




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

Quarterly Activities & Cash Report and 4C

30 September 2021

Arovela Therapeutics Limited
ABN 35 090 987 250

ASX Release

27 October 2021

APPENDIX 4C: FIRST QUARTER FY 2022

PERTH, AUSTRALIA 27 October 2021: 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 first quarter of FY 2022.

Key highlights for the quarter included:

- Dr Sandhya Buchanan appointed as VP Manufacturing and Quality for the iNKT cell therapy platform
- Dr Debora Barton appointed as a Non-Executive Director to Arovella's Board
- Professor Tassos Karadimitris appointed as the chair of Arovella's iNKT cell therapy Scientific Advisory Board
- Additional members added to Arovella's Scientific Advisory Board
- Arovella entered into a Collaborative Research Agreement with Imperial College London
- Arovella entered into a Licence and Distribution Agreement with STADA for ZolpiMist®

Arovella enhanced its management team, Board of Directors and established a Scientific Advisory Board for its iNKT Cell Therapy

During the quarter, Arovella appointed Dr Sandhya Buchanan as its VP of Manufacturing and Quality for its newly acquired iNKT cell therapy platform. Dr Buchanan joined Arovella from Atara Biotherapeutics, a biotechnology company pioneering off-the-shelf cell therapies for treating cancer and autoimmune disease. During her time at Atara Biotherapeutics, Dr Buchanan served as the chemistry manufacturing and control technical lead for autologous CAR T programs and head of Viral Vector Development; managing both internal and external collaborations. Prior to Atara Biotherapeutics, Dr Buchanan held senior roles at Torque Therapeutics (now Repertoire Immune Medicines), FujiFilm Diosynth Biotechnologies, Penn Medicine, a world-renowned academic medical centre in Philadelphia, and Novartis. Dr Buchanan has more than 20 years' experience working in cell & gene therapy and vaccine development.

In August, Arovella enhanced its board through the appointment of Dr Debora Barton. Dr Barton has over 20 years' experience in the field of oncology. After practicing oncology as a physician and clinical trial investigator, she spent five years at Novartis and five years at Celgene in roles of increasing responsibilities in Medical Affairs and Clinical Development. Dr Barton has extensive experience working with cell therapy products, formerly as the Senior Vice President, Clinical and Head of Safety, of the clinical stage company, Iovance, who is developing T cell therapies for cancer treatment. Dr Barton is currently the Chief Medical Officer of Carisma Therapeutics, a clinical stage

biopharmaceutical company, developing innovative immunotherapies, including the first in class chimeric antigen receptor (CAR) macrophages for the treatment of certain cancers.

In conjunction with a Collaborative Research Agreement, Professor Tassos Karadimitris was appointed as the Chair of Arovella's Scientific Advisory Board for its iNKT cell therapy platform. Professor Karadimitris' research group was the first to demonstrate that iNKT cells are protective against graft versus host disease (GVHD). The iNKT cell platform has a critical advantage, that it may be used "off-the-shelf", meaning that the cells can be isolated from a healthy donor, modified to enhance their activity against cancer and stored frozen, ready to be administered to cancer patients as needed.

Two world renowned experts joined Arovella's Scientific Advisory Board, Dr Reuben Benjamin and Dr John Maher. Dr Benjamin is an internationally recognised expert in the field of cellular immunotherapies for the treatment of blood cancer. Dr Benjamin was the Chief Investigator of the CALM clinical trial, the first allogeneic (off-the-shelf) CAR-T cell study for relapsed adult B-cell acute lymphoblastic leukemia (B-ALL). Dr Maher is an internationally recognised clinical immunologist, focused on the development of CAR T cell therapies. Dr Maher played a key role in the early development of second-generation CAR technology while a visiting fellow at Memorial Sloan Kettering Cancer Center in the US. Dr Maher is the scientific founder and Chief Scientific Officer of Leucid Bio, a clinical stage cell therapy company with a pipeline of novel CAR T cell therapies developed using its proprietary engine.

Collaborative Research Agreement with Imperial College London

Arovella entered into a Collaborative Research Agreement (CRA) with Imperial College London and the laboratory of Professor Karadimitris. Under the CRA, Arovella will fund ongoing research in the laboratory of Professor Karadimitris, which will focus on creating additional intellectual property for its iNKT cell therapy platform. The initial focus of the platform is for the treatment of blood cancers and the research will enable Arovella to optimise the therapy and to expand into additional cancers of unmet need, creating additional intellectual property for the platform. The research agreement is for a period of two years and is extendable by mutual agreement from each party.

Arovella signed a Licence and Distribution Agreement with STADA for its most advanced product ZolpiMist

In August, Arovella entered into an exclusive License and Distribution Agreement for ZolpiMist® in Australia with STADA Pharmaceuticals Australia Pty Ltd, a member of the global, German-based STADA Group. Arovella will submit a further application to the TGA for a modification to the current spray unit, incorporating in the application a more economical, elegant, and user-friendly child resistant lock (CRL). It is anticipated that the new CRL will be implemented from the second batch of product produced for STADA onward.

Corporate Update

Arovella finished the quarter with a bank balance of \$5.089m at 30 September. The net outflow from operating activities for the quarter was \$1.589m. The current funds will support the initial manufacturing efforts for the iNKT cell therapy and further development of the oral spray products.

ASX: ALA

Arovella Therapeutics Limited
ACN 090 987 250



The net cash used in operating activities during the quarter was \$1.589m compared to \$0.909m the previous quarter to 30 June 2021. The increase is mainly due to the upfront costs for the Licence Agreement with Imperial College London.

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:

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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. 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

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 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")

30 September 2021

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	10	10
1.2 Payments for		
(a) research and development	(560)	(560)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	(32)	(32)
(e) staff costs	(440)	(440)
(f) administration and corporate costs	(567)	(567)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
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)	-	-
1.9 Net cash from / (used in) operating activities	(1,589)	(1,589)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(21)	(21)
(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	(21)	(21)

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	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(17)	(17)
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	(17)	(17)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,717	6,717
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,589)	(1,589)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(21)	(21)

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)	(17)	(17)
4.5	Effect of movement in exchange rates on cash held	(1)	(1)
4.6	Cash and cash equivalents at end of period	5,089	5,089

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	2,039	5,667
5.2	Call deposits	3,050	1,050
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)	5,089	6,717

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	247
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.

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.</i>		
<i>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.		
N/A		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,589)
8.2 Cash and cash equivalents at quarter end (item 4.6)	5,089
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	5,089
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.2
<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: 27 October 2021

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.