ASX Announcement
24 January 2024

Quarterly Activities Report
for the period ending 31 December 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 31 December 2023 (Q2 FY24), together with its Appendix 4C Quarterly Cash Flow Report.

HEALTH ECONOMIC MODELLING

Autism Spectrum Disorder

During the quarter, the Company appointed a leading Health Economic consultancy to identify and quantify the value proposition in Australia for patients with Autism Spectrum Disorder (ASD).

Previous analysis has shown that within the Australian context, early intervention in autism has a material cost saving to the National Disability Insurance Scheme (NDIS). To date, such interventions relate largely to occupational therapies, as effective drug therapies for autism are lacking. In contrast, based on the Phase I/II clinical trial evidence for NTI164 in ASD generated over 52 weeks, coupled with Neurotech's pending Phase II/III clinical trial results which are anticipated in Q1 CY2024, the Company believes in the potential for NTI164 in autism as a cost-effective, safe, long term therapy for patients.

"A cost benefit analysis of autism specific early intervention has shown that for every dollar invested into autism-specific early intervention a societal return of $6.16 is released into the community, and from that, a direct cost saving of $4.58 to the National Disability Insurance Scheme (NDIS)."[1]

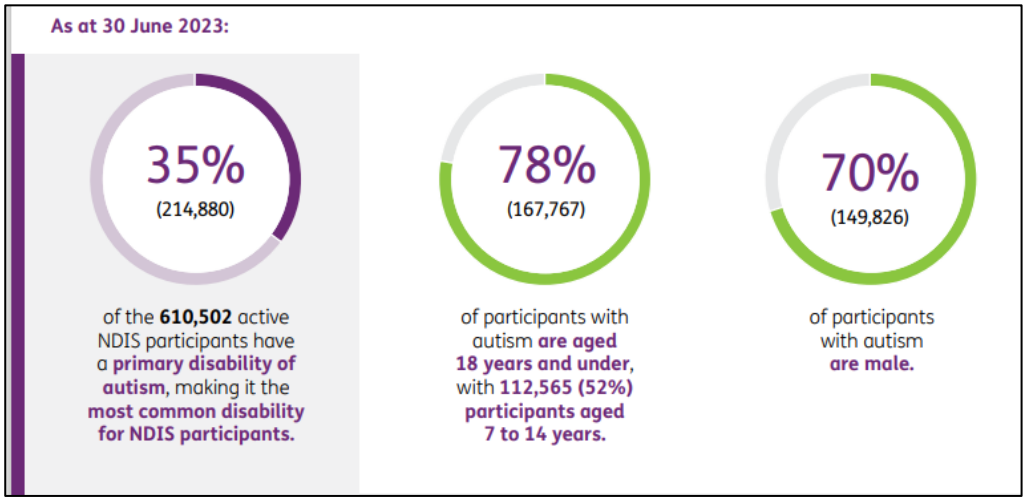
The analysis currently being undertaken by Neurotech is expected to greatly assist the Company in future discussions with government and private payers relating to the appropriate pricing and reimbursement for Neurotech's proprietary broad spectrum cannabinoid therapy NTI164.

Preliminary cost-effectiveness (CE) and pricing analyses for NTI164 in ASD will be modelled and to provide price estimates sufficient for determining the feasibility of Pharmaceutical Benefits Scheme (PBS) reimbursement for NTI164. The PBS Schedule lists all of the medicines available to be dispensed to patients at a Government-subsidised price.

In addition, the feasibility assessment will review the strength, quality and applicability of the clinical evidence base that will be available at the time of a PBAC submission. Under a PBAC submission, Neurotech will be required to provide an economic evaluation of NTI164, including its proposed cost-effectiveness.

According to NDIS data, 35% or 214,880 NDIS participants have a diagnosis of autism (this increased to 223,650 at 30 September 2023). In addition, 78% of participants with autism were aged 18 years and under, and 52% of participants were aged 7 to 14 years, with 70% of participants being male, as shown below.

