

#### Neurotech International Limited Appendix 4D Half Year Report

#### 1.Company details

Name of entity: Neurotech International Limited

ACN: 610 205 402

Reporting period: For the half-year ended 31 December 2024 Previous period: For the half-year ended 31 December 2023

#### 2. Results for announcement to the market

				\$000
Revenues from ordinary activities	down	100%	to	0
Loss from ordinary activities after tax attributable to the owners of Neurotech International Limited	up	922%	to	(7,445)
Loss for the period attributable to the owners of Neurotech International Limited	up	922%	to	(7,445)

#### Comments

The loss for the Group after providing for income tax amounted to \$7,444,902 (31 December 2023: \$728,872) The loss from ordinary activities includes \$5,690,862 (31 December 2023: \$2,237,138) in Research and Development expenditure.

#### 3. Net tangible assets

3. Net tallgible assets	Reporting period Cents	Previous period Cents
Net tangible assets per ordinary security (cents)	0.6	0.5

#### 4. Dividends

There were no dividends paid, recommended or declared during the financial period.

#### 5. Audit review

This report is based on the financial statements which have been reviewed by BDO Audit Pty Ltd.

#### 6 Attachments

The interim financial report for the period ended 31 December 2024 is attached.

Signed

Mark Davies Chairman

27 February 2025



# **NEUROTECH INTERNATIONAL LIMITED**

ACN 610 205 402

# CONSOLIDATED INTERIM FINANCIAL REPORT FOR THE HALF-YEAR ENDED 31 DECEMBER 2024

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#### **CORPORATE DIRECTORY**

DIRECTORS Mark Davies (Non-Executive Chairman)

Anthony Filippis (Managing Director/CEO) – appointed 1 February 2025

Thomas Duthy (Executive Director)

Robert Maxwell Johnston (Non-Executive Director)

Gerald Quigley (Non-Executive Director)

**COMPANY SECRETARY** 

Alessandra Gauvin

**REGISTERED AND PRINCIPAL OFFICE** 

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The Directors present their report together with the financial report of Neurotech International Limited and its controlled entities (**Group**) for the half-year ended 31 December 2024 and the Auditor's Report thereon.

#### **BOARD OF DIRECTORS**

The names and details of the Directors in office during the financial period and until the date of this report are set out below.

Mark Davies Non-Executive Chairman
 Anthony Filippis Managing Director & CEO
 Thomas Duthy Executive Director

Inomas Dutny Executive Director
 Robert Maxwell Johnston Non-Executive Director
 Gerald Quigley Non-Executive Director

#### **PRINCIPAL ACTIVITIES**

Neurotech International Limited (ASX:NTI) is a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders. The lead product is NTI164, a broad-spectrum cannabinoid drug therapy which is delivered orally as an oil formulation.

The Group's mission is to focus on the development and commercialisation of innovative neurological therapies that improve quality of life. The Group is dedicated to advancing research, developing innovative treatments, and providing compassionate care to improve the lives of children affected by neurological disorders.

#### **OPERATING RESULTS**

The consolidated Group's net loss after providing for income tax for the half-year ended 31 December 2024 amounted to \$7,447,902 (31 December 2023: \$728,771). At 31 December 2024, the Group has \$5,948,610 Cash and Cash Equivalents (30 June 2024: \$11,610,480). Refer to Note 1(d) on the preparation of the financial statements on a going concern basis.

#### **REVIEW OF OPERATIONS**

#### **Autism Spectrum Disorder (ASD)**

During the half year, the Group 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.

In November 2024, the Group announced the publication of new NTI164 pre-clinical data in the peer-reviewed Journal Biomolecules. The publication is titled "Evaluation of the Efficacy of a Full-Spectrum Low-THC Cannabis Plant Extract Using In Vitro Models of Inflammation and Excitotoxicity" described the immunomodulatory and neuroprotective effects of NTI164, Neurotech broad spectrum cannabinoid drug therapy.

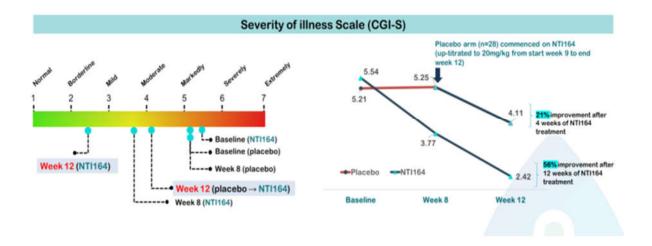
In July 2024, the Group announced several important clinical updates for the NTIASD2 Phase II/III clinical trial, which previously reported statistically significant and clinically meaningful improvements in ASD in Q4 FY24. The trial met the primary and all key secondary endpoints.

