

ASX Release

16 April 2025

APPENDIX 4C: THIRD QUARTER FY25**Highlights for the quarter:**

- **Cash and cash equivalents at 31 March of \$23.5 million**
- **Completed \$15 million placement to fully fund enrolment and report initial safety and efficacy data for the phase 1 trial for ALA-101**
- **Successfully transferred ALA-101 manufacturing process into cGMP environment in readiness for clinical batches**
- **Entered sponsored research agreement with University of North Carolina to advance solid tumour and IL-12-TM armouring programs**
- **Generated functional Claudin 18.2-targeting chimeric antigen receptor**
- **Held the first meeting of the recently formed clinical advisory board**
- **Key milestones anticipated in 2025 for ALA-101 including GMP manufacturing, IND submission, and commencement of phase 1 study**

MELBOURNE, AUSTRALIA 16 April 2025: Arovella Therapeutics Limited (ASX: ALA) (**Arovella** or the **Company**), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell therapy platform, today releases its Appendix 4C for the third quarter of FY25.

Arovella is both technically and financially well positioned for significant progress towards its phase 1 first-in-human clinical trial for ALA-101. The Company finished the third quarter with cash of \$23.5 million, following the recent \$15 million placement, funding the Company to complete patient enrolment for the phase 1 clinical trial for ALA-101. The funding will also support the advancement of the Company's solid tumour programs (CLDN18.2-CAR-iNKT targeting gastric cancer) and its armouring program (IL-12-TM).

During the quarter, Arovella continued to progress ALA-101 towards the clinic, engaging with key opinion leaders and holding the first meeting of its Clinical Advisory Board (CAB) to optimise the clinical trial design. The Company completed the transfer of its CAR-iNKT manufacturing process into a current Good Manufacturing Practice (cGMP) compliant environment in readiness for manufacture of clinical batches of ALA-101 and conducted pivotal non-clinical studies required to support an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA).

During the remainder of FY25, Arovella will complete the manufacture of clinical batches of ALA-101 in preparation for first-in-human studies and aims to file its IND. This will enable the Company to commence its phase 1 trial for ALA-101 in CD19-positive blood cancer patients in CY25. Arovella will continue to expand its innovative iNKT cell therapy platform, and expects to present proof-of-concept data for its CLDN18.2-CAR-iNKT cell gastric cancer program.

Arovella's CEO and MD, Dr Michael Baker Commented, "Thank you to our shareholders for enabling us to raise sufficient capital to allow the Company to reach key value inflection points expected in the form of human clinical data. The sector is currently facing a very difficult time off the back of political uncertainty. However, we continue to make important strides taking ALA-101 into clinic and can continue to develop our programs as planned, which is exceptional."

AROVELLA FULLY FUNDED TO COMPLETE PHASE 1 ENROLMENT WITH \$15 MILLION PLACEMENT

On 26 February 2025, Arovella announced a placement to raise \$15 million via the issue of 120 million shares at \$0.125 per share. Funds raised under the Offer will allow Arovella to complete enrolment and report initial safety and efficacy data for the planned phase 1, first-in-human clinical trial for Arovella's lead product, ALA-101. The phase 1 clinical trial will enrol patients with CD19-positive non-Hodgkin's lymphoma and leukemia. Funds raised under the placement will also be used to strengthen Arovella's iNKT cell therapy pipeline and advance Arovella's solid tumour products, and for general working capital purposes. Placement investors also received one (1) Attaching Option for every three (3) New Shares issued under the Placement, exercisable at A\$0.15 and expiring on 24 May 2027.

On 10 January 2025, Arovella announced a \$20 million placement, backed by an Australian private investor, which had agreed to subscribe for \$15 million in Arovella shares at a close-to-market subscription price, under a binding subscription agreement. Unfortunately, as announced by Arovella on 26 February 2025, the investor failed to meet its settlement obligations, constituting a breach of the subscription agreement. Arovella is seeking remedy under this agreement. Whilst this was a disappointing outcome for Arovella, the Company wants to reassure shareholders that the investor's default should not be taken as indicative of any internal challenges within Arovella or any of its programs.

