ASX Release

30 April 2024

APPENDIX 4C: THIRD QUARTER FY 2024

Highlights for the quarter:

- **Completed a $12.5 million Placement to provide funding for preliminary phase 1 data. The pro forma cash balance is now $15.31m**
- **In-licenced novel cytokine armouring technology, IL-12-TM, to enhance the iNKT cell platform for solid tumours.**
- **Presented new data at AACR describing the potential benefits of ALA-101.**
- **Professor Gianpietro Dotti, a renowned CAR-iNKT cell pioneer and inventor of the IL-12-TM technology, was appointed to the Scientific Advisory Board.**

MELBOURNE, AUSTRALIA 30 April 2024: Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell therapy platform for cancer treatment, today releases its Appendix 4C for the third quarter of FY24.

During the quarter, Arovella continued to advance its iNKT cell therapy towards first-in-human clinical trials. Arovella's technology provides key advantages over existing CAR-T cell therapies and has the potential to be applied to both blood cancers and solid tumours.

Arovella is in a solid financial position with pro-forma cash and cash equivalents of $15.3 million as at 31 March 2024, including the proceeds from its recent $12.5 million Placement announced on 26 March, 2024. This is expected to provide Arovella with sufficient funding to obtain preliminary data in its planned first-in-human clinical trial for its lead product, ALA-101.

Over the remainder of CY24, **Arovella** expects to achieve several critical milestones, including:

- Presenting initial proof-of-concept data for its CLDN18.2-iNKT program
- Manufacturing clinical batches of ALA-101 for phase 1 clinical trials
- Regulatory approval(s) to conduct a phase 1 clinical trial in non-Hodgkin's lymphoma and
- Commencing a phase 1 clinical trial in non-Hodgkin's lymphoma.

ARMOURING iNKT CELLS

In January, Arovella signed a global, exclusive License Agreement with the University of North Carolina Lineberger Comprehensive Cancer Center (UNC Lineberger) to incorporate UNC Lineberger's novel IL-12-TM (cytokine technology) into Arovella's CAR-iNKT cell therapy platform. The technology was developed by Professor Gianpietro Dotti, a pioneer of CAR-iNKT cells, and was published in the prestigious peer-reviewed journal Nature Communications.[1]

[1] https://www.nature.com/articles/s41467-023-44310-y

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The data demonstrates that IL-12-TM enhances CAR-iNKT cell persistence, cell number and antitumour activity in several animal cancer models including solid tumour cancers, such as neuroblastoma. Arovella intends to incorporate the IL-12-TM technology into its solid tumour programs and will be the only iNKT cell company incorporating the technology.

IL-12-TM is a modified version of the human cytokine, interleukin 12 (IL-12). Due to bridging the innate and adaptive immune systems and potently stimulating the production of IFN-γ, a cytokine coordinating natural mechanisms of anticancer defence, IL-12 was considered the ideal candidate for human tumour immunotherapy. However, side effects associated with systemic administration limited its use as a stand-alone therapeutic.

IL-12-TM has been modified to include a 'membrane anchor', which keeps the IL-12 attached to the CAR-iNKT cell and prevents it from circulating freely in the patient's bloodstream. This enables the IL-12-TM to have the desired effect on the CAR-iNKT cell and reduces the risk of off-target effects and toxicity.

When IL-12-TM is added to CAR-iNKT cells, it promotes the proliferation and survival of the CAR-iNKT cells. This means that when the CAR-iNKT cell comes in contact with a target tumour cell, it proliferates more, leading to higher numbers of CAR-iNKT cells. In addition, the cells do not get 'exhausted' as quickly and therefore survive longer, again contributing to higher CAR-iNKT cell numbers.

The IL-12-TM technology was tested in a mouse model of neuroblastoma, a cancer that can affect various regions of the central nervous system. When the number of CAR-iNKT cells was assessed in the mice four weeks after dosing, CAR-iNKT cells containing IL-12-TM were found at much higher numbers in the bloodstream (>8-10 times) than CAR-iNKT cells that did not contain IL-12-TM. This correlated with substantially better antitumour activity and survival outcomes in the mice with approximately 75% of mice still alive 60 days after treatment for the IL-12-TM group while all mice in the group treated with CAR-iNKT cells lacking IL-12 had died (Figure 1).