The Group reported the final analysis at 8 weeks on the effects of NTI164 on anxiety, depression and mood (ADAMS) versus placebo (a secondary endpoint). There was a marked treatment effect of NTI164 versus placebo to week 8 with a significant improvement in the ADAMS scale (p<0.001). Approximately 40-50% of children with

autism experience clinically significant levels of anxiety. The prevalence of depression in autistic children has been estimated at 10-20%. Patients on placebo saw a deterioration in their ADAMS score, despite 43% of these patients already receiving existing treatments for their anxiety/depression.

An additional further analysis was conducted on the effect of NTI164 in children who were receiving placebo for 8 weeks and then crossed-over to NTI164 from the end of week 8 (beginning of week 9) to week 12 per the trial protocol. In addition, CGI-S information was analysed at week 12 for those patients who were initially enrolled in the NTI164 arm of the trial.

Neurotech observed further significant improvements in ASD patients who received NTI164 following the primary endpoint analysis at 8 weeks as previously reported. At 12 weeks, NTI164 patients showed a mean CGI-S score of 2.42, representing a 56% improvement from baseline (CGI-S: 5.54) with children re-classified under this scale as borderline ill (CGI-S score of 2.42). In general, for a CGI-S score of 2, ASD symptoms are present but only just noticeable and not significantly impairing for the child. This is a very significant improvement at 12 weeks for those patients on NTI164 relative to their baseline score of 5.54 (markedly ill), and versus 8 weeks (mildly ill, CGI-S 3.77). Markedly ill patients show significant impairments, needing substantial, consistent support to manage daily life.



The Group 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%. 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.

#### **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.

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.

On 9 July 2024, the Group announced the filing of an ODD with the US FDA for PANDAS/PANS. On 4 October

2024, the Group announced it was unsuccessful with the orphan drug designation ODD request from the FDA. The development plans for PANDAS/PANS remain unaffected by the FDA's decision, as new therapies are urgently needed.

During the half year, the results of the proteomic analysis undertaken as part of the 15 patient, open-label Phase I/II clinical trial of NTI164 ("NTIPANS1") in PANDAS/PANS children was undertaken. NTI164 was shown to positively modify immune cell function and gene translation dysregulation, improving overall health and functional outcomes of children. The disease-modifying potential of NTI164 may improve children with PANDAS/PANS by normalising their immune function and gene translation profiles. NTI164 appears to have both significant anti-inflammatory effects, as well as potential as an epigenetic modulator.

Further genomic analysis was reported also during the half. The genomic analysis 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).

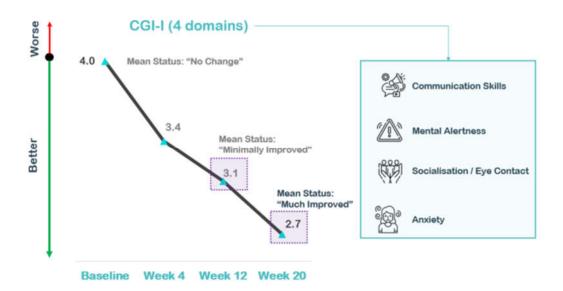
#### **Rett Syndrome**

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.

On 31 July 2024, the Group announced further clinical efficacy and the safety results for all 14 female paediatric patients who completed 20 weeks of daily oral treatment with NTI164 under the Company's one year extension period of the Phase I/II clinical trial investigating the use of NTI164 in Rett Syndrome.

There were no serious adverse events (SAEs), no adverse events (AEs) reported between 12 weeks to 20 weeks and no weight loss (mean weight was stable versus 12 weeks and weight recorded at baseline). At 12 weeks, two patients (14%) experienced nausea/vomiting effects. This safety profile compares favourably with the only FDA approved treatment for Rett Syndrome, DAYBUE™ (trofinetide).

Overall, the 20 week data showed an improvement of 33% versus baseline (compared to 23% improvement at 12 weeks). Between 12 to 20 weeks, there was an additional CGI-I improvement of -0.4, representing a significant, additional improvement of 13% (p=0.007), which continues the trajectory of clinical improvement overall. This is shown below.



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, the Group announced the US Food and Drug Administration (FDA) granted (ODD) for the use of NTI164 in children and adults diagnosed with Rett Syndrome. 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 2024, 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.

#### **IND-ENABLING TOXICOLOGY & HUMAN OK TRIAL COMMENCES**

During the half year, the Group continued to progress its animal pharmacology and toxicology studies across two species in certified laboratories in the United States. 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, the Group 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.

#### **GLOBAL PARTNERING & REGISTRATION STRATEGY**

During the half year, the Group announced its targeted global partnering strategy and registration-directed initiatives in Australia. Neurotech is committed to securing one or more strategic partnerships for NTI164 in the United States (US), Europe and certain Asian territories (e.g. Japan). Such partner(s) will have the necessary financial resources and experience in late-stage drug development, clinical trials, and commercialisation.

