ASX Release

29 October 2024

APPENDIX 4C: FIRST QUARTER FY 2025

Highlights for the quarter:

- **Strong cash and cash equivalents position of $9.9 million at the end of the quarter**
- **Positive pre-IND meeting with FDA confirming pathway to a phase 1 clinical trial for ALA-101**
- **Clinical Advisory Board assembled in readiness for IND acceptance**
- **Continuing to advance ALA-101 towards a first-in-human clinical trial for CD19-positive blood cancers**

MELBOURNE, AUSTRALIA 29 October 2024: Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell therapy platform for cancer treatment, today releases its Appendix 4C for the first quarter of FY25.

During the quarter, Arovella continued to advance its iNKT cell therapy towards first-in-human clinical trials. Arovella's CAR-iNKT provides key advantages over existing CAR-T cell therapies, being readily available to be used off-the-shelf and having the potential to be applied to both blood cancers and solid tumours.

Arovella has a solid financial position with cash and cash equivalents of $9.9 million as of 30 September 2024. On 25 October Arovella announced the receipt of an R&D Tax Incentive Rebate for FY24 of $3.0 million, with an additional $0.3 million to be received in the months ahead, equating to a 30 September 2024 pro-forma cash position of $13.2 million to progressively invest into the business. This is expected to provide Arovella with sufficient funding to obtain preliminary data in its planned first-in-human clinical trial for ALA-101.

Throughout FY25. Arovella expects to achieve several critical milestones, including:

- Manufacturing clinical batches of ALA-101 for phase 1 clinical trials;
- Securing an Investigational New Drug application (IND) with the U.S. Food and Drug Administration (FDA) to conduct a phase 1 clinical trial in CD19-positive blood cancers;
- Commencing a phase 1 clinical trial for ALA-101 in patients with CD19-positive blood cancers;
- Presenting proof-of-concept data for its gastric cancer CLDN18.2-iNKT program, and;
- Presenting proof-of-concept data for membrane-anchored interleukin-12 (IL-12-TM) as an armouring technology for Arovella's CAR-iNKT cell platform.

POSITIVE INTERACTION WITH FDA VIA pre-IND MEETING

In July, Arovella received positive feedback from the FDA during a pre-IND meeting, in preparation for its phase 1 clinical trial of ALA-101 as a treatment for CD19-positive blood cancers.

Feedback from the pre-IND meeting, which was held via teleconference with the FDA, supported Arovella's development plans to commence a phase 1, first-in-human clinical trial. The meeting provided a clear path to submitting an IND for ALA-101, with no major changes proposed for the development program. Allogeneic CAR-iNKT cell therapy manufacturing is highly complex and few allogeneic CAR-iNKT cell companies have received an IND acceptance to start first-in-human trials, so this pre-IND feedback was critical to ensure that Arovella's development plan for ALA-101 aligns with FDA expectations. The FDA guidance included a review of Arovella's CMC program, the plan for nonclinical safety and efficacy studies, and the proposed phase 1 clinical trial design.

Based on the precise information provided by the FDA, Arovella expects to file its IND for ALA-101 in early Q1 CY25.

FORMATION OF CLINICAL ADVISORY BOARD

In September, Arovella announced the appointment of three key opinion leaders and clinical oncologists to establish its Clinical Advisory Board (CAB).

The CAB will provide expert clinical insight and strategic advice focusing on CD19-positive haematological malignancies (blood cancers), as the Company looks to file its IND and commence its first-in-human phase 1 clinical trial. The founding members of Arovella's CAB are:

- **Dr Salvatore Fiorenza**, Deputy Director and Cell Therapy Lead at Epworth Healthcare;
- **Professor Sattva Neelapu**, Professor and Deputy Chair at the Department of Lymphoma and Myeloma at The University of Texas MD Anderson Cancer Center, Houston, Texas, USA; and
- **Dr Debora Barton**, a Medical Oncologist who is also currently a Non-executive Director at Arovella.

Each member has been carefully selected, due to their experience working with cell therapies in early-stage clinical trials.

Dr Salvatore (Sam) Fiorenza

Dr Salvatore (Sam) Fiorenza (MBBS, PhD, BSc (Hons), MPH, FRACP, FRCPA) is a consultant haematologist, Deputy Director and Medical Lead of cell therapy at Epworth Healthcare in Melbourne, and a senior postdoctoral research scientist at the University of Sydney with Professor Cameron Turtle. Dr Fiorenza holds a PhD in cellular immunotherapy and a Master of Public Health, and completed a postdoctoral research fellowship funded by The Haematology Society of Australia and New Zealand in CAR-T at the Fred Hutchinson Cancer Center in Seattle, USA.

Dr Fiorenza is recognised for his expertise in developing and applying CAR-T cell therapies. His clinical and research efforts are focused on advancing treatments for patients with haematological malignancies.

