arovella
THERAPEUTICS

Quarterly Activities & Cash Report and 4C

30 June 2022

Arovella Therapeutics Limited
ABN 35 090 987 250

ASX Release

29 July 2022

APPENDIX 4C: FOURTH QUARTER FY 2022

MELBOURNE, AUSTRALIA 29 July 2022: Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell platform for cancer treatment and its oral spray delivery technology to treat cancer and conditions that affect the central nervous system, today released its Appendix 4C for the fourth quarter of FY 2022.

Highlights for the quarter:

- Q-Gen Service Agreement signed to initiate manufacturing of ALA-101
- Dr Elizabeth Stoner was appointed as interim Chairperson, and Mr Gary Phillips appointed as a Non-Executive Director
- Anagrelide patent granted by the US Patent and Trademark Office
- ZolpiMist launched in Australia by STADA Australia
- Arovella adopted the WEF Framework for ESG Reporting
- Quarterly cash burn to reduce now HCBP settled

ALA-101 (CAR19-iNKT) MANUFACTURING UPDATE

Arovella signed a Services Agreement with Q-Gen on 20 April 2022. The agreement to manufacture ALA-101 (CAR19-iNKT) is the preceding stage of a Master Manufacturing Services Agreement. This Services Agreement allows Arovella to initiate work with Q-Gen to manufacture the product for later-stage clinical trials. Q-Gen is currently completing the technology transfer process to manufacture ALA-101, which is an important step for the project.

Arovella's selected lentivirus manufacturer, an essential reagent to manufacture the therapy, is continuing as planned.

BOARD CHANGES

Dr Elizabeth Stoner accepted the position as interim Chairperson on 30 June 2022 upon Mr Paul Hopper stepping down from his role as Non-Executive Chairman.

Dr Stoner is currently Executive Partner at MPM Capital, a world-leading biotechnology investment firm. She currently serves on the Board of Triplett Therapeutics, is a member of the Albert Einstein College of Medicine Board of Governors, and is a member of the Weill Cornell Medical College Clinical and Translational Science Center External Advisory Board.

Dr Stoner has previously held a key position in Merck Research Laboratories as Senior Vice President of Global Clinical Development Operations. In this role, Dr Stoner was responsible for clinical development programs in more than 40 countries.

Mr Gary Phillips joined the board as a Non-Executive Director on 1 July 2022. 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. Gary Phillips holds a Bachelor of Pharmacy Honours degree from Nottingham University in the U.K. and an MBA from Henley Management College, UK. Mr Phillips is also a Graduate of the Australian Institute of Company Directors (GAICD).

OROMIST UPDATE

Anagrelide patent granted by the US Patent and Trademark Office

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 (ASX Release 5 April 2022)

Anagrelide is being developed to treat metastatic disease in patients with certain solid tumour cancers. Clinical experience has shown that increased platelet numbers associated with several solid tumour cancers decrease 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 and the lung, two likely sites of metastases.

Arovella seeks co-development partners to fund ongoing research or out-licence the anagrelide intellectual property. Anagrelide has potential in several cancer types, including melanoma, mesothelioma, ovarian, vulvar, cervical, renal cell, lung, glioblastoma, pancreatic, endometrial and colorectal cancer.

ZolpiMist

STADA Australia initiated its commercial launch for ZolpiMist (zolpidem tartrate), a product indicated for the short-term treatment of insomnia in adults (ASX release 22 June 2022).

Arovella entered into a licence and distribution agreement with STADA in August 2021. Following the successful manufacturing of the product, STADA has initiated its commercial launch in Australia. Under the terms of the agreement, Arovella will coordinate the product's manufacturing through its Australian manufacturer. Arovella is in the process of implementing a more economical, elegant, and user-friendly child-resistant lock and will receive a milestone payment of $40,000 upon the anticipated TGA approval. Arovella will receive a 10% royalty on net product sales following TGA approval of the new child-resistant lock. STADA has an option to commercialise the product throughout New Zealand and is considering expanding its footprint for sales.

Strides termination of the Development, Licence and Supply Agreement

On 28 June 2022, Arovella announced that Strides Global Pharma Pte Ltd (Strides) indicated its intention to cease the Development, Licence and Supply Agreement (Agreement) that was entered into 8 November 2018[1] due to changes in market conditions.

CORPORATE UPDATE

Arovella Therapeutics Adopted the WEF Framework for ESG Reporting

Arovella presented its first Environmental Social Governance (ESG) Report (also known as the 'Sustainability Report') on 8 June 2022. The Report responds to the 21 core metrics identified by the World Economic Forum (WEF) in its stakeholder capitalism framework[2].

The WEF framework is organised into four 'pillars' of Governance, Planet, People and Prosperity. The metrics cover core ESG matters of governance, anti-corruption practices, ethical behaviour, human rights, carbon emissions, land use, ecological sensitivity, water consumption, diversity, inclusion, pay equality and tax payments.

Change of Share Registry

Arovella Therapeutics has changed its provider for share registry services to Automic Pty Ltd:

Automic Registry Services
Level 35
477 Collins Street
Melbourne VIC 3000
Ph: 1300 288 664
GPO Box 5193
Sydney NSW 2001

Shareholders can manage their holdings via Automic's secure and highly accessible online investor portal (https://investor.automic.com.au)

Shareholders with queries concerning their Arovella Therapeutics Limited holdings are advised to contact Automic at hello@automicgroup.com.au or on 1300 288 664 (within Australia) or +61 2 9698 5414 (outside Australia).

FINANCIAL UPDATE

The net cash used in operating activities during the quarter was $2.04m compared to $2.47m the previous quarter to 31 March 2022. During the quarter, expenditure included the $549k final payment to HC Berlin Pharma (HCBP) under the negotiated settlement in 2018. Going forward, the Company expects quarterly cash expenditure to reduce as the HCBP payments will cease.

[1] Refer to ASX announcement on 8 November 2018 'SUDA signs exclusive agreement for SUD-001H for the US Market'
[2] www3.weforum.org/docs/WEF_IBC_Measuring_Stakeholder_Capitalism_Report_2020.pdf

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:

Dr Michael Baker
Chief Executive Officer & Managing Director
Arovella Therapeutics Ltd
Tel +61 (0) 403 468 187
mbaker@arovella.com

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'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 expanding its DKK1-peptide targeting technology licenced from MD Anderson and 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 consists of 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 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	**Quarter ended ("current quarter")**
35 090 987 250	30 June 2022

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	118	447
1.2	Payments for		
	(a) research and development	(601)	(3,044)
	(b) product manufacturing and operating costs	(98)	(289)
	(c) advertising and marketing	(23)	(25)
	(d) leased assets	(23)	(121)
	(e) staff costs	(381)	(1,680)
	(f) administration and corporate costs	(489)	(2,089)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2	4
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)	(549)	(549)
1.9	**Net cash from / (used in) operating activities**	**(2,044)**	**(6,822)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(3)	(25)
	(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 (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(3)**	**(25)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	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	(25)	(549)
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**	**(25)**	**6,217**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	8,123	6,717
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,044)	(6,822)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(3)	(25)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(25)	6,217
4.5	Effect of movement in exchange rates on cash held	20	(16)
4.6	**Cash and cash equivalents at end of period**	**6,071**	**6,071**

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	6,021	6,573
5.2	Call deposits	50	1,550
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)**	**6,071**	**8,123**

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	142
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)	(2,044)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,071
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	6,071
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3

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: 29 July 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.