This strategy, if successful, will allow the Group to focus its financial resources and expertise towards registration of NTI164 in Australia, where the Company intends to maintain 100% commercial ownership of NTI164 in the Australian market. The Group believes there is a large opportunity for NTI164 for all three neurological disorders.

The Group is committed to accelerating NTI164 registration in Australia by exploring a provisional registration pathway. The provisional determination process is expected to complete in 2H CY2025 with the Group (if successful) to file for provisional registration also in the second half of the 2025 calendar year.

#### **SIGNIFICANT CHANGES IN STATE OF AFFAIRS**

Other than detailed in the Review of Operations, there were no significant changes in the state of affairs of the Group during the half-year.

#### MATTERS SUBSEQUENT TO THE END OF THE PERIOD

#### **Operational**

#### Appointment of Managing Director and CEO - Dr Anthony Filippis

The Group was pleased to announce the appointment of Dr Anthony Filippis as Managing Director and CEO in November 2024 (with an effective appointment date of 1 February 2025), 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.

#### **R&D** tax Incentive

On 31 January 2025, the Group received a research and development (R&D) tax incentive refund of \$2,444,143 under the Australian Federal Government's R&D Tax Incentive scheme. The tax refund relates to eligible R&D activities for the financial year ended 30 June 2024.

#### Positive Opinion for Orphan Designation from European Medicines Agency (EMA)

On 27 February 2025, the Company announced that the EMA has issued a positive opinion on the Company's Orphan Medicinal Product Designation (OMPD) application of NTI164 for the treatment of Rett Syndrome. The Company filed for OMPD in Europe in late October 2024. Neurotech anticipates the issuance of the official decision by the European Commission in due course.

Other than detailed above no other matters or circumstances have arisen since 31 December 2024 that have significantly affected, or may significantly affect the Group's operations, the results of those operations, or the Group's state of affairs in future financial years.

#### **OUTLOOK**

The Group's primary mission is to improve the lives of people with neurological conditions. The Group is dedicated to advancing research, developing innovative treatments, and providing compassionate care to improve the lives of children affected by neurological disorders. With a steadfast commitment to understanding the unique needs of each child, the Group strives to empower families, inspire breakthroughs in paediatric neurology, and create a future where every child can thrive and reach their full potential, irrespective of neurological obstacles.

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 \$5,948,610 (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. The Company received an additional \$2,444,143 from the R&D tax incentive refund in January 2025.

In the half year to 31 December 2024, the Group has made substantial progress towards its operational objectives in the development of NTI164 in the treatment of paediatric neurological disorders.

The Group has a number of important clinical and regulatory milestones planned for the first half 2025 calendar year, including:

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

#### **AUDITOR'S INDEPENDENCE DECLARATION**

The Auditor's Independence Declaration as required under section 307C of the *Corporations Act 2001* for the half-year ended 31 December 2024 has been received and can be found on page 11.

This report is made in accordance with a resolution of Directors, pursuant to section 306(3)(a) of the *Corporations Act 2001*.

Signed on behalf of the Board of Directors.

**Mark Davies** 

Non-Executive Chairman

Dated at Perth, Western Australia, 27 February 2025



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# DECLARATION OF INDEPENDENCE BY GLYN O'BRIEN TO THE DIRECTORS OF NEUROTECH INTERNATIONAL LIMITED

As lead auditor for the review of Neurotech International Limited for the half-year ended 31 December 2024, I declare that, to the best of my knowledge and belief, there have been:

- No contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the review; and
- 2. No contraventions of any applicable code of professional conduct in relation to the review.

This declaration is in respect of Neurotech International Limited and the entities it controlled during the period.

Glyn O'Brien

Director

**BDO Audit Pty Ltd** 

Gun O'res

Perth

27 February 2025

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# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE HALF-YEAR ENDED 31 DECEMBER 2024		CONSOLID	ATED
	Notes	31 December 2024	31 December 2023
		(\$)	(\$)
CONTINUING OPERATIONS			
Revenue		232	1,507
R&D Grant income		-	3,175,370
Other income		113,489	33,701
Professional consultant and advisory expenses		(245,309)	(182,813)
Professional legal expenses		(80,602)	(30,140)
Corporate and administration expenses		(368,371)	(295,652)
Depreciation and amortisation expenses		(289)	(293)
Advertising and marketing expenses		(3,077)	(5,530)
Employee benefits expense		(314,369)	(252,837)
Research and development expense	2	(5,690,862)	(2,237,138)
Share based payments expense	3	(855,641)	(926,405)
Equipment and materials direct cost		-	(2,501)
Other expenses		(103)	(6,040)
LOSS BEFORE INCOME TAX		(7,444,902)	(728,771)
Income tax benefit		-	-
LOSS AFTER INCOME TAX		(7,444,902)	(728,771)
Other comprehensive income/(loss)		-	-
Items that may be reclassified subsequently to profit or loss:			
Exchange difference on translation of foreign operations		(1,431)	(101)
Total comprehensive loss for the period		(7,446,333)	(728,872)
Basic and diluted loss per share (cents per share)	4	(0.73)	(0.08)

The Consolidated Statement of Profit or Loss and Other Comprehensive Income are to be read in conjunction. with the accompanying notes.