IND PROGRESS UPDATE

Arovella continues to focus on progressing its lead product, ALA-101, into the clinic. In 2024, Arovella announced that it had completed process development and scale-up of its proprietary CAR-iNKT manufacturing process and held a successful pre-IND meeting with the FDA. During the previous quarter, Arovella completed the transfer of its manufacturing process from the process development lab into the cGMP environment at Cell Therapies, including implementing key cGMP reagents in the process. The transfer process took more time than anticipated due to technical challenges that arose. The types of challenges faced are not uncommon when pioneering a novel cell therapy manufacturing process and transferring it into a cGMP environment. Importantly, resolving the challenges strengthens the know-how that Arovella possesses relating to its manufacturing process for its CAR-iNKT cell therapy platform. The learnings have helped produce a more robust process for ALA-101 and are also applicable to Arovella's platform for future CAR-iNKT products. This is a large benefit as Arovella continues to expand its product pipeline.

Arovella has now successfully manufactured ALA-101 in the cGMP suite using all cGMP reagents and at a scale that is sufficient to meet clinical requirements. Arovella will proceed to manufacture clinical batches for phase 1 in the current quarter.

During the March quarter, Arovella also completed key IND-enabling studies for ALA-101. This included an *in vivo* efficacy study in a highly aggressive mouse model of lymphoma. Briefly, immunodeficient NSG mice were injected with the Raji cell line, derived from a B-cell non-Hodgkin's lymphoma. Following engraftment of the tumour cells, mice were treated with either ALA-101 or a Phosphate Buffered Saline (PBS; saline solution) control. ALA-101 tested in this model, which was manufactured using Arovella's clinic-ready process, provided strong efficacy and substantially enhanced the survival of treated mice (Figure 1). The Raji B-cell lymphoma model was selected as it does not have CD1d on its surface, which iNKT cells naturally recognise and target, which means ALA-101 successfully targeted cells that were CD19 positive.