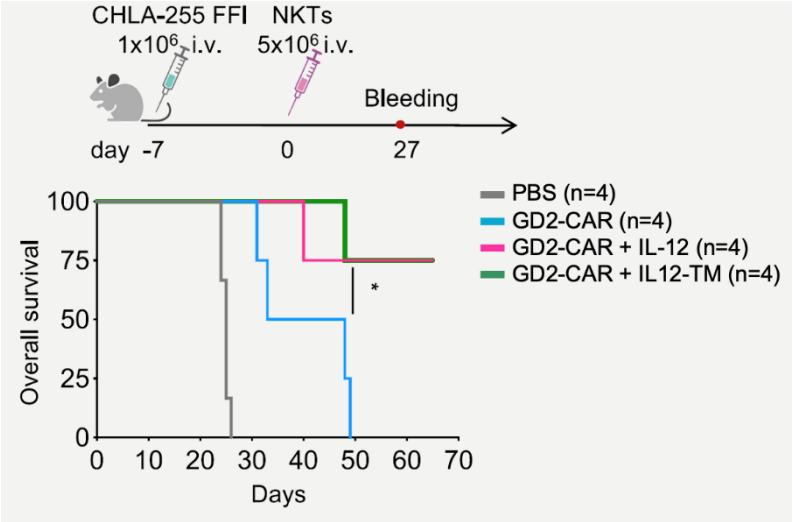

Figure 1. *CHLA-255 neuroblastoma cells were engrafted into mice before treatment with PBS, iNKT cells expressing a CAR to target GD2 lacking the cytokine technology (GD2-CAR), GD2 targeting iNKT cells with secreted IL-12 (GD2-CAR +IL-12) or GD2 targeting iNKT cells with a membrane anchored IL-12 (GD2-CAR + IL-12-TM). Landoni et al 2024, Nature Communications.*

The full publication for the IL-12-TM data is available from the Nature Communications website and can be found here - https://www.nature.com/articles/s41467-023-44310-y.

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Arovella's CEO, Dr Michael Baker, also presented a webinar describing the technology and Arovella's approach which is available online (https://www.arovella.com/news-presentations) and can be viewed by clicking the image below.

Armouring CAR-iNKT cells to treat solid tumours

Arovella's CAR-iNKT cells are being developed as an off-the-shelf solution for cancer treatment. They have inherent properties that may make them amenable to targeting solid tumours, such as:

(i) the ability to infiltrate tissues and tumours[i,ii],
(ii) the ability to block or kill cells that promote tumour survival such as myeloid-derived suppressor cells (MDSCs) and tumour-associated macrophages (TAMs),[iii] and
(iii) the ability to release cytokines to stimulate an immune response and recruit other immune cells to target tumour cells.[iv,v]

Armouring CAR-iNKT cells is one of Arovella's strategies to further enhance and differentiate its platform to tackle solid tumours. IL-12-TM is expected to complement Arovella's CLDN18.2 program, recently licensed from Sparx Group. Arovella is developing the world's first CAR-iNKT cell therapy targeting CLDN18.2 to treat gastric cancers (GC), gastroesophageal junction cancers (GEJC), pancreatic cancers (PC), and other solid tumours that express CLDN18.2. GC and GEJC continue to present as high unmet medical needs with over one million new cases diagnosed per annum globally and 789,000 deaths, making it the fourth most fatal cancer globally.[vi] Over 496,000 individuals were diagnosed with PC worldwide in 2020 with an estimated 466,000 deaths the same year.[vii] Stage 4 pancreatic cancer has a five-year survival rate of 1% with the average patient living for approximately 1 year after their diagnosis.[viii] The global gastric cancer market size was valued at $2.1 billion in 2021, and is projected to reach $10.7 billion by 2031, growing at a CAGR of 17.9% from 2022 to 2031.[ix]

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PROGRESSING ALA-101 TOWARDS THE CLINIC AND NEW DATA AT AACR

Arovella is developing ALA-101 to treat CD19+ lymphomas and leukemias and continues to make solid progress developing its clinical-ready GMP manufacturing process. In January, Arovella announced the release of its GMP lentiviral vector, a key input in the manufacturing process for ALA-101. Arovella continues to work with its partner, Cell Therapies Pty Ltd, based within the Peter MacCallum Cancer Centre in Melbourne, to scale-up and optimise the GMP manufacturing process for ALA-101.