# **CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

AS AT 31 DECEMBER 2024		CONSOLIDATED	
	Notes	31 December 2024	30 June 2024
		(\$)	(\$)
CURRENT ASSETS			
Cash and cash equivalents	5	5,948,610	11,610,480
Term deposits	5	15,000	15,000
Trade and other receivables		468,424	318,053
Prepayments		628	269,564
TOTAL CURRENT ASSETS		6,432,662	12,213,097
NON-CURRENT ASSETS			
Property, plant and equipment		-	289
TOTAL NON-CURRENT ASSETS		-	289
TOTAL ASSETS		6,432,662	12,213,386
CURRENT LIABILITIES			
Trade and other payables		695,141	314,699
TOTAL CURRENT LIABILITIES		695,141	314,699
TOTAL LIABILITIES		695,141	314,699
NET ASSETS		5,737,521	11,898,687
EQUITY			
Contributed Equity	6	48,389,346	46,734,820
Reserves	7	6,350,372	6,721,162
Accumulated Losses		(49,002,197)	(41,557,295)
TOTAL EQUITY		5,737,521	11,898,687

The Consolidated Statement of Financial Position is to be read in conjunction with the accompanying notes.

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE HALF-YEAR ENDED 31 DECEMBER 2024

(Loss) for the period       -       (7,444,902)       -       -       (7,444,902)         Exchange difference       -       -       -       -       (1,431)       (7,444,902)         Total comprehensive (loss)       -       (7,444,902)       -       (1,431)       (7,444,902)         Exercise of options – Note 6       434,000       -       -       -       4         Share based payments – Note 3       525,000       -       330,641       -       8         Share issue to Fenix       700,000       (700,000)       (700,000)       -       -       -       -       -         Share issue costs       (4,474)       -       -       -       -       -       -       -		Contributed Equity (\$)	Accumulated Losses (\$)	Share-based Payment Reserve (\$)	Foreign Currency Translation Reserve (\$)	Total (\$)
(Loss) for the period       - (7,444,902)       - (7,444         Exchange difference       (1,431)       - (1,431)         Total comprehensive (loss)       - (7,444,902)       - (1,431)       (7,444         Exercise of options – Note 6       434,000       4       - 4         Share based payments – Note 3       525,000       - 330,641       - 8         Share issue to Fenix       700,000       (700,000)          Share issue costs       (4,474)	HALF-YEAR ENDED 31 DECEMBER 2024					
Exchange difference       -       -       -       (1,431)       (7,444)         Total comprehensive (loss)       -       (7,444,902)       -       (1,431)       (7,444)         Exercise of options – Note 6       434,000       -       -       -       -       4         Share based payments – Note 3       525,000       -       330,641       -       8         Share issue to Fenix       700,000       (700,000)       (700,000)         Share issue costs       (4,474)       -       -       -       -	Balance at 1 July 2024	46,734,820	(41,557,295)	7,026,501	(305,339)	11,898,687
Total comprehensive (loss)         -         (7,444,902)         -         (1,431)         (7,444)           Exercise of options – Note 6         434,000         -         -         -         4           Share based payments – Note 3         525,000         -         330,641         -         8           Share issue to Fenix         700,000         (700,000)         -	(Loss) for the period	-	(7,444,902)	-	-	(7,444,902)
Exercise of options – Note 6       434,000       -       -       -       4         Share based payments – Note 3       525,000       -       330,641       -       8         Share issue to Fenix       700,000       (700,000)       -	Exchange difference	-	-	-	(1,431)	(1,431)
Share based payments – Note 3       525,000       -       330,641       -       8         Share issue to Fenix       700,000       (700,000)         Share issue costs       (4,474)       -       -       -       -	Total comprehensive (loss)	-	(7,444,902)	-	(1,431)	(7,446,333)
Share issue to Fenix       700,000       (700,000)         Share issue costs       (4,474)       -       -       -       -	Exercise of options – Note 6	434,000	-	-	-	434,000
Share issue costs (4,474)	Share based payments – Note 3	525,000	-	330,641	-	855,641
	Share issue to Fenix	700,000		(700,000)		-
Balance at 31 December 2024 48,389,346 (49,002,197) 6,657,142 (306,770) 5,7	Share issue costs	(4,474)	-	-	-	(4,474)
	Balance at 31 December 2024	48,389,346	(49,002,197)	6,657,142	(306,770)	5,737,521

The Consolidated Statement of Changes in Equity is to be read in conjunction with the accompanying notes.