Dr Fiorenza has played a significant role in implementing CAR-T therapies in Australia, participating in both clinical trials and treatment protocols aimed at improving outcomes for patients with relapsed or refractory blood cancers. Through his leadership, Epworth Healthcare has become a growing centre for

CAR-T therapy, and his work has contributed to the increasing body of evidence supporting CAR-T as a transformative treatment for patients with few other therapeutic options. Dr Fiorenza will also Chair the CAB.

Professor Sattva Neelapu

Dr Sattva Neelapu, MD, is a Professor and Deputy Chair in the Department of Lymphoma and Myeloma at The University of Texas MD Anderson Cancer Center, Houston, Texas, USA. He is internationally recognised for pioneering contributions to developing immunotherapies for blood cancers, particularly CAR-T therapies. His research and clinical practice focus on lymphomas, including diffuse large B-cell lymphoma (DLBCL), follicular lymphoma, and other haematological malignancies.

Dr Neelapu has led numerous clinical trials, notably those that led to the FDA approval of CAR-T cell therapies, such as axicabtagene ciloleucel (Yescarta). This therapy revolutionised the treatment options for patients with relapsed or refractory large B-cell lymphoma, offering a potential cure for patients who had previously exhausted other treatment avenues. Dr Neelapu has also been a clinical advisor and investigator for several allogeneic cell therapy products in development.

Dr Neelapu has authored over 300 peer-reviewed articles in prestigious medical journals such as *The New England Journal of Medicine*, *Nature Medicine*, and *The Lancet Oncology*. His work is widely cited in the field of immunotherapy, and he has delivered numerous keynote presentations at international oncology conferences. His achievements have earned him multiple awards and recognition within the oncology community, and he was recently elected as a fellow of the American Association for the Advancement of Science.

Dr Neelapu is recognised as a leader in immuno-oncology and continues to drive advancements in cancer treatment through his research and clinical leadership.

