



  
T H E R A P E U T I C S

# Quarterly Activities & Cash Report and 4C

31 March 2022

Arovela Therapeutics Limited  
ABN 35 090 987 250

**ASX Release**

28 April 2022

**APPENDIX 4C: THIRD QUARTER FY 2022**

**MELBOURNE, AUSTRALIA 28 April 2022:** Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell platform and its oral spray delivery technology to treat cancer and conditions that affect the central nervous system, today released its Appendix 4C for the third quarter of FY 2022.

Key highlights for the quarter included:

- Commenced work with our selected plasmid and lentiviral vector manufacturer for ALA-101 (CAR19-iNKT)
- After the reporting period, Arovella entered into a Services Agreement with its chosen cell therapy manufacturer, Q-Gen, to initiate manufacturing of CAR-iNKT cells
- Dr Mini Bharathan appointed as VP of Development and Translational Medicine
- After the reporting date, Arovella received notification from USPTO that its anagrelide patent would proceed to grant
- Arovella completed a \$4.57m placement with cornerstone participation from well-known life sciences institutional investor, Merchant Group, and an oversubscribed \$2m Share Purchase Plan.

**ALA-101 (CAR19-iNKT) Manufacturing update**

Arovella rigorously screened numerous contract manufacturing organisations (CMOs) to produce two important components of its ALA-101 therapy, plasmid and lentiviral vector. Arovella selected the CMO and work began in the week commencing 10 January 2022. Once the lentiviral vector has been produced, it will be used to produce CAR19-iNKT cells (ALA-101).

After the reporting period, on 20 April 2022, Arovella announced it had entered into a Services Agreement with Q-Gen, to manufacture ALA-101 (CAR19-iNKT). The Services Agreement will be followed up by a proposed Master Manufacturing Services Agreement. The proposed Services Agreement allows Arovella to begin to work with Q-Gen to manufacture the product for later stage clinical trials.

Q-Gen is at the forefront of manufacturing immunotherapies and cell therapies. Established in 2002 to support clinical translation and discoveries by the Institute's researchers, the facility now manufactures for academic and biopharmaceutical partners nationally and internationally. Q-Gen is accredited by Australia's Therapeutic Goods Administration as a Good Manufacturing Practice (GMP) facility. The facility can produce cellular immunotherapies for patients in Australia, Asia, the United

States and Europe. Q-Gen has successfully produced autologous and allogenic cell therapy products for clinical trials

### **Dr Mini Bharathan appointed as VP of Development and Translational Medicine**

On 25 January 2022, the Company announced the appointment of Dr Mini Bharathan as its VP of Development and Translation Medicine. Dr Bharathan joins Arovella from Cellectis, a biotechnology company using its pioneering gene editing platform to develop allogenic therapies, which entails collecting the starting material for the cell therapy from a healthy donor as opposed to the patient suffering from the cancer.

During her time at Cellectis, Dr Bharathan served as the Director of Translational Medicine and Clinical Development, where she coordinated the development programs for key products, recommended patient stratification and biomarker strategies and oversaw the development and validation of novel clinical stage assay methodologies, patient selection markers and biomarkers for multiple global allogenic CAR-T clinical trials. Dr Bharathan also held senior roles at Celgene, Celularity and Immatix, all focused on the development of cell therapies.

Dr Bharathan has more than 15 years' experience in the field of immunology, with more than 12 years focused on the development of cell therapies. Dr Bharathan is a Doctor of Veterinary Medicine and holds a PhD in immunology from Virginia Tech, where she received the Sigma Xi Outstanding Ph.D. Research Award. Dr Bharathan has co-authored numerous research articles and patents.

### **USPTO to grant anagrelide patent in the United States**

The Company announced on 5 April 2022 that USPTO (US Patent and Trademark Office) will grant Arovella's Application No. 15/538,326 titled "Use of Anagrelide for Treating Cancer". The patent has an expiry of December 2035 and it adds to the granted patents in Europe, Japan and Australia.