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

	Contributed Equity (\$)	Accumulated Losses (\$)	Share-based Payment Reserve (\$)	Foreign Currency Translation Reserve (\$)	Total (\$)
HALF-YEAR ENDED 31 DECEMBER 2023					
Balance at 1 July 2023	35,164,844	(36,488,044)	5,219,652	65,511	3,961,963
(Loss) for the period	-	(728,771)	-	-	(728,771)
Exchange difference	-	-	-	(101)	(101)
Total comprehensive (loss)	-	(728,771)	-	(101)	(728,872)
Exercise of options – Note 6	260,052	-	-	-	260,052
Placement Shares	-	-	-	-	-
Share based payments – Note 3	375,000	-	926,405	-	1,301,405
Options to be issued	-	-	-	-	-
Share issue costs	-	-	-	-	-
Balance at 31 December 2023	35,799,896	(37,216,815)	6,146,057	65,410	4,794,548

The Consolidated Statement of Changes in Equity is to be read in conjunction with the accompanying notes.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE HALF-YEAR ENDED 31 DECEMBER 20	24		
		CONSOLIDATED	
	Notes	31 December 2024	31 December 2023
		(\$)	(\$)
CASH FLOWS FROM OPERATING ACTIVITIES			
Receipts from customers		232	1,507
Other receipts		-	3,175,370
Payments to suppliers and employees		(6,205,117)	(4,080,874)
Interest received		113,489	33,701
NET CASH USED IN OPERATING ACTIVITIES	_	(6,091,396)	(870,296)
CASH FLOWS FROM INVESTING ACTIVITIES	_		
(Investing activities- nil)		-	-
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issue of shares		429,526	260,052
Proceeds from borrowings		-	63,876
NET CASH PROVIDED BY FINANCING ACTIVITIES	_	429,526	323,928
Net increase/(decrease) in cash held	=	(5,661,870)	(546,368)
Cash and cash equivalents at beginning of financial		11 625 490	E 02E 70E
period		11,625,480	5,025,795
Cash and cash equivalents at end of financial period		5,963,610	4,479,427

The Consolidated Statement of Cash Flows is to be read in conjunction with the accompanying notes.

#### 1. STATEMENT OF MATERIAL ACCOUNTING POLICIES

#### (a) Basis of preparation of half-year financial statements

The consolidated interim financial report is a general-purpose financial report, which has been prepared in accordance with the requirements of the *Corporations Act 2001* and applicable accounting standards including AASB 134 'Interim Financial Reporting', Accounting Interpretation and other authoritative pronouncements of the Australian Accounting Standards Board ('AASB'). Compliance with AASB 134 ensures compliance with IAS 34 'Interim Financial Reporting'.

These general-purpose financial statements do not include all the notes of the type normally included in annual financial statements. It is recommended that this financial report be read in conjunction with the annual financial statements of the Group for the year ended 30 June 2024 together with any public announcements made during the half-year ended 31 December 2024 in accordance with the continuous disclosure requirements arising under *Corporations Act 2001* and the ASX Listing Rules.

The accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period.

All amounts are presented in Australian dollars, unless otherwise noted.

These half-year financial statements were approved by the Board of Directors on 27 February 2025.

#### (b) New or amended Accounting Standards and interpretations adopted

The consolidated entity has adopted all of the new or amended Accounting Standards and interpretations issued by the Australian Accounting Standards Board that are mandatory for the current reporting period.

#### (c) Significant Accounting Judgments, Estimates and Assumptions

The preparation of the half-year financial report requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, income and expense. Actual results may differ from these estimates.

In preparing this half-year financial report, the significant judgments made by management in applying the Group's accounting policies and the key sources of estimation uncertainty were the same as those that applied to the annual financial statements as at and for the year ended 30 June 2024.

#### (d) Going Concern

The Directors are satisfied that the going concern assumption has been appropriately applied in preparing the financial statements and the historical financial information has been prepared on a going concern basis, which contemplates the continuity of normal business activity and the realisation of assets and the settlement of liabilities in the normal course of business.

