

ASX: ALA

Arovella Therapeutics Limited
ACN 090 987 250



ASX Release

28 July 2025

APPENDIX 4C: FOURTH QUARTER FY25

Highlights for the quarter:

- Cash and cash equivalents at 30 June of \$20.9 million
- Progressed preparation of Investigational New Drug (IND) application for ALA-101
- Obtained an exclusive Option from Baylor College of Medicine to evaluate and license two novel CARs targeting solid tumours, including neuroblastoma and hepatocellular carcinoma
- Appointed a new Senior Director of Clinical Development in preparation for the first-in-human clinical trial for ALA-101
- Commenced research activities at UNC to advance ALA-105, a novel CAR-iNKT product targeting Claudin 18.2
- Set up a research laboratory within Jumar Biocubator to increase research capacity for solid tumour programs
- Key milestones expected in CY25 for ALA-101 include GMP manufacturing and IND submission for the start of a phase 1 study in H1 CY26.

MELBOURNE, AUSTRALIA 28 July 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 fourth quarter of FY25.

Arovella continues to progress its lead product, ALA-101, towards a first-in-human clinical trial and to expand its platform into solid tumours. The Company finished the fourth quarter with cash of \$20.9 million, which is expected to fund the Company through to the completion of 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).

Arovella's CEO and MD, Dr Michael Baker, remarked, "It was a productive quarter at Arovella. We made significant progress preparing for submission of our IND application, and we believe we are positioning the Company for the best chance of success with the FDA. We remain enthusiastic about our expanding pipeline targeting solid tumours, including ALA-105, which employs a CAR that recognises the clinically validated target, CLDN18.2, as well as the potential for additional CARs targeting GD2 and GPC3, as outlined in the Option agreement with Baylor. With an active IND for ALA-101, we anticipate being able to file INDs for solid tumours more efficiently.

IND PROGRESS UPDATE

During the quarter, Arovella continued to progress ALA-101 towards the clinic, generating data required for its IND application with the US Food and Drug Administration (FDA). The Company continued to optimise its manufacturing process in the current Good Manufacturing Process (cGMP) environment and conduct testing and release of key cGMP reagents as required ahead of clinical batch manufacturing. In addition, IND-enabling non-clinical studies were completed and drafting of the IND documentation is well underway.

The Company is also considering an extra interaction with the FDA before submitting its IND application to ensure agreement on testing requirements for one of its cGMP reagents. Although this may delay the IND application to

later this calendar year, the Company believes it is crucial to maximise the chances of a successful outcome.

CLINIC READINESS

During the quarter, Arovella expanded its management team in readiness for its first-in-human phase 1 clinical trial for ALA-101 with the appointment of Jacqui Cumming as Senior Director, Clinical Development.

Jacqui is a senior clinical operations leader with over 20 years of international experience across pharmaceuticals, clinical research organisations, biotechnology start-ups, and public health. Before joining Arovella, she was the Director of the Centre for Biostatistics and Clinical Trials at Peter MacCallum Cancer Centre, managing a portfolio of more than 40 oncology trials. Jacqui offers extensive expertise in operational leadership, stakeholder engagement, and delivering complex clinical programs in highly regulated settings, including jurisdictions regulated by the Food and Drug Administration (FDA; USA), Therapeutic Goods Administration (TGA; Australia), and Pharmaceutical and Medical Devices Agency (PMDA; Japan). She has held regional leadership roles at CSL and senior positions across the Asia-Pacific region, supporting numerous successful new product registrations. Jacqui holds a BSc in Biomedical Science and an MBA from Melbourne Business School.

ALA-105, A SOLID TUMOUR PRODUCT TARGETING CLAUDIN 18.2

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 capabilities for IL-12-TM and solid tumour programs. Arovella also recruited a post-doctoral scientist, Dr Clinton Heinze, who will be embedded within Professor Dotti's team to support the research efforts.

During the quarter, Arovella commenced research activities at UNC and began generating data required to advance its first solid tumour program, ALA-105, a claudin 18.2-targeting product. Data generated continues to support the functionality of the in-licensed SPX-101 sequence as a CAR. Over the coming months, Arovella will continue to test the claudin 18.2-targeting CAR in iNKT cells and incorporate the CAR into Arovella's proprietary manufacturing process.

OPTION WITH BAYLOR COLLEGE OF MEDICINE

During the quarter, Arovella entered into an exclusive option to licence multiple patent families from Baylor College of Medicine to expand the utility and improve the performance of its iNKT cell platform (Option). The patent families covered by the Option include technologies to integrate two additional CARs targeting solid tumours, as well as technology that may boost the functionality of CAR-iNKT cells in humans. If Arovella moves forward with the licence, it will further differentiate the company within the iNKT cell sector and raise the barriers to entry for other companies developing iNKT cell therapeutics.

The two CARs included under the Option target GD2 and GPC3, which are clinically validated targets for solid tumours and have been studied in FDA IND-enabled clinical trials. Significant capital and resources have been dedicated to the development of these CARs so far.

- GD2 is found on the surface of numerous solid tumours, including neuroblastoma, melanoma, glioma, small-cell lung carcinoma, and various types of breast cancer. It was also the focus of a recent study from researchers at Stanford University that demonstrated benefits for children and young adults with rapidly growing brain and spinal cord cancers. The GD2 CAR included under the Option was recently used in an autologous CAR-iNKT trial for paediatric patients with neuroblastoma, where one patient showed a durable complete response lasting more than 12 months.

- GPC3 is seen as a promising cancer target because it is highly present on the surface of many cancers, especially hepatocellular carcinoma (HCC; liver cancer), and is limited in healthy tissues. HCC remains a leading cause of cancer death worldwide. The CAR discussed in the Option was recently published in Nature, showing that when used in CAR-T cells, it produces encouraging results for patients with HCC.