ASX: ALA

Arovella Therapeutics Limited
ACN 090 987 250

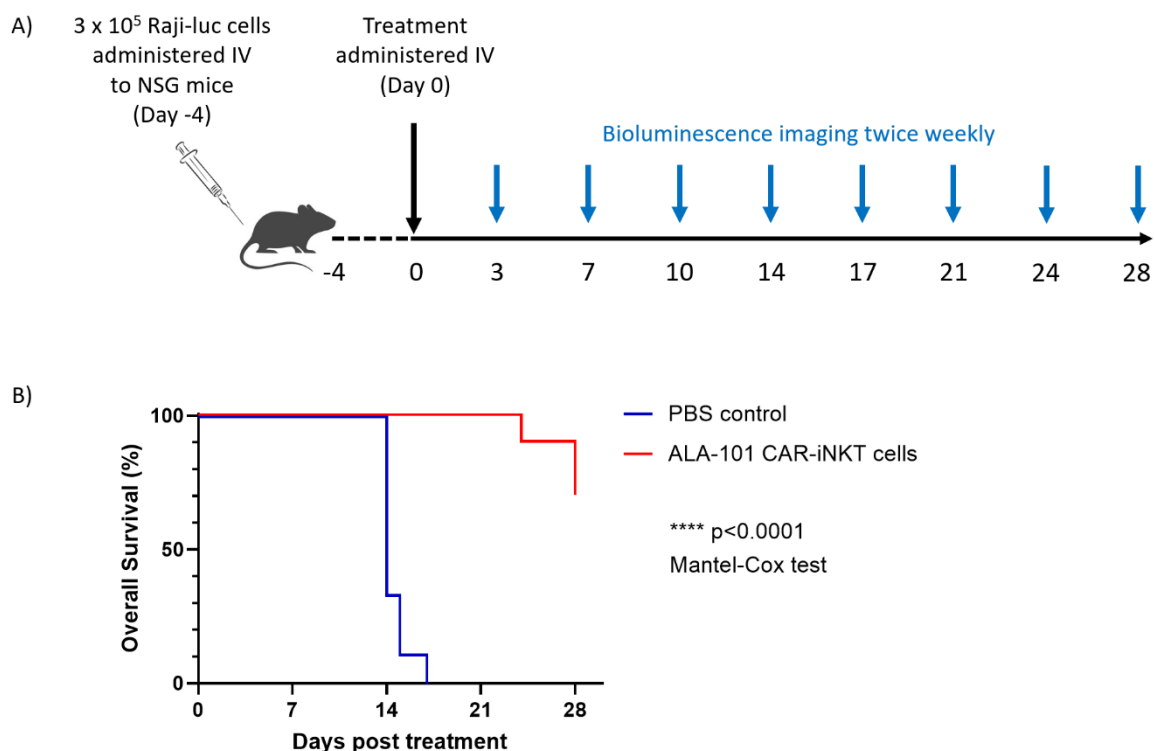


Figure 1. (A) Schematic of the Raji CAR-iNKT cell study. **(B)** Overall survival of mice in a Raji lymphoma model. After 28 days, 70% of mice treated with ALA-101 (5M CAR+ iNKT cells) remained alive (n=10). All mice in the PBS control group died between days 14 and 17 (n=10).

Arovella is continuing to conduct the remaining non-clinical studies required to support the IND and expects to complete these studies in the current quarter.

CLINIC READINESS

Arovella continued to prepare for a first-in-human phase I clinical trial for ALA-101. During the quarter, it held the first meeting of its recently formed Clinical Advisory Board (CAB). The CAB discussed key aspects of the phase 1 trial design and provided important input into the protocol. Arovella is now working with regulatory consultants to finalise the clinical trial protocol in readiness for the IND.

Arovella has also continued to engage with potential clinical sites and investigators for the phase 1 study. The Company continues to be pleased by the enthusiasm for the program and the opportunity to treat Australian patients with a novel therapy, and looks forward to engaging with key clinical sites in the current quarter.

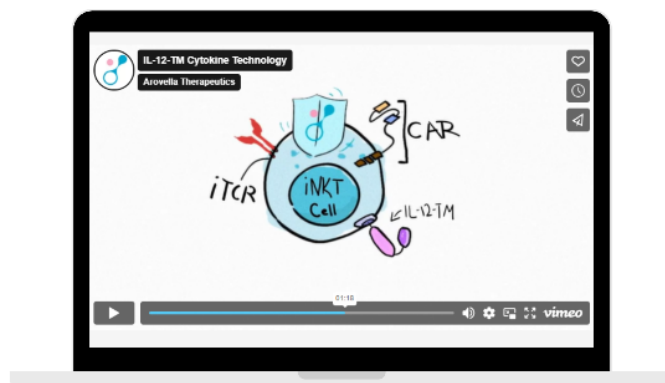
ARMOURING TECHNOLOGY AND SPONSORED RESEARCH AGREEMENT

In March, Arovella entered into a Sponsored Research Agreement (SRA) with Professor Gianpietro Dotti's research group at the University of North Carolina (UNC), to expand its research capability for IL-12-TM and solid tumour programs. Arovella has also recruited a post-doctoral scientist, Dr Clinton Heinze, who will be embedded within Professor Dotti's team to complement the research efforts.

This is an exciting advance for Arovella and provides additional capacity to accelerate the IL-12-TM and solid tumour research efforts. Recent work from the laboratory of Professor Dotti was published in the prestigious peer

reviewed journal, Nature Cancer, comparing CAR-T and CAR-iNKT cells against a range of solid tumours. His team's work demonstrated that CAR-iNKT cells are superior to CAR-T cells at eliminating solid tumours¹. By entering into a SRA, Arovella strengthens its relationship with Professor Dotti and his team and expands its research capability, which will facilitate the development of its solid tumour programs, in addition to accessing resources and expertise in Professor Dotti's laboratory.

Arovella has also prepared a new explanatory video to explain more about the IL-12-TM armoring technology and how it enhances the activity of CAR-iNKT cells. To view the video, click [here](#).



CLDN18.2 CHIMERIC ANTIGEN RECEPTOR (CAR) UPDATE

During the quarter, Arovella made important progress on one of its solid tumour programs being developed to tackle gastric cancer and potentially pancreatic cancer, ALA-105. The Arovella team successfully generated a functional CLDN18.2-targeting CAR, based on the licensed SPX-101 sequence. The CAR was tested initially in T cells, where the CLDN18.2-targeting CAR-T cells mediated specific killing of human cells expressing CLDN18.2.