In April, Arovella also presented new data, characterising ALA-101, at the American Association for Cancer Research (AACR) Annual Meeting in San Diego. The data summarised two distinct phenotypes of cells within the drug product, each of which plays a different role in responding to tumour cells. In particular, ALA-101 CAR-iNKT cells were separated based on whether or not they produced CD4 on their surface (CD4+ vs CD4-). Cells negative for CD4 (CD4-) were better able to kill target tumour cells via the CD19 Chimeric Antigen Receptor (CAR). In contrast, CD4+ cells proliferated faster in response to CD19+ tumour cells. The two groups of cells also produced a different cytokine response following CAR activation.

The outcomes of these studies have shown encouraging results, supporting the potential benefit of having diverse subsets among CAR19-iNKT cells for treating CD19+ cancers. Arovella's proprietary iNKT manufacturing method is specifically designed to maintain the highly cytotoxic CD4- population, thus maintaining a healthy balance of cells with different mechanisms of responding to tumour cells.

A copy of the poster is available on the Company's website https://www.arovella.com/news-presentations.

STRENGTHENING THE SCIENTIFIC ADVISORY BOARD

In April, Arovella announced that it had appointed Professor Gianpietro Dotti to its Scientific Advisory Board. Professor Dotti's appointment strengthens Arovella's expertise in using CAR-iNKT cells to treat blood cancers and solid tumours. Professor Dotti is a pioneer and one of the first individuals to create CAR-iNKT cell strategies for cancer treatment. He has been involved in the development of two products using CAR-iNKT cells that have been used in blood cancer patients and paediatric patients with neuroblastoma.

Professor Dotti has spent more than twenty years using his medical and scientific training to create engineered immune cells for cancer treatment. His research has led to more than 200 peer-reviewed articles, and he has consistently received the Highly Cited Researchers (Top 1%) award from Web of Science, Clarivate Analytics in 2020, 2021, 2022, and 2023.

Professor Dotti received his medical degree from the University of Milan, Italy and completed his clinical training and Board certification in haematology from the University of Parma. He completed his post-doctoral fellowship at the Center for Cell and Gene Therapy at the Baylor College of Medicine in Houston, Texas. Professor Dotti is currently a Professor of Microbiology and Immunology, and the Director of the Cellular Immunotherapy Program at Lineberger Comprehensive Cancer Center at the University of North Carolina.

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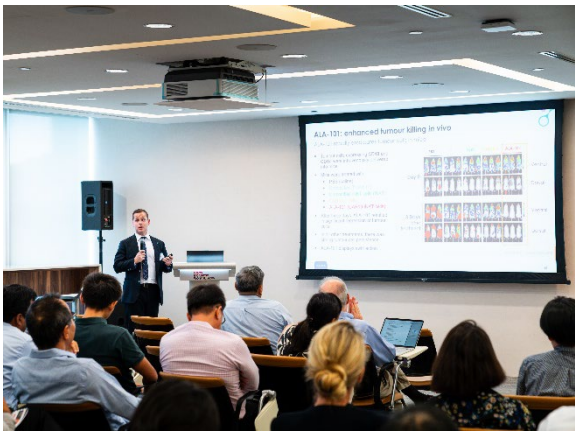
INVESTOR RELATIONS AND NEWS

Over the quarter, CEO Dr Michael Baker presented at several investor events, including Spark Plus Singapore Healthcare Day, NWR Virtual Healthcare Conference and ASX Gems Conference. Copies of these presentations are available on the Company's website.

In January, Arovella joined the new Jumar Bioincubator, a joint venture between CSL, Walter and Eliza Hall Institute of Medical Research (WEHI) and University of Melbourne that is supported by Breakthrough Victoria. The Jumar Bioincubator brings together a vibrant community of entrepreneurs within CSL's new flagship building housing its Global Headquarters and Centre for R&D. Arovella is proud to be a member of this exciting community.

In February, Arovella was proud to sponsor the international CD1-MR1 conference, the premier conference for iNKT cell biology, when it was held in Hobart. Arovella's COO, Dr Nicole van der Weerden presented at the conference, which brings together researchers from across the globe to discuss all things related to unconventional immune surveillance, including invariant Natural Killer T (iNKT) cells, the focus of Arovella's cell therapy platform.

Above: Dr Nicole van der Weerden presenting at the CD1-MR1 conference in Hobart, TAS.



Above: Dr Michael Baker presenting to investors at the Spark+ Healthcare Day in Singapore.

Above: Dr Michael Baker presenting at the Jumar Bioincubator grand opening.