As previously announced (22 September 2020), anagrelide is being developed for the treatment of metastatic disease in patients who have certain solid tumour cancers. Clinical experience has shown that increased platelet numbers associated with several solid tumour cancers decreases progression-free life expectancy. Anagrelide advantageously lowers blood platelets and has been shown to inhibit cancer cell movement towards platelet-producing cells, megakaryocytes, principally found in the bone marrow but also the lung, two likely sites of metastases.

Arovella is actively seeking co-development partners to fund ongoing research or to out-licence the anagrelide intellectual property to entities focused on development of cancer therapies, where increased platelets play a role in the progression of the disease. This includes a number of cancer types, including melanoma, mesothelioma, ovarian, vulvar, cervical, renal cell, lung, glioblastoma, pancreatic, endometrial and colorectal cancer.

### **Corporate Update**

On 24 January 2022, the Company announced that it received commitments from institutional and sophisticated investors for a \$4.57m Share Placement via issue of 120,230,220 new fully paid ordinary shares in the Company at a price of \$0.038 per share. The Placement received strong support from institutional and sophisticated investors and included cornerstone participation by specialist life sciences institutional investor, Merchant, which subscribed for \$3 million of the Placement. In

addition, the Company raised \$2m through a Share Purchase Plan, which Arovella increased from \$1.5m and closed early due to overwhelming demand.

Arovella will use funds raised under the SPP and placement for manufacturing of components for its CAR19-iNKT cell therapy, to perform preclinical studies for DKK1-CAR-iNKT, as well as for general working capital purposes.

The net cash used in operating activities during the quarter was \$2.47m compared to \$0.7m the previous quarter to 31 December 2021. The increase in costs was mainly due to the licence fees for the DKK1-peptide targeting monoclonal antibody, the research and development costs for work performed by Imperial College London and preliminary costs associated with ALA-101 manufacturing.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of the Appendix 4C incorporates directors' fees, remuneration and superannuation at commercial rates.

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

**Dr Michael Baker**  
**Chief Executive Officer & Managing Director**  
**Arovella Therapeutics Ltd**  
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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 disease. Arovella's two focus areas are oncology and conditions that impact the central nervous system. Arovella is developing its invariant natural killer T (iNKT) cell therapy platform from Imperial College London to treat blood cancers. Arovella is also developing its DKK1-peptide targeting technology licenced from MD Anderson to be used in conjunction with its iNKT cell therapy platform. The Company is also developing low-risk oral sprays to reformulate existing pharmaceuticals. The potential benefits of administering drugs through the oral mucosa (i.e. cheeks, tongue, gums and palate) include ease of use, lower dosage, reduced side effects and faster response time. Arovella's product pipeline includes an oral spray for the platelet-lowering drug anagrelide to treat metastatic disease in the background of high platelets, and 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. Other products in development include oral sprays to treat migraine headaches, motion sickness, and drug-resistant epilepsy.

For more information, visit [www.arovella.com](http://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 actions of third parties and financial terms. These factors and assumptions are based upon currently available information and the forward-looking statements contained herein speak only as of the date hereof. Although the expectations and

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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; 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 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	22	329
1.2 Payments for		
(a) research and development	(1,530)	(2,443)
(b) product manufacturing and operating costs	(85)	(191)
(c) advertising and marketing	(2)	(2)
(d) leased assets	(37)	(98)
(e) staff costs	(373)	(1,299)
(f) administration and corporate costs	(464)	(1,600)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	2
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	524
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,468)</b>	<b>(4,778)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	(22)
(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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>-</b>	<b>(22)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	6,761	6,766
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	(507)	(524)
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)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>6,254</b>	<b>6,242</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	4,386	6,717
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,468)	(4,778)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(22)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	6,254	6,242
4.5	Effect of movement in exchange rates on cash held	(49)	(36)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>8,123</b>	<b>8,123</b>

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	6,573	2,336
5.2	Call deposits	1,550	2,050
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>8,123</b>	<b>4,386</b>

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	132
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.*

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.

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

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<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)	-	-
<b>7.4 Total financing facilities</b>	-	-
<b>7.5 Unused financing facilities available at quarter end</b>		-
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		

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,468)
8.2 Cash and cash equivalents at quarter end (item 4.6)	8,123
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	8,123
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	3.3
<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: 28 April 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.