Under a licence agreement, Arovella aims to incorporate these CARs into its proprietary manufacturing process to develop allogeneic CAR-iNKT products targeting GD2 and GPC3.

The technology included with the Baylor Option may improve the functionality of CAR-iNKT cells in treating cancer. Arovella will examine how to incorporate the improvements into its current and future product pipeline.

One of the leading inventors of the patents under Option is Professor Leonid Metelitsa, Director of the Center for Advanced Innate Cell Therapy (AICT) at the Texas Children's Cancer Center, Baylor College of Medicine. He is a recognised authority in developing CAR-iNKT cells, having published extensively on the development and use of CAR-iNKT cells for blood cancers and solid tumours. At Baylor College of Medicine, his group, in close collaboration with the Center for Cell and Gene Therapy (CAGT) led by Professor Helen Heslop, has taken two CAR-iNKT cell programs into clinical trials through the US FDA IND pathway and established manufacturing protocols for producing GMP-grade material for phase 1 clinical trials.

EXPANDING RESEARCH CAPACITY AT JUMAR

During the quarter, Arovella set up its own research laboratory within the Jumar Biocubator. This new facility will enable Arovella to speed up its research output as it expands its solid tumour programs and to continue building on its IP portfolio.

As part of this expansion, Arovella has appointed a new Research Scientist, Dr Alfie Baker. Alfie completed his PhD in molecular immunology and oncology at Monash University in Melbourne and has since undertaken postdoctoral research at Monash University and University College London, UK. Before joining the team at Arovella, Alfie contributed to developing a novel $\gamma\delta$ T cell immunotherapy. He brings over 10 years' experience in conventional and unconventional T cell biology and immunology, to Arovella. Alfie is currently establishing and managing Arovella's research and development lab at the Jumar Biocubator in Melbourne.

RETIREMENT OF NON-EXECUTIVE CHAIRMAN

At the end of the quarter, the Company announced that Dr Thomas Duthy would be retiring as a Non-Executive Director and Chairman of the Company, effective 1 July 2025, to pursue new business opportunities. Dr Duthy was Chairman of Arovella since March 2023.

Dr Elizabeth Stoner, one of Arovella's current Non-Executive Directors, will serve as interim Chair while the Company undertakes a thorough global process to appoint a new Chair. Dr Stoner has previously held the position of interim Chair at Arovella, making her well qualified to step into the role again.

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INVESTOR RELATIONS AND NEWS

Investor Webinar

In April, Arovella CEO and MD, Dr Michael Baker, presented an investor webinar to provide an update following the release of the Company's Appendix 4C quarterly while outlining next steps for Arovella throughout the rest of 2025 as it moves toward Phase 1 in-human trials.

[View presentation & recording](#)



Gold Coast Investment Showcase presentation

Arovella CEO and MD, Dr Michael Baker, was pleased to attend and present at the Gold Coast Investment Showcase which was held from 25-26 June. The event allows investors to engage up-front with some of Australia's most successful and exciting ASX listed companies.

[View presentation & recording](#)

Equity Story CEO Interview

In May, Equity Story interviewed Arovella CEO and MD, Dr Michael Baker as he discussed Arovella's CAR-iNKT cell platform.

[View recording of the interview](#)



American Society of Cell and Gene Therapy

The Arovella team was delighted to be at ASGCT on May 13-17 in New Orleans, to talk about CAR-iNKT cells and to see the progress in the field of cell therapies.

Left, from left: Dr Robson Dossa, Dr Clinton Heinze and Dr Michael Baker

BIO International Convention

CEO and MD, Dr Michael Baker represented Arovella Therapeutics at BIO 2025 in Boston, meeting investors, potential partners and collaborators. Dr Baker commented, "There is so much to be excited about for biotechnology companies globally. Thank you to everyone for the inspiring meetings and being generous with your time!"



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FINANCIAL UPDATE

Arovella maintains a strong financial position, with \$20.9 million in cash and cash equivalents as at 30 June 2025.

The net cash outflow from operating activities during the quarter was \$2.8 million and the research and development and staff costs for the quarter represented 89% 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 \$160,465 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 remains in a strong financial position with a solid balance sheet as it advances its lead program, ALA-101, towards a first-in-human Phase 1 clinical trial. The trial is expected to commence early in 2026, and the Company is funded to complete enrolment and report initial safety and efficacy data. Additionally, the Company is making progress with 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 review new technologies for acquisition that could enhance the CAR-iNKT cell platform or expand its application to target various 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

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Quarter ended ("current quarter")

30 June 2025

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(2,179)	(6,920)
(b) product manufacturing and operating costs	(26)	(135)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(519)	(2,138)
(f) administration and corporate costs	(296)	(1,935)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	44	391
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)	180	411
1.9 Net cash from / (used in) operating activities	(2,796)	(7,023)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(22)	(413)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 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 (Security deposits)	(19)	(19)
2.6	Net cash from / (used in) investing activities	(41)	(432)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	14,965
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	269	1,845
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(79)	(1,196)
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	190	15,614

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	23,525	12,714
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,796)	(7,023)

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Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(41)	(432)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	190	15,614
4.5	Effect of movement in exchange rates on cash held	(1)	4
4.6	Cash and cash equivalents at end of period	20,877	20,877

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	612	903
5.2	Call deposits	20,265	22,622
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)	20,877	23,525

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	160
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	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>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.</i>		
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)	(2,796)
8.2 Cash and cash equivalents at quarter end (item 4.6)	20,877
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	20,877
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	7.5
<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.

28 July 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.