#### 2. RESEARCH EXPENSE

Research and Development is a key focal area for the Group and the associated revenue and expenditure is broken down as follows:

	CONSOLID	ATED
	31 December 2024	<b>31</b> December <b>2023</b>
	(\$)	(\$)
Research and development grant income	come -	
Research and development expenses		
Product development & formulation	140,783	92,271
Clinical programme	5,503,222	2,123,242
Patent and IP expenses	46,857	20,825
Other	-	800
Total research and development expense	5,690,862	2,237,138

#### 3. SHARE BASED PAYMENTS EXPENSE

The primary purpose of share-based payments is to remunerate Directors, other Key Management Personnel and Service providers for the services rendered to the Group.

#### **Share, Options and Performance Rights**

	CONSOLIDATED		
	31 December 2024 (\$)	31 December 2023 (\$)	
Options issued to Management			
Expense recognised for the period related to previously issued options to Dr Alex Andrews (COO)	-	461	
Options issued to Directors			
Expense recognised for the period related to previously issued options to directors	14,591	231,333	
Share and Performance Rights issued to Service Provider			
Class B, C, D, and E Performance right to be issued to Fenix	331,872	-	
Conversion of Class A performance rights to 7,500,000 shares	509,178	-	
Options issued to Merchant Corporate	-	694,611	
Total share-based payments expense	855,641	926,405	

#### **Options issued to Directors**

The share-based payment expenses recognized for the period represent the cost of the options issued to Thomas Duthy as an equity incentive component of his remuneration package as an Executive Director. At the General Meeting held on September 10, 2024, shareholders approved the addition of a cashless exercise facility to the terms and conditions of the Duthy Option.

The option holder may elect not to provide payment of the exercise price for the number of options specified in a notice of exercise. Instead, upon exercise of those options, the company will transfer or allot to the option holder a number of shares equal in value to the positive difference between the then-market value of the shares at the time of exercise and the exercise price that would otherwise be payable to exercise each of those options, with the number of shares rounded down to the nearest whole share.

#### **Shares and Performance Right issue to Fenix Innovative Group**

On 31 May 2024, the Company had signed an agreement with Fenix Innovative Group to work exclusively with Neurotech in the development of the Company's broad spectrum cannabinoid drug therapy NTI164 for neurological disorders. On 10 September 2024, the shareholders had approved to issue Fenix (or its nominees) 10 million shares and 50 million performance rights, with vesting conditions based upon the achievement of certain milestones and retention conditions.

The expense of these Performance Rights was calculated by reference to the following inputs:

Input	Class A*	Class B	Class C	Class D**	Class E**	Total
Number of performance rights	7,500,000	7,500,000	5,000,000	10,000,000	20,000,000	50,000,000
Share price on agreement date	\$0.07	\$0.07	\$0.07	\$0.07	\$0.07	
Probability of vesting	100%	100%	100%	100%	100%	
Fair value	\$525,000	\$525,000	\$350,000	\$400,000	\$700,000	
Agreement date	31/05/2024	31/05/2024	31/05/2024	31/05/2024	31/05/2024	
Expiry date	17/09/2027	17/09/2027	17/09/2027	17/09/2027	17/09/2027	
Expensed in the half-year ended 31 December 2024	\$509,178	\$88,219	\$58,813	\$67,215	\$117,625	\$841,050

<sup>\*</sup> The vesting condition has been met, and 7,500,000 performance rights have been converted to shares for Fenix on 2 December 2024.

<sup>\*\*</sup>Class D and E Rights were valued using the Up and In Trinomial Model. The details of the significant assumptions used are in tables below:

Rights	Class D	Class E
Risk-free rate	4.433%	4.433%
Underlying security spot price	\$0.07	\$0.07
Life of the Rights	3 years	3 years
Volatility	75%	75%
Valuation per Rights	\$0.040	\$0.035

The vesting conditions for each class of Performance Rights is as follows:

(i) Class A Performance Rights:

**Vesting condition**: The Company's broad spectrum cannabinoid therapy 'NTI164' (NTI164) receiving an 'Orphan Drug Designation' in the United States of America (US) for any paediatric neurological condition.

Retention conditions: The Collaboration Agreement not having been terminated before the Expiry Date.

(ii) Class B Performance Rights:

Vesting condition: NTI164 receiving an 'Orphan Drug Designation' in the European Union (EU) for any

paediatric neurological condition.

Retention conditions: The Collaboration Agreement not having been terminated before the Expiry Date.

#### (iii) Class C Performance Rights:

**Vesting condition**: The Company receiving either an 'Investigational New Drug Application' from the Food and Drug Administration of the US or a 'Competent Authority' clearance from the EU for a human clinical trial in any paediatric neurological indication in respect of NTI164.

Retention conditions: The Collaboration Agreement not having been terminated before the Expiry Date.

