



Quarterly Appendix 4C and Activities Report

30 September 2022

Arovella Therapeutics Limited
ABN 35 090 987 250

ASX Release

31 October 2022

APPENDIX 4C: FIRST QUARTER FY 2023

MELBOURNE, AUSTRALIA 31 October 2022: Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell platform for cancer treatment, today released its Appendix 4C for the first quarter of FY 2023.

Highlights for the quarter:

- Entered into a Strategic Collaboration with Imugene to combine Imugene's onCARlytics platform and Arovella's iNKT cell therapy platform in preclinical trials
- Appointed Mr Gary Phillips as a Non-Executive Director
- Completed a strategic review of the Company's operations; decision to close the Perth R&D Facility.

IMUGENE AND AROVELLA STRATEGIC COLLABORATION

On 26 September 2022, Arovella announced that it will collaborate with clinical stage immune-oncology company, Imugene (ASX: IMU). Through the collaboration, Arovella and Imugene will test Arovella's CAR19-iNKT (ALA-101) cell therapy with Imugene's onCARlytics platform to tag and destroy solid tumours. The read out from the preclinical studies performed through the collaboration is expected in H1 CY 2023.

Arovella's lead iNKT product, ALA-101, contains a Chimeric Antigen Receptor (CAR) that targets tumour cells producing CD19 on their surface. Typically, CD19 expression is on the cell surface of blood cancers. Imugene's onCARlytics platform enables solid tumour cancers to express CD19 on their surface, which creates the opportunity to use ALA-101 to tag and destroy the solid tumour cells. Currently, ALA-101 is being developed for CD19-producing blood cancers. Working with Imugene raises the possibility of using ALA-101 to treat solid tumour cancers.

Imugene is evaluating a range of CD19 targeting therapies in combination with onCARlytics, of which Arovella's ALA-101 will be included, allowing Arovella to benchmark its iNKT therapy for the treatment of solid tumours. Initial pre-clinical data from Arovella demonstrates that ALA-101 cells outperform conventional T cells in haematological malignancies that produce CD19 and CD1d. Achieving compelling data in this study would open up a new therapeutic area of potential indications in solid tumours for Arovella's iNKT cell therapy products.

Solid tumours represent 90% of diagnosed cancer cases¹, and as of 2021, the solid tumour market was valued at US\$210 billion². The combination has the potential to be a novel approach to treating certain solid tumour cancers.

ADDITION OF GARY PHILLIPS AS A NON-EXECUTIVE DIRECTOR

Mr Gary Phillips joined the board as a Non-Executive Director. Mr Phillips has more than 30 years of operational management experience in the pharmaceutical and healthcare industry in Europe, Asia and Australia. Mr Phillips is currently the CEO, and Managing Director of ASX-listed Pharmaxis (ASX:PXS), where he has overseen a company restructure focused on building value, forging new partnerships, and fostering the development of the Pharmaxis product pipeline. In previous roles, Mr Phillips was CEO at Ciba Geigy in Hungary, which merged to form Novartis in 1996, where he led the successful launch of a portfolio of new products. Mr Phillips joined Novartis Australia as Group Company Head and Chief Executive Officer of its Pharmaceutical Division, successfully launching leading oncology and ophthalmology products. Mr Phillips holds a Bachelor of Pharmacy Honours degree from Nottingham University in the U.K. and an MBA from Henley Management College, UK. He is also a Graduate of the Australian Institute of Company Directors (GAICD).

STRATEGIC REVIEW OF AROVELLA'S OPERATIONS

As announced on 26 October 2022, following a strategic review of its development pipeline, Arovella will close its Perth-based research and development facility (Facility), ceasing expenditure on the OroMist platform.

The Company will focus its resources and efforts entirely on the development of its iNKT cell therapy platform, which has significant potential to generate allogeneic cell therapies that target both blood cancers and solid tumours. The Company's belief in its platform was underlined in the news that it will collaborate with Imugene to combine Arovella's iNKT cell platform and Imugene's onCARlytics platform, to test against solid tumours. The combination of two specialised platforms can potentially create a "one, two punch" to solid tumours and brain metastases.

The closure of the Facility will incur one-off restructuring costs not expected to exceed \$300k in FY 2023, but thereafter provides an estimated cost saving of \$1.5m per annum based on historical costs.

As a result of the Company's decision to close the Facility, the Company is currently undertaking a review of its contractual arrangements relating to its ZolpiMist product. Arovella will continue to keep shareholders apprised of updates in this regard, in accordance with its continuous disclosure obligations.

During the period, the Company also agreed to mutually terminate its agreement with Cann Pharma Australia and will no longer continue development work for a pharmaceutical-grade cannabis product.

¹ <https://www.cancer.gov/types/common-cancers>

² <https://www.databridgemarketresearch.com/reports/global-solid-tumors-market#:~:text=Data%20Bridge%20Market%20Research%20analyses,period%20of%202022%20to%202029.>

Lastly, the company continues to seek co-development partners to fund ongoing research or out-licence the anagrelide intellectual property. The Company will no longer commit capital to research and development efforts for the drug.

FINANCIAL UPDATE

The net cash used in operating activities during the quarter was \$1.82 million compared to \$2.04 million the previous quarter to 30 June 2022. The total of \$1.45 million from research and development and staff costs represent approximately 80% of the net cash used in operating activities. Winding down of the Perth R&D Facility operations, and eventual closure, will reduce the Company's quarterly expenditure.

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, remuneration and superannuation at commercial rates.

For and on behalf of the Board and 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 therapies to treat human diseases. Arovella is developing its invariant natural killer T (iNKT) cell therapy platform from Imperial College London to treat blood cancers and solid tumours. Arovella is also expanding its DKK1-peptide targeting technology licenced from MD Anderson and used in conjunction with its iNKT cell therapy platform. The Company is also commercialising ZolpiMist™, a first-in-class oral spray of zolpidem tartrate to treat short-term insomnia. ZolpiMist is approved by the FDA and the TGA and is marketed in the USA. Arovella has rights to the product outside of the US and Canada.

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-

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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")

30 September 2022

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	(915)	(915)
(b) product manufacturing and operating costs	(12)	(12)
(c) advertising and marketing	(36)	(36)
(d) leased assets	-	-
(e) staff costs	(534)	(534)
(f) administration and corporate costs	(417)	(417)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	5	5
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	91	91
1.9 Net cash from / (used in) operating activities	(1,818)	(1,818)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(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	-	-

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	4	4
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
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 (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	4	4

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,071	6,071
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,818)	(1,818)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	4	4
4.5	Effect of movement in exchange rates on cash held	10	10
4.6	Cash and cash equivalents at end of period	4,267	4,267

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	4,267	4,267
5.2	Call deposits	-	-
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)	4,267	4,267

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	126
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>		

Item 6.1 Reflects amounts paid to directors including director's fees, salaries, superannuation and consulting fees at normal commercial rates including GST where applicable.

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.		
	N/A		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,818)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,267
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	4,267
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.3
	<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.

Date: 31 October 2022

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.