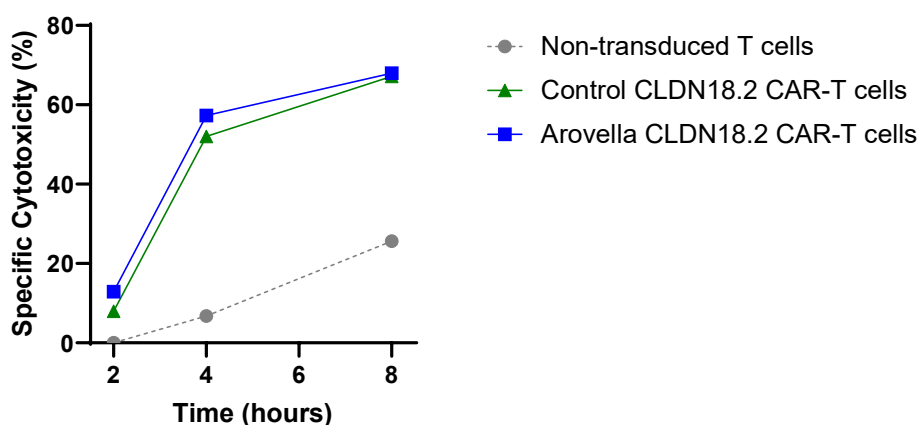


Figure 2. Cytotoxicity of CAR-T cells made using Arovella's CLDN18.2-CAR sequence relative to CAR-T cells using a control CLDN18.2-CAR and non-transduced T cells. Arovella's CLDN18.2-targeting CAR-T cells show specific killing of CLDN18.2-positive cells.

The CAR will now be optimised and transferred into Arovella's proprietary CAR-iNKT manufacturing process to generate CAR-iNKT cells. This work will be conducted in Professor Gianpietro Dotti's laboratory under the recently signed SRA.

¹ <https://www.nature.com/articles/s43018-024-00830-0>

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INVESTOR RELATIONS AND NEWS

Euroz Hartleys Healthcare Forum

On 4 February, Arovella MD & CEO, Dr Michael Baker presented key pre-clinical data and clinical plans for Arovella's CAR-iNKT cell therapy platform and described how Arovella's technology provides important advantages over existing T-cell therapies and has the potential to be applied to both blood cancers and solid tumours.

[View presentation](#)



Spark Plus Healthcare Day

On 24 March, Dr Baker presented at the Spark Plus Singapore Healthcare Day 2025. The event provided opportunities for networking and discussions featuring ASX-listed healthcare companies, investors, and institutions.

[View presentation](#)

Biotech Showcase

Dr Baker also attended Biotech Showcase in San Francisco from 13-15 January. Here he explored potential collaborations, cutting-edge advancements, and shared insights with global leaders in the life science ecosystem.



MST analyst coverage initiation

In December, MST Access released a research report detailing its analysis on Arovella Therapeutics, its investment case, technologies and market opportunity. The report can be accessed at: <https://www.arovella.com/analyst-coverage>.

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FINANCIAL UPDATE

Arovella remains in a solid financial position, with cash and cash-equivalents of \$23.5 million at the end of the March quarter. This cash position was strengthened by the \$15 million (before costs) Placement completed in March 2025.

The net cash outflow from operating activities during the quarter was \$2.4 million and the research and development and staff costs for the quarter represented 87% of the Company's operating outflows.

Payments to Related Entities

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of Appendix 4C incorporates directors' fees, salaries and superannuation. Payments made for the quarter total \$178,226 and relate to payments to the CEO/Managing Director in accordance with employment contracts and payments to the Non-Executive Directors.

OUTLOOK FOR 2025

Arovella continues to be in a solid financial position with a strong balance sheet, as it advances its lead program, ALA-101, toward a first-in-human phase 1 clinical trial. The trial is expected to commence in 2025, and the Company is funded to complete enrolment for the study and report initial safety and efficacy data. In addition, the Company continues to make progress developing its solid tumour program targeting CLDN18.2 and looks forward to generating data using the CLDN18.2 CAR in iNKT cells, as well as integrating IL-12-TM. The company continues to pursue its strategy to review and acquire novel technologies that either enhance the CAR-iNKT cell platform or broaden its utility to target a range of cancer types. The Company looks forward to providing updates in due course.