#### (iv) Class D Performance Rights:

#### **Vesting condition**

- (a) The Company executing a Licence Agreement with a third party for any of the US, EU, Japanese, Canadian or Australian markets in respect of the registration and subsequent sales of NTI164; and
- (b) the volume weighted average price (VWAP) of the Shares remaining at or above \$0.25 per Share for a period of 5 consecutive trading days on which trades in the Shares occur on ASX.

Retention conditions: The Collaboration Agreement not having been terminated before the Expiry Date.

#### (v) Class E Performance Rights:

#### **Vesting condition**

- (a) NTI164 receiving approval (provisional or otherwise) from the Therapeutic Goods Administration of the Federal Government of Australia allowing the Company to market and sell NTI164 in Australia for the treatment of any paediatric neurological disorder; and
- (b) the volume weighted average price (VWAP) of the Shares remaining at or above \$0.30 per Share for a period of 5 consecutive trading days on which trades in the Shares occur on ASX.

Retention conditions: The Collaboration Agreement not having been terminated before the Expiry Date.

#### 4. LOSS PER SHARE

The calculation of basic loss per share for the period ended 31 December 2024 was based on the loss attributable to ordinary shareholders of \$7,447,902 (31 December 2023: \$728,771) and a weighted average number of ordinary shares outstanding at the end of the period of 1,023,030,596 (31 December 2023: 876,821,145).

	CONSOL	CONSOLIDATED	
	31 December 2024	31 December 2023	
	(\$)	(\$)	
c loss per share (cents per share)	(0.73)	(0.08)	
Reconciliation of earnings to operating loss			
Loss attributable to ordinary shareholders after tax	(7,447,902)	(728,771)	
Loss used in the calculation of EPS	(7,447,902)	(728,771)	
Weighted average number of ordinary shares (WANOS) outstanding during the half year			
WANOS used in calculating basic loss per share	1,023,030,596	876,821,145	
	Reconciliation of earnings to operating loss  Loss attributable to ordinary shareholders after tax  Loss used in the calculation of EPS  Weighted average number of ordinary shares (WANOS) outstanding during the half year	C loss per share (cents per share) (0.73)  Reconciliation of earnings to operating loss  Loss attributable to ordinary shareholders after tax (7,447,902)  Loss used in the calculation of EPS (7,447,902)  Weighted average number of ordinary shares (WANOS) outstanding during the half year	

Effect of dilutive securities: Share options are not considered dilutive as the conversion of options to ordinary shares will result in a decrease in the net loss per share.

#### 5. CASH AND CASH EQUIVALENTS

	CONSOLIDAT	ED
	31 December 2024	30 June 2024
	(\$)	(\$)
Cash at bank and on hand	5,948,610	11,610,480
Term Deposit <sup>1</sup>	15,000	15,000
otal cash and cash equivalents	5,963,610	11,625,480

<sup>1</sup>As at 31 December 2024, NTI holds \$15,000 in an interest earning cash deposit account maturing on 2 August 2025.

#### 6. CONTRIBUTED EQUITY

		CONSOLIDATED		
	31 December 2024 (Shares)	31 December 2023 (Shares)	31 December 2024 (\$)	31 December 2023 (\$)
Ordinary Shares	1,042,121,921	891,739,236	48,389,346	34,585,074
Total Share Capital	1,042,121,921	891,739,236	48,389,346	34,585,074

#### Movements of share capital during the period

Date	Details	No of shares	Issue price (\$)	\$
Opening Bala	nce at 1 July 2024	1,017,388,587		46,734,820
27/08/2024	Exercise of NTIOPT26S	200,000	0.06	12,000
13/09/2024	Exercise of NTIOPT26S	7,033,334	0.06	422,000
17/09/2024	Issue of 10,000,000 shares to Fenix	10,000,000	0.07	700,000
02/12/2024	Conversion of 7,500,000 Class A NTIPERR2 Performance Rights - Fenix	7,500,000	0.07	525,000
	Capital raising costs			(4,474)
Closing Balan	ce at 31 December 2024	1,042,121,921		48,389,346

The holder of Ordinary Shares is entitled to participate in dividends and the proceeds on winding up of the Group in proportion to the number of and amounts paid on the shares held. On a show of hands every holder of ordinary shares present at a meeting in person or by proxy, is entitled to one vote, and upon a poll each share is entitled to one vote.

Ordinary Shares have no par value and the Group does not have a limited amount of authorised capital.

On 2 December 2024, the Company converted 7,500,000 Class A Performance rights into Shares to Fenix as outlined in a client contract dated May 31, 2024. Fenix Innovation Group has committed to work exclusively with Neurotech in the development of the Company's broad spectrum cannabinoid drug therapy NTI164 for neurological disorders.