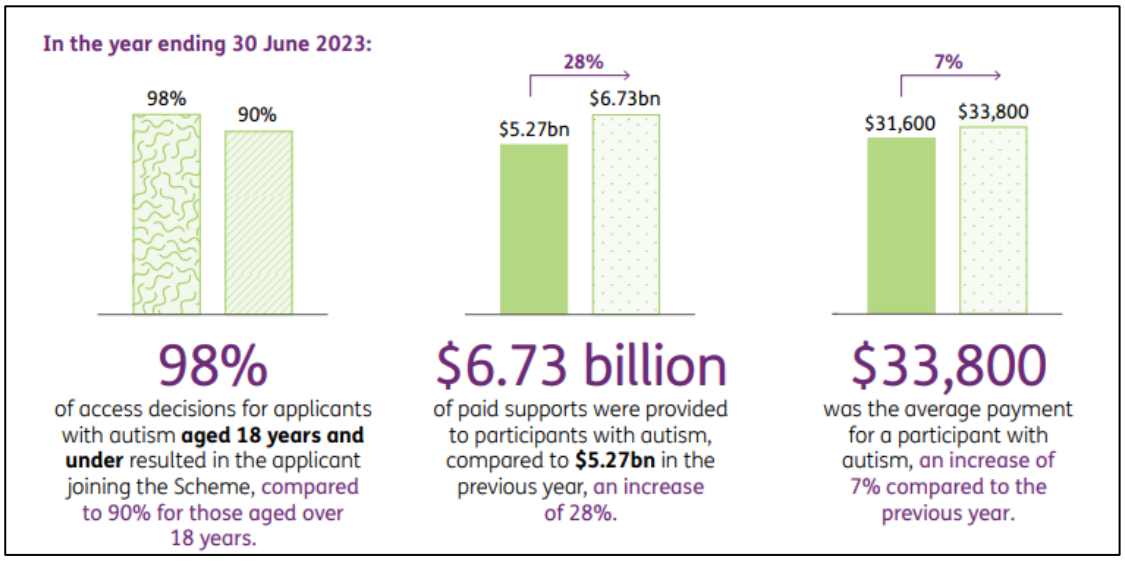
[1] Lucas, F. (2023, March 31). Autism specific interventions yield high long term returns: AEIOU.



Source: NDIS data

In the year ending 30 June 2023, the NDIS spent $6.73 billion in paid supports to people with autism, a significant 28% increase from the preceding year's total of $5.27 billion. This allocation encompasses payments directed to both individuals with autism and service providers as shown below.

During the 2023 financial year, the average support payment made to a participant with autism amounted to $33,800, reflecting a 7% increase from the previous year. The primary focus of payments of that financial year was centred on core support for daily activities, totalling just under $2.7 billion.



Source: NDIS data

CLINICAL UPDATES

Autism Spectrum Disorder

In December, Neurotech announced Human Research Ethics Committee (HREC) approval to extend the current Phase II/III clinical trial in ASD patients to allow for patients who turn 18 years of age to remain on treatment with NTI164 during the extension phase of the trial for up to 54 weeks of total treatment. The previous HREC approval covered treatment with NTI164 in a paediatric population of ASD, reflecting the inclusion criteria for the current Phase II/III clinical trial ("NTIASD2").

In late December, the Company announced the completion of patient recruitment of the NTIASD2 clinical trial. The trial has recruited a total of 56 patients with Level 2 (requiring substantial support) and Level 3 (requiring very substantial support) autism. All patients were enrolled at the Paediatric Neurology Unit at Monash Medical Centre, through the trial's Principal Investigator Professor Michael Fahey, Head of the Paediatric Neurology Unit and Director of Neurogenetics.

This world first clinical trial seeks to confirm the therapeutic effects of the NTI164 broad-spectrum cannabinoid therapy as demonstrated in a previous clinical trial over 52 weeks of daily oral treatment.

With the explosion in autism-associated costs under the Australian NDIS, there is an urgent need for new enabling treatments like NTI164, which has been shown to significantly improve adaptive behaviours and socialisation and improve these children's quality of life while reducing caregiver burden. The results of this trial will inform Company discussions with the Therapeutic Goods Administration to understand the appropriate regulatory pathway to market approval in Australia as the first market opportunity. The prevalence of autism is estimated at 1 in 50 across the population, representing a 40 fold increase in the last 20 years.