This announcement has been authorised for release by the Company's Board of Directors.

For further information, please contact:

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NOTES TO EDITORS:**About Arovella Therapeutics Ltd**

Arovella Therapeutics Ltd (ASX: ALA) is a biotechnology company focused on developing its invariant natural killer T (iNKT) cell therapy platform from Imperial College London to treat blood cancers and solid tumours. Arovella's lead product is ALA-101. ALA-101 consists of CAR19-iNKT cells that have been modified to produce a Chimeric Antigen Receptor (CAR) that targets CD19. CD19 is an antigen found on the surface of numerous cancer types. Arovella is also expanding into solid tumour treatment through its CLDN18.2-targeting technology licensed from Sparx Group. iNKT cells also contain an invariant T cell receptor (iTCR) that targets α -GalCer bound CD1d, another antigen found on the surface of several cancer types. ALA-101 is being developed as an allogeneic cell therapy, which means it can be given from a healthy donor to a patient.

Glossary: **iNKT cell** – invariant Natural Killer T cells; **CAR** – Chimeric Antigen Receptor that can be introduced into immune cells to target cancer cells; **TCR** – T cell receptors are a group of proteins found on immune cells that recognise fragments of antigens as peptides bound to MHC complexes; **B-cell lymphoma** – A type of cancer that forms in B cells (a type of immune system cell); **CD1d** – Cluster of differentiation 1, which is expressed on some immune cells and cancer cells.

For more information, visit www.arovella.com

This announcement contains certain statements which may constitute forward-looking statements or information ("forward-looking statements"), including statements regarding negotiations with third parties and regulatory approvals. These forward-looking statements are based on certain key expectations and assumptions, including assumptions regarding the actions of third parties and financial terms. These factors and assumptions are based upon currently available information, and the forward-looking statements herein speak only of the date hereof. Although the expectations and assumptions reflected in the forward-looking statements are reasonable in the view of the Company's directors and management, reliance should not be placed on such statements as there is no assurance that they will prove correct. This is because forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could influence actual results or events and cause actual results or events to differ materially from those stated, anticipated or implied in the forward-looking statements. These risks include but are not limited to: uncertainties and other factors that are beyond the control of the Company; global economic conditions; the risk associated with foreign currencies; and risk associated with securities market volatility. The Company assumes no obligation to update any forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements, except as required by Australian securities laws and ASX Listing Rules.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Arovella Therapeutics Limited

ABN

35 090 987 250

Quarter ended ("current quarter")

31 March 2025

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,719)	(4,741)
	(b) product manufacturing and operating costs	(32)	(109)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(462)	(1,619)
	(f) administration and corporate costs	(305)	(1,639)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	102	347
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	3,303
1.8	Other (GST)	4	231
1.9	Net cash from / (used in) operating activities	(2,412)	(4,227)

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(32)	(391)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) 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	Net cash from / (used in) investing activities	(32)	(391)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	14,965	14,965
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	354	1,576
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1,102)	(1,117)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (reallocation 3.1 for Placement funds received in March quarter when shares were issued in April 2024)	-	-
3.10	Net cash from / (used in) financing activities	14,217	15,424

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	11,751	12,714
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,412)	(4,227)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(32)	(391)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	14,217	15,424
4.5	Effect of movement in exchange rates on cash held	1	5
4.6	Cash and cash equivalents at end of period	23,525	23,525

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	903	62
5.2	Call deposits	22,622	11,689
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	23,525	11,751

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	178
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		
The amount at 6.1 includes Director fees and salary (including superannuation) for the CEO and Managing Director and Non-Executive Directors.		

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

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,412)
8.2	Cash and cash equivalents at quarter end (item 4.6)	23,525
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	23,525
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	9.8
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>		
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1	Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
	Answer: 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?	
	Answer: 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?	
	Answer: N/A	
<i>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.</i>		

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.

16 April 2025

Date:

Board of Directors

Authorised by:
(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.