also been active with a series of marketing activities including a targeted online marketing exercise and the opening of the first three neurofeedback centres throughout Italy.

Since the release of the US clinical trial results, the Company has seen a surge in enquiries from potential distributors from other geographies, and Neurotech management expects to broaden its reach with new distribution agreements through 2018 and 2019, with a focus on establishing a presence in the UK, France and Spain.

Another focus for management will be continuing to spread awareness of Mente Autism via conference participation in the coming months in various locations. This includes the World Autism Organisation International Congress, the World Congress of Psychophysiology, the Applied Neuroscience Society of Australasia Conference and the Australasian Society for Autism Research Conference. Neurotech CEO Wolfgang Storf will also be joined by the US clinical trial lead investigator Professor Frederick Carrick in Australia for a series of marketing and public relations activities in the near term.

To coincide with the availability of the next batch of the Mente Autism device, an updated website has been launched with direct calls to action, pre-sales assessment for potential users of the device as well as usability improvements.

In September, Neurotech is aiming to initiate multi-center studies that will further promote the effectiveness of Mente Autism across different regions. These smaller studies, for which the Company's investment is typically limited to the cost of providing research devices, are aimed at promoting further awareness and acceptance of the technology while also potentially assisting with the reimbursement process for Mente Autism in those regions. The process to apply for such reimbursement is being planned with an initial focus on Germany and Australia.

Neurotech's board and management looks forward to bringing investors continued updates during what will be a pivotal second half of CY2018.

For more information about Neurotech and Mente Autism please visit:

<http://www.neurotechinternational.com>.

<http://www.mentetech.com>.

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### **About Neurotech**

Neurotech International Limited is a medical device and solutions company incorporated in Australia and operating through its wholly-owned, Malta-based subsidiary AAT Research Limited. Neurotech's primary mission is to improve the lives of people with neurological conditions, with a vision of becoming the global leader in home-use and clinical neurotechnology solutions that are both accessible and affordable. Through flagship device Mente Autism and its associated platform, Neurotech is focused on the development and commercialisation of technological solutions for the diagnosis and treatment of such conditions, starting with autism.

*For more information please contact:*

Matthew Wright

[matt@nwrcommunications.com.au](mailto:matt@nwrcommunications.com.au)

Tel: +61 451 896 420

## Appendix 4C

### Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

**Name of entity**

Neurotech International Limited

**ABN**

73 610 205 402

**Quarter ended ("current quarter")**

30 June 2018

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	36
1.2 Payments for		
(a) research and development	(210)	(897)
(b) product manufacturing and operating costs	(211)	(770)
(c) advertising and marketing	(50)	(80)
(d) leased assets	-	-
(e) staff costs	(237)	(806)
(f) administration and corporate costs	(232)	(807)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	6	30
1.5 Interest and other costs of finance paid	-	(17)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(934)</b>	<b>(3,311)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
	(d) intellectual property	(31)	(582)
	(e) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	2
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	<b>Net cash from / (used in) investing activities</b>	<b>(31)</b>	<b>(580)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of shares	17	4,017
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	-	(240)
3.5	Proceeds from borrowings	15	23
3.6	Repayment of borrowings	-	(397)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	<b>Net cash from / (used in) financing activities</b>	<b>32</b>	<b>3,403</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of quarter/year to date	3,139	2,637
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(934)	(3,311)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(31)	(580)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	32	3,403

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.5	Effect of movement in exchange rates on cash held	20	77
4.6	<b>Cash and cash equivalents at end of quarter</b>	<b>2,226</b>	<b>2,226</b>

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	1,220	21
5.2	Call deposits	1,006	3,118
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>2,226</b>	<b>3,139</b>

**6. Payments to directors of the entity and their associates**

- 6.1 Aggregate amount of payments to these parties included in item 1.2
- 6.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

Current quarter  
\$A'000

42

Includes \$42,500 directors fee for the period to 30 June 2018

**7. Payments to related entities of the entity and their associates**

- 7.1 Aggregate amount of payments to these parties included in item 1.2
- 7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

Current quarter  
\$A'000

22

Administration services fees of \$22,500 paid to associates entity for services provided to 30 June 2018.

**8. Financing facilities available**

*Add notes as necessary for an understanding of the position*

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
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8.1 Loan facilities

-

-

8.2 Credit standby arrangements

-

-

8.3 Other (please specify)

-

-

8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.

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9. Estimated cash outflows for next quarter	\$A'000
9.1 Research and development	12
9.2 Product manufacturing and operating costs	355
9.3 Advertising and marketing	135
9.4 Leased assets	-
9.5 Staff costs	230
9.6 Administration and corporate costs	284
9.7 Other	-
<b>9.8 Total estimated cash outflows</b>	<b>1,016</b>

10. Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1 Name of entity		
10.2 Place of incorporation or registration		
10.3 Consideration for acquisition or disposal		
10.4 Total net assets		
10.5 Nature of business		



### 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.



Sign here: .....  
(Company secretary)

Date: ..31 July 2018.....

Print name: .....FLEUR HUDSON.....

### Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly 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 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.