NTIASD2 is a randomised, double-blind, placebo-controlled, Phase II/III clinical trial that has recruited patients with ASD to determine the efficacy and safety of NTI164 versus placebo. The study comprises an 8-week treatment period followed by an 8-week open-label maintenance period followed by a 2-week wash-out period. Participants who choose to continue receiving NTI164 beyond the duration of the study may do so for an additional 38 weeks. They will undergo the 2-week down-titration phase at the end of their extension phase.

The results of the NTIASD2 clinical trial are expected in Q1 CY2024 (Q3 FY24).

PANDAS/PANS

On 6 October 2023, the Company was delighted to report a world first successful clinical trial of NTI164 in Paediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Paediatric Acute-Onset Neuropsychiatric Syndrome (PANS), collectively PANDAS/PANS. This is a rare (orphan) disorder with substantial heterogeneity across geography and time. The Company reported statistically significant and clinically meaningful results with the primary endpoints of anxiety/depression and severity of illness met across the 15 patients in the trial.

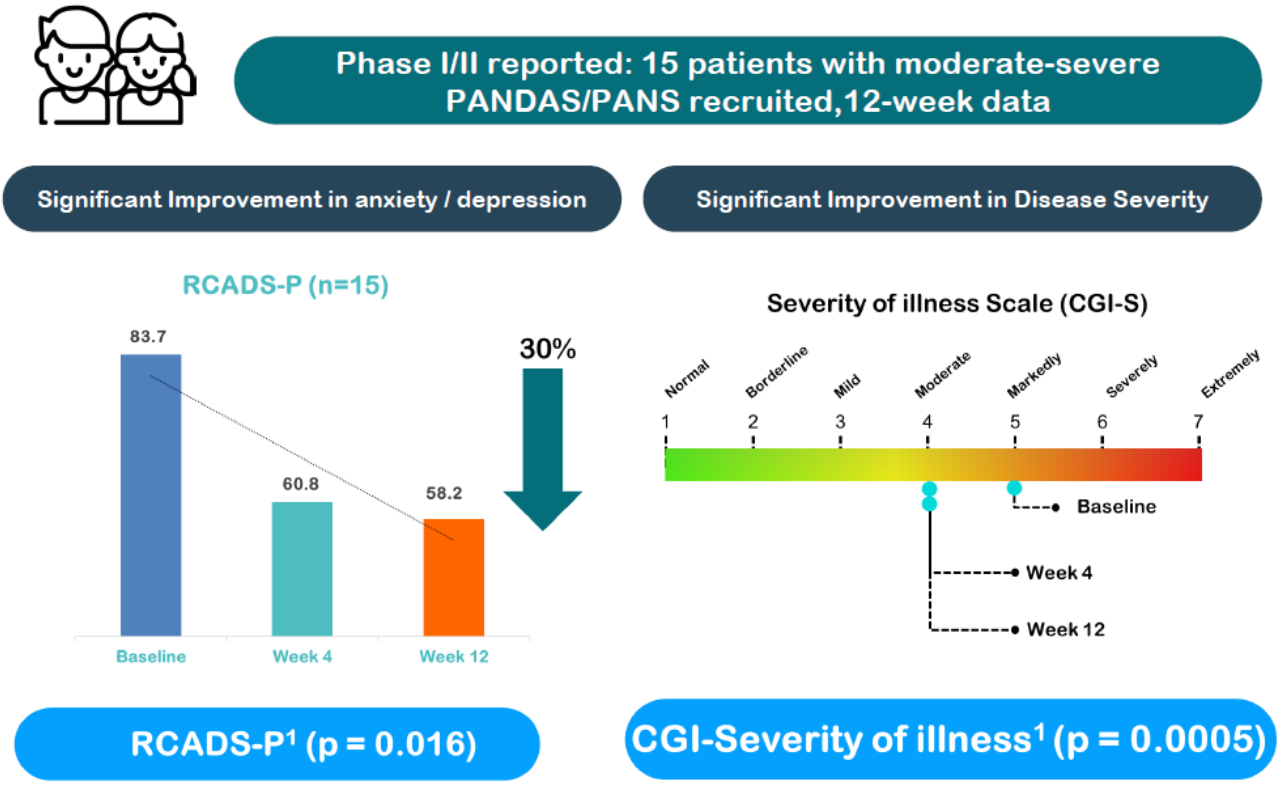
Professor Russell Dale, Professor of Paediatric Neurology, University of Sydney and Children's Hospital at Westmead and Co-Principal investigator of the NTIPANS1 trial said *"I am very pleased with the clinical results reported to date and wish to thank all patients and their families for participating 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."*