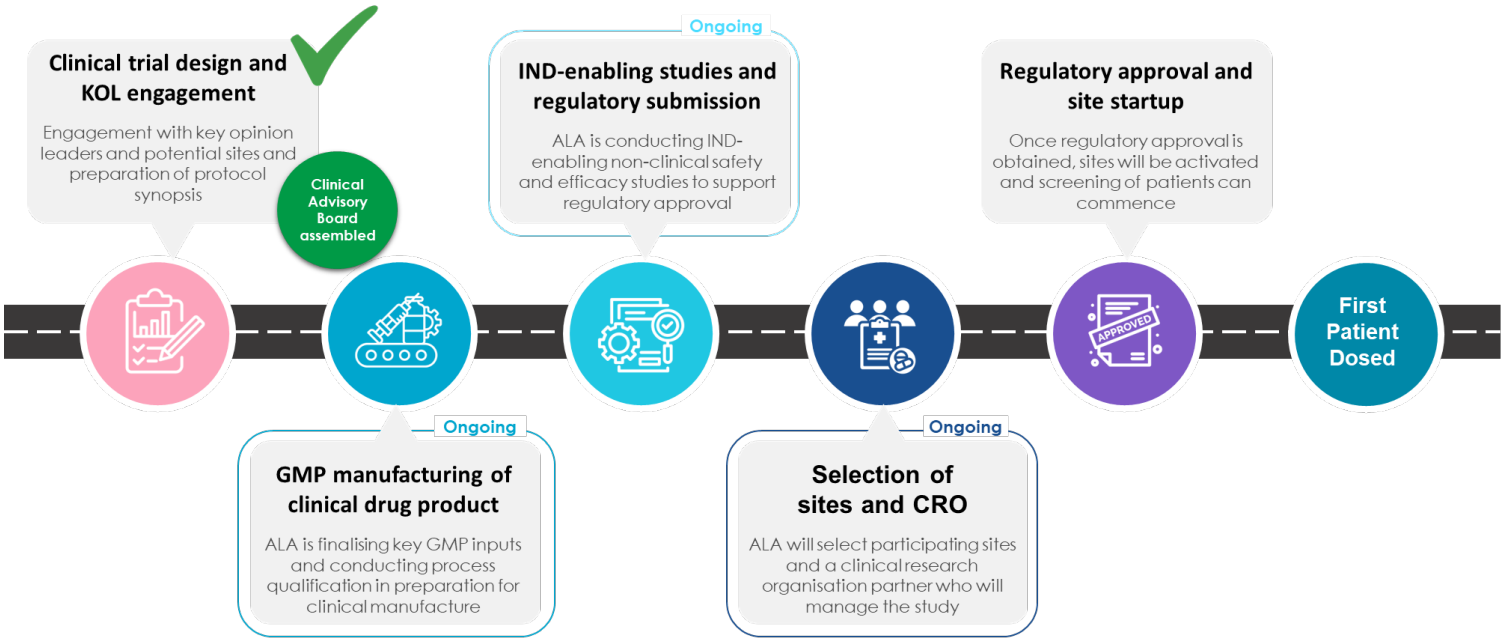
Dr Debora Barton

Dr Debora Barton, MD, currently a Non-executive Director at Arovella Therapeutics, is a highly regarded oncologist focusing on cell therapies. Throughout her career, Dr Barton has been Chief Medical Officer of several biotechnology companies developing novel cell therapies and has extensive experience designing and running clinical trials from first-in-human phase 1 through phase 3. She has worked to optimise patient outcomes and minimise adverse effects, ensuring that this cutting-edge treatment can be safely integrated into broader cancer care.

Dr Barton's involvement in immunotherapy and haematologic oncology is highly recognised within the oncology community. Her work continues to impact the evolving landscape of cancer treatments, particularly through her focus on innovative cellular therapies like Arovella's CAR-iNKT cell platform.

PROGRESSING ALA-101 TOWARDS THE CLINIC

During the reported quarter, Arovella continued to progress its preparatory activities for its phase 1 first-in-human clinical trial to treat patients with CD19-positive blood cancers. The key activities to be conducted over the coming months are outlined in the figure below.



***Abbreviations**: CRO, Clinical Research Organization; GMP, Good Manufacturing Practice; IND, Investigational New Drug Application; KOL, Key Opinion Leader*

INVESTOR RELATIONS AND NEWS

Investor Webinar

In September, Arovella held an Investor Webinar where CEO and Managing Director Dr Michael Baker presented Arovella's achievements in manufacturing process development and its pathway to clinic for ALA-101. The webinar can be viewed on-demand by clicking on the image below.

Non-deal roadshow and events

In July, Dr Baker presented a non-deal roadshow in Perth, Brisbane, Sydney, and Melbourne to update investors on Arovella's exciting progress. During the Quarter, Dr Baker also attended several investor conferences to engage with new and existing investors. These included the TechKnow Invest Roadshow in Sydney and Melbourne in July and the Spark Plus Australian Equities Day in Singapore in September.

TechKnow Invest Roadshow in Sydney

Spark Plus Australian Equities Day in Singapore

FINANCIAL UPDATE

- Arovella remains in a solid financial position, with cash and cash-equivalents of 13.2 million at the end of the September quarter, which includes the R&D Tax Incentive Rebate for FY24 of $3.3 million announced October 25, 2024.
- The net cash outflow from operating activities during the quarter was $2.71 million (including a one-off settlement payment to Teva Pharmaceuticals of US$300k as announced to ASX on 13 June 2024), compared with $1.82 million for the previous quarter, ending 30 June 2024.
- R&D and staff costs totalling $2.05 million represented 76% of the Company's net operating cashflows.

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 $304,353 and relate to payments to the CEO/Managing Director in accordance with employment contracts, including short-term incentives and payments to the Non-Executive Directors.

For and on behalf of the Board and for further information, please contact:

Dr Michael Baker
Chief Executive Officer & Managing Director
Arovella Therapeutics Ltd
investor@arovella.com

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. iNKT cells also contain an invariant T cell receptor (iTCR) that targets glycolipid 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. Arovella is also expanding into solid tumour treatment through its CLDN18.2-targeting technology licensed from Sparx Group. Arovella will also incorporate its IL-12-TM technology into its solid tumour programs.

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; **aGalCer** – alpha-galactosylceramide is a specific ligand for human and mouse natural killer T cells. It is a synthetic glycolipid.

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	**Quarter ended ("current quarter")**
35 090 987 250	30 September 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,373)	(1,373)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(36)	(36)
	(d) leased assets	-	-
	(e) staff costs	(676)	(676)
	(f) administration and corporate costs	(892)	(892)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	94	94
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (GST)	174	174
1.9	**Net cash from / (used in) operating activities**	**(2,709)**	**(2,709)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(216)	(216)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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**	**(216)**	**(216)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	75	75
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(3)	(3)
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**	**72**	**72**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	12,714	12,714
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,709)	(2,709)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(216)	(216)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	72	72
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**9,861**	**9,861**

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	64	98
5.2	Call deposits	9,797	12,616
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)**	**9,861**	**12,714**

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	304
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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.

The amount at 6.1 includes Director fees and salary (including superannuation) for the CEO and Managing Director and Non-Executive Directors. The September quarter also includes the cash bonus paid to the CEO under the Short-Term Incentive Plan for FY24.

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		
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)	(2,709)
8.2	Cash and cash equivalents at quarter end (item 4.6)	9,861
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	9,861
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3.6

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?

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

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.

29 October 2024

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.