arovella
THERAPEUTICS

Quarterly Activities & Cash Report and 4C

31 December 2021

Arovella Therapeutics Limited
ABN 35 090 987 250

ASX Release

31 January 2022

APPENDIX 4C: SECOND QUARTER FY 2022

PERTH, AUSTRALIA 31 January 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 second quarter of FY 2022.

Key highlights for the quarter included:

- Arovella acquired an exclusive global licence to the patent rights for a monoclonal antibody that can be used as a chimeric antigen receptor (CAR) for cell therapy to treat various forms of cancer
- The company completed its name change and re-branding to introduce Arovella Therapeutics
- The manufacturer of the plasmid and vector was selected for Arovella's lead program, ALA-101 (CAR19-iNKT)
- Dr Elizabeth Stoner appointed as a Non-executive Director to Arovella's Board
- Arovella's commercialisation partner Teva received approval from Chile's Ministry of Health for ZolpiMist®
- Arovella received a refund of $524,042 from the Australian Taxation Office under the R&D Tax Incentive for the 2021 financial year

Acquisition of the exclusive global rights to the DKK1-peptide mAb/CAR to treat various forms of cancer

On 13 December 2021, the Company announced that it signed a global, exclusive licence agreement with The University of Texas MD Anderson Cancer Center for the patent rights to a novel monoclonal antibody (mAb) developed for cancer treatment.

This is the first mAb directed against a DKK1 peptide (DKK1) found linked by the HLA-A2 protein to the surface of cancer cells. DKK1 is a target that is found in many cancer types, including blood cancers and solid tumours and 40-50% of the population is HLA-A2 positive, meaning that this technology may be applicable across a wide spectrum of cancers that affect a significant proportion of the population.

Higher levels of DKK1 in cancer patients may serve as a prognostic biomarker for cancers such as Multiple Myeloma, Head and Neck Squamous Cell Carcinoma (HNSCC), Pancreatic Adenocarcinoma (PAAD), and Lung Squamous Cell Carcinoma (LUSC). Higher DKK1 production has been observed in bladder cancer and increased production of DKK1 may assist Non-small Cell Lung Carcinoma (NSCLC) cell invasion and migration. It has also been suggested that increased DKK1 levels may cause resistance to chemotherapy in cancers such as ovarian cancer.

Numerous studies have shown that multiple myeloma cells overproduce DKK1. It is also documented that multiple myeloma cells produce CD1d, which is recognised by invariant Natural Killer T (iNKT) cells, the core of Arovella's iNKT cell therapy platform. Arovella expects that by combining the DKK1-CAR with its iNKT cell therapy platform, it will lead to a more effective product to treat multiple myeloma and potentially other cancers. To date, the DKK1 mAb has shown promise in treating multiple myeloma when used as a single agent in mouse models. When incorporated as CAR, DKK1-CAR-T cells successfully eliminate cancer in numerous animal cancer models, including multiple myeloma, pancreatic cancer, lung cancer and triple negative breast cancer.

More than a decade of work has gone into the production and testing of the DKK1 mAb. Professor Qing Yi, now at Houston Methodist, developed the technology during his time at MD Anderson as a tenured Professor of Medicine. At Houston Methodist, Professor Yi has continued the research, assessing the potential of the DKK1-CAR. Professor Yi was recruited to Houston Methodist in 2018 through a US$6m Cancer Prevention and Research Institute of Texas (CPRIT) award.

The company completed its name change and rebranding to introduce Arovella Therapeutics

On 14 October 2021, shareholders voted to approve the resolution to change the name of the Company to Arovella Therapeutics Limited. On 25 October 2021, the Company began trading under the new ticker ALA.

The name change reflects the acquisition of the Company's iNKT cell therapy platform for cancer treatment and the strategic direction of working with new therapeutic platforms to impact human health positively. The new name better reflects that the Company has broadened its strategy to include multiple therapeutic platforms. The Company focuses on specific disease areas, oncology and conditions that affect the central nervous system. Arovella is a combination of two essential words in the arena of drug discovery; arrow, which references the targeting of specific diseases and novella, which has the meaning of "new" in Italian (the feminine version of novello). The combined name, Arovella Therapeutics, encompasses the Company's strategic goal to target specific disease areas using novel platforms.