Mr James Fletcher, President of the non-profit organisation PANS Australia and New Zealand Advocacy and Support Inc. said *"We here at PANS Australia and New Zealand Advocacy and Support Inc are very pleased to see the results of the Neurotech Clinical Trial regarding the use of NTI164 for children diagnosed with PANS. As our researchers continue to expand their understanding of PANS, they also help us to raise awareness of PANS within the general medical community. This in turn leads to earlier intervention and better long-term outcomes for children and adults with PANS. A targeted treatment for PANS in the form of NTI164 is a very exciting development indeed. Many thanks to the researchers for their work on this therapy and to the children and families who participated in the study."*

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. NTI164 showed clinically significant and meaningful improvements in clinical function, with excellent safety and tolerability over 12 weeks of daily oral treatment.

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)



Source: Neurotech Investor Presentation October 2023

All patients have entered the 54-week extension phase of the trial. The Company continued to advance its planned ODD filings for NTI164 in PANDAS/PANS in the US and Europe.

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[2].

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

The NTIRTT1 Phase I/II clinical trial will examine the effects of daily oral treatment of NTI164 in 14 Rett Syndrome patients. The trial is an open-label, exploratory study over 16 weeks of treatment with NTI164 at the maximum tolerated dose or 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 Q1 CY2024.

Cerebral Palsy

During the quarter, the Company completed a proposed clinical trial protocol for NTI164 in paediatric patients with Spastic Diplegia Cerebral Palsy (Spastic CP) and submitted for Human Research Ethics Committee (HREC) approval. The Phase I/II trial is proposed to be a single-arm, open-label clinical trial that will recruit up to 15 paediatric patients with a clinical diagnosis of Spastic CP patients to determine the efficacy and safety of NTI164 in these patients from baseline to twelve (12) weeks of treatment. The Lead Investigator of the trial is Professor Michael Fahey, Head of the Paediatric Neurology Unit and Director of Neurogenetics. Professor Fahey has significant experience with NTI164 having led both Neurotech's Phase I/II and Phase II/III clinical trials in autism.

Spastic CP is the most common form of CP, representing up to 80% of cases[3]. CP is the leading cause of childhood disability. Approximately 750,000 children and adults in the United States have CP. In Australia, there are approximately 34,000 persons living with CP.

Although there are several approved drug therapies used in the treatment of spastic CP, they are often associated with sedation, confusion, memory loss, and attention deficits. For first-line treatment with oral Baclofen the actual evidence of efficacy remains somewhat subjective and not necessarily supportive of widespread use in spastic CP.

Neurotech remains excited by the adaption of NTI164 in spastic CP, where the available evidence indicates that inflammation is pathogenic in CP and may persist in various forms including immune and genetic changes, years after the original injury, with such inflammation more pronounced in children.[4] Neurotech is targeting paediatric neurological disorders where there is literature supporting inflammation, particularly neuroinflammation, where Neurotech has demonstrated effectiveness of NTI164 in various pre-clinical models.

The Company anticipates HREC approval in early Q1 CY2024 and to commence a Phase I/II trial in the first half of CY2024.