#### 7. OTHER RESERVES

Share based payments	(369,359)	-	(369,359)
Foreign exchange movement	-	(1,431)	(1,431)
Balance at 1 July 2024	7,026,501	(305,339)	6,721,162
	Share Based Payments Reserve (\$)	Foreign Currency Translation Reserve (\$)	Total Reserves (\$)

#### (a) Share-based payments Reserve

The share-based payments reserve represents the value of options and share rights issued to key management personnel, vendors and for services in relation to capital raisings. The share-based payments reserve is used to record the value of the share-based payments provided to employees, consultants and for options issued pursuant to any acquisition or in exchange for services.

#### (b) Foreign Currency Reserve

The foreign currency reserve records foreign currency differences arising from the translation of financial information of the Group's Maltese subsidiaries which have a functional currency of the Euro.

#### 8. INTERESTS IN OTHER ENTITIES

		Ownership Interest held by the Group		
Name of Entity	Place of business/country of incorporation	31 December 2024	30 June 2024	Principal Activities
AAT Research Ltd	Malta	100%	100%	Parent Group of AAT Medical Ltd
AAT Medical Ltd	Malta	100%	100%	Executing medical research projects and developing novel technological devices that are marketable

#### 9. CONTINGENT LIABILITIES

The Board is not aware of any circumstances or information, which leads them to believe there are any material contingent liabilities outstanding as at 31 December 2024.

#### 10. MATTERS SUBSEQUENT TO THE END OF THE PERIOD

#### **Operational**

#### **Appointment of Managing Director and CEO – Dr Anthony Filippis**

The Group was pleased to announce the appointment of Dr Anthony Filippis as Managing Director and CEO in November 2024 (with an effective appointment date of 1 February 2025), 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.

#### **R&D** tax Incentive

On 31 January 2025, the Group received a \$2.44 million research and development (R&D) tax incentive refund under the Australian Federal Government's R&D Tax Incentive scheme. The tax refund relates to eligible R&D activities for the financial year ended 30 June 2024.

#### Positive Opinion for Orphan Designation from European Medicines Agency (EMA)

On 27 February 2025, the Company announced that the EMA has issued a positive opinion on the Company's Orphan Medicinal Product Designation (OMPD) application of NTI164 for the treatment of Rett Syndrome. The Company filed for OMPD in Europe in late October 2024. Neurotech anticipates the issuance of the official decision by the European Commission in due course.

#### **DIRECTORS DECLARATION**

In the opinion of the Directors of Neurotech International Limited (Group):

- (a) the Financial Statements, comprising the consolidated statement of profit or loss and other comprehensive income, consolidated statement of financial position, consolidated statement of cash flows, consolidated statement of changes in equity, and Notes set out on pages 12 to 23 are in accordance with the *Corporations Act 2001*, including:
  - (i) giving a true and fair view of the Group's financial position as at 31 December 2024 and of their performance, for the financial period ended on that date; and
  - (ii) complying with Australian Accounting Standards (including the Australian Accounting Interpretations) and Corporations Regulations 2001; and other mandatory professional reporting requirements.
- (b) there are reasonable grounds to believe that the Group will be able to pay its debts as and when they become due and payable.

The Directors have been given the declarations required by Section 295A of the *Corporations Act 2001* by the Financial Officer for the financial period ended 31 December 2024

Signed in accordance with a resolution of the Directors.

**Mark Davies** 

**Non-Executive Chairman** 

Dated at Perth, Western Australia, 27 February 2025



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#### INDEPENDENT AUDITOR'S REVIEW REPORT

To the members of Neurotech International Limited

#### Report on the Half-Year Financial Report

#### Conclusion

We have reviewed the half-year financial report of Neurotech International Limited (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 31 December 2024, the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the half-year ended on that date, material accounting policy information and other explanatory information, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of the Group does not comply with the *Corporations Act 2001* including:

- Giving a true and fair view of the Group's financial position as at 31 December 2024 and of its financial performance for the half-year ended on that date; and
- Complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001.

#### Basis for conclusion

We conducted our review in accordance with ASRE 2410 Review of a Financial Report Performed by the Independent Auditor of the Entity. Our responsibilities are further described in the Auditor's Responsibilities for the Review of the Financial Report section of our report. We are independent of the Company in accordance with the auditor independence requirements of the Corporations Act 2001 and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 Code of Ethics for Professional Accountants (including Independence Standards) (the Code) that are relevant to the audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We confirm that the independence declaration required by the *Corporations Act 2001* which has been given to the directors of the Company, would be the same terms if given to the directors as at the time of this auditor's review report.

#### Responsibility of the directors for the financial report

The directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

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#### Auditor's responsibility for the review of the financial report

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2024 and its financial performance for the half-year ended on that date and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

**BDO Audit Pty Ltd** 

GATA Chare

Glyn O'Brien

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Director

Perth, 27 February 2025