The manufacturer of the plasmid and vector was selected for Arovella's lead program, ALA-101 (CAR19-iNKT)

During the quarter, the Company screened numerous contract manufacturing organisations (CMOs) for the production of two important components for the therapy, plasmid and lentiviral vector. The CMO has been selected and work began in the week commencing 10 January 2022. Once the lentiviral vector has been produced, the final component, the iNKT cells can be manufactured. Work continues to select the iNKT cell manufacturer, which is expected to be finalised in Q1 CY22.

Dr Elizabeth Stoner appointed to the board of directors

On 10 November 2021, the Company appointed Dr Elizabeth Stoner, M.S. M.D., as an independent Non-Executive Director. Dr Stoner, based in Boston, has over 30 years' experience in the life-sciences sector, spanning early-stage research, drug development and venture investing. She is currently Executive Partner at MPM Capital, a leading US healthcare investment firm, with over two decades of experience founding and investing in life-sciences companies that seek to translate scientific innovations into cures for major diseases. In her role, Dr Stoner serves as a clinical advisor to several of MPM Capital's portfolio companies, including AlloVir, and Rhythm Pharmaceuticals. Additionally,

Dr Stoner served as the interim CEO of the cell therapy biotechnology company, Semma Therapeutics, which was acquired by Vertex in 2019 for US$950 million.

Prior to joining MPM Capital, Dr Stoner was Senior Vice President of Global Clinical Development Operations at Merck Research Laboratories where she was responsible for its clinical development activities in more than 40 countries. While at Merck, she also oversaw the clinical development activities of its Japanese subsidiary and played a leading role in Merck/Schering Plough Joint Venture's development of Vytorin and Zetia, blockbuster cholesterol lowering drugs. Previously, she led the 5-alpha reductase clinical development program, establishing Merck as a leader in the field of prostate disease.

Dr Stoner currently serves on the board of Triplett Therapeutics. She is also a member of the Albert Einstein College of Medicine Board of Governors, and the Weill Cornell Medical College Clinical and Translational Science Center External Advisory Board.

Dr Stoner received her M.D. from the Albert Einstein College of Medicine and prior to joining the biopharma industry, she was an Assistant Professor of Paediatrics at Cornell University Medical College.

Arovella's commercialisation partner Teva received approval from Chile's Ministry of Health for ZolpiMist®

On 21 October 2021, the company announced that that the Ministry of Health, Chile, has approved the registration of the Company's most advanced product ZolpiMist (zolpidem tartrate) by Teva Pharmaceuticals for the treatment of short-term insomnia in adults. Teva, Arovella's commercialisation partner, submitted a Marketing Authorisation Application (MAA) with the new supplemental API supplier and the Australian final product manufacturer to the Chilean authority for ZolpiMist in May 2021. This approval was granted significantly earlier than the expected date of April 2022.

Corporate Update

Arovella finished the quarter with a bank balance of $4.39m at 31 December 2021. The net outflow from operating activities for the quarter was $0.7m. The current funds will support the initial manufacturing efforts for the iNKT cell therapy products and further development of the oral spray products.

The net cash used in operating activities during the quarter was $0.7m compared to $1.59m the previous quarter to 30 September 2021. The decrease in costs is mainly due to the fact that the Company Received a refund of $524,042 from the Australian Taxation Office under the R&D Tax Incentive for the 2021 financial year. The incentive recognises the research and development activities undertaken by Arovella during the last financial year. The receipt of the additional funding further supports Arovella's development work for the current year. In addition, the company re-negotiated the payments terms for the HCBP settlement, with the final remaining payment due at the end of FY2022.

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. 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

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	**Quarter ended ("current quarter")**
35 090 987 250	31 December 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	297	307
1.2	Payments for		
	(a) research and development	(353)	(913)
	(b) product manufacturing and operating costs	(106)	(106)
	(c) advertising and marketing	-	-
	(d) leased assets	(29)	(61)
	(e) staff costs	(486)	(926)
	(f) administration and corporate costs	(570)	(1,137)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	1	1
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	524	524
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(722)**	**(2,311)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(1)	(22)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 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**	**(1)**	**(22)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	5	5
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)
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**	**5**	**(12)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	5,089	6,717
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(722)	(2,311)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1)	(22)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	5	(12)
4.5	Effect of movement in exchange rates on cash held	15	14
4.6	**Cash and cash equivalents at end of period**	**4,386**	**4,386**

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	2,336	2,039
5.2	Call deposits	2,050	3,050
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)**	**4,386**	**5,089**

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	209
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** *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.

N/A

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(722)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,386
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,386
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	6.1

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.

Date: 31 January 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.