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:

- HREC approval for a Phase I/II clinical trial in paediatric spastic cerebral palsy (Q3 FY24)
- Results of the Phase I/II Rett Syndrome clinical trial (Q3 FY24)
- Results of the Phase II/III ASD clinical trial (Q3 FY24)
- Orphan Drug Designations (ODDs) for NTI164 in PANDAS/PANS with US and EU regulatory bodies

[3] https://www.cerebralpalsy.org/
[4] Paton MCB, Finch-Edmondson M, Dale RC, Fahey MC, Nold-Petry CA, Nold MF, Griffin AR, Novak I. Persistent Inflammation in Cerebral Palsy: Pathogenic Mediator or Comorbidity? A Scoping Review. J Clin Med. 2022 Dec 12;11(24):7368

- Orphan Drug Designations (ODDs) for NTI164 in Rett Syndrome 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 $1.9 million (Q1 FY2024: $2.4 million), consisting of research and development $1.6 million (Q1 FY24: $1.9 million), along with advertising, marketing, staff costs, administrative, and corporate costs of $0.36 million (Q1 FY24; $0.48 million). The Company received a $0.15 million GST refund for the quarter (Q1 FY24: $0.23 million). Total operating cash inflows for the quarter were $1.3 million (Q1 FY24: $2.1 million outflow), driven by the $3.2 million R&D tax incentive rebate paid during the current quarter. R&D investment during the quarter reflected investment into the Phase II/III ASD clinical trial, and Phase I/II clinical trials in Rett Syndrome and the completion/54-week extension phase of the Phase I/II PANDAS/PANS clinical trial along with drug product manufacturing costs.

The Company closed the quarter with cash and cash equivalents of $4.5 million (Q4 FY23: $2.9 million), which is sufficient to 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 ($97,000) and corporate services, accounting and company secretarial fees ($38,000).

Authority
This announcement has been authorised for release by the Board of Neurotech International Limited.

Further Information
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About Neurotech
Neurotech International Limited (ASX:NTI) is a clinical-stage biopharmaceutical development company focused predominately on paediatric neurological disorders. 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	**Quarter ended ("current quarter")**
73 610 205 402	31 December 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	1	2
1.2	Payments for		
	(a) research and development	(1,626)	(3,565)
	(b) product manufacturing and operating costs	0	0
	(c) advertising and marketing	(27)	(125)
	(d) leased assets	0	0
	(e) staff costs	(42)	(114)
	(f) administration and corporate costs	(287)	(598)
1.3	Dividends received (see note 3)	0	0
1.4	Interest received	5	47
1.5	Interest and other costs of finance paid	(2)	(3)
1.6	Income taxes paid	0	0
1.7	Government grants and tax incentives (R&D Rebate)	3,175	3,175
1.8	Other (GST refunds)	145	379
1.9	**Net cash from / (used in) operating activities**	**1,342**	**(802)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	0	0
	(b) businesses	0	0
	(c) property, plant and equipment	0	0
	(d) investments	0	0
	(e) intellectual property	0	0

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	(f) other non-current assets	0	0
2.2	Proceeds from disposal of:		
	(a) entities	0	0
	(b) businesses	0	0
	(c) property, plant and equipment	0	0
	(d) investments	0	0
	(e) intellectual property	0	0
	(f) other non-current assets	0	0
2.3	Cash flows from loans to other entities	0	0
2.4	Dividends received (see note 3)	0	0
2.5	Other (provide details if material)	0	0
2.6	**Net cash from / (used in) investing activities**	**0**	**0**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	0	0
3.2	Proceeds from issue of convertible debt securities	0	0
3.3	Proceeds from exercise of options	260	260
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**	**260**	**260**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	2,876	5,022
4.2	Net cash from / (used in) operating activities (item 1.9 above)	1,342	(802)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	0	0

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	260	260
4.5	Effect of movement in exchange rates on cash held	1	(1)
4.6	**Cash and cash equivalents at end of period**	**4,479**	**4,479**

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	2,507	2,861
5.2	Call deposits	2,015	15
5.3	Bank overdrafts	(43)	0
5.4	Other (provide details)	0	0
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**4,479**	**2,876**

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 ($97,000) and corporate services, accounting and company secretarial fees ($38,000).

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	65	(43)
7.2	Credit standby arrangements	0	0
7.3	Other (please specify)	0	0
7.4	**Total financing facilities**	65	(43)

7.5	**Unused financing facilities available at quarter end**	22

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 0.6181.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	1,342
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,479
8.3	Unused finance facilities available at quarter end (item 7.5)	22
8.4	Total available funding (item 8.2 + item 8.3)	4,501
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3.35

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: 24 January 2024
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Authorised by: The Board of Directors
.....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.