Above: Sally Capp AO, Lord Mayor of Melbourne and Dr Andrew Nash, CSL's Chief Scientific Officer and Jumar Chair unveiling the official Jumar grand opening plaque.

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In March, Arovella announced that Imugene had advised Arovella that it would be terminating the research collaboration between the parties. As such, *in vivo* data for the combination of ALA-101 and onCARlytics will no longer be generated. The termination of the collaboration will not impact Arovella's development of ALA-101 for CD19-positive blood cancers or development of its Claudin 18.2 and IL-12-TM products.

FINANCIAL UPDATE

Arovella continues to be in a solid financial position with a closing pro-forma cash balance at the end of the March quarter of $15.31 million, compared to $4.76 million at the end of the previous quarter. The net cash used in operating activities during the quarter was $2.45 million compared with $0.66 million for the previous quarter to 31 December 2023. The previous quarter included receipt of the Company's R&D Tax Incentive rebate for FY23 of $1.94 million. Expenditure on R&D and staff costs totalling $2.16 million represented 83% of the Company's total operating outflows.

On 26 March 2024, Arovella announced that it had completed a Placement to institutional and sophisticated investors to raise approximately $12.5 million (before costs) under a placement of 125 million new fully paid ordinary shares in the Company (Shares) at A$0.10 per Share (Placement), with an attaching 1-for-1 Option with an exercise price of $0.15 (a 50% premium to the Placement price) and an exercise period of three years.

The Placement was oversubscribed and received strong support from domestic and international institutional and sophisticated investors. Funds raised under the Placement will be used to progress Arovella's lead product, ALA-101, into a Phase 1 clinical trial and generate preliminary data from patients dosed with ALA-101. The Phase 1 clinical trial is for patients with CD19-positive non-Hodgkin's lymphoma. Funds raised under the placement will also be used to strengthen Arovella's iNKT cell therapy pipeline and advance Arovella's solid tumour products, and for general working capital purposes.

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
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NOTES TO EDITORS:

About Arovella Therapeutics Ltd

Arovella Therapeutics Ltd (ASX: ALA) is a biotechnology company focused on 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 into solid tumour treatment through its CLDN18.2-targeting technology licensed from Sparx Group. Additional tumour targeting technologies are anticipated to be

used in conjunction with Arovella's iNKT cell therapy platform. Arovella's lead product is ALA-101. ALA-101 consists of CAR19-iNKT cells that have been modified to produce a Chimeric Antigen Receptor (CAR) that targets CD19. CD19 is an antigen found on the surface of numerous cancer types. iNKT cells also contain an invariant T cell receptor (iTCR) that targets α-GalCer bound CD1d, another antigen found on the surface of several cancer types. ALA-101 is being developed as an allogeneic cell therapy, which means it can be given from a healthy donor to a patient.

Glossary: iNKT cell – invariant Natural Killer T cells; **CAR** – Chimeric Antigen Receptor that can be introduced into immune cells to target cancer cells; **TCR** – T cell receptors are a group of proteins found on immune cells that recognise fragments of antigens as peptides bound to MHC complexes; **B-cell lymphoma** – A type of cancer that forms in B cells (a type of immune system cell); **CD1d** – Cluster of differentiation 1, which is expressed on some immune cells and cancer cells; **aGalCer** – alpha-galactosylceramide is a specific ligand for human and mouse natural killer T cells. It is a synthetic glycolipid.

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.

[i] https://pubmed.ncbi.nlm.nih.gov/29967365/
[ii] https://pubmed.ncbi.nlm.nih.gov/33046868/
[iii] https://pubmed.ncbi.nlm.nih.gov/19411762/
[iv] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4517377/
[v] https://doi.org/10.4049/jimmunol.163.9.4647
[vi] https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(22)00134-1/fulltext
[vii] https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21660
[viii] https://www.hopkinsmedicine.org/health/conditions-and-diseases/pancreatic-cancer/pancreatic-cancer-prognosis
[ix] https://www.alliedmarketresearch.com/gastric-cancer-market-A74458#:~:text=The%20global%20gastric%20cancer%20market,cells%20lining%20of%20the%20stomach

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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 March 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,853)	(5,169)
	(b) product manufacturing and operating costs	-	(4)
	(c) advertising and marketing	(41)	(116)
	(d) leased assets	-	-
	(e) staff costs	(309)	(1,018)
	(f) administration and corporate costs	(400)	(1,096)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	40	114
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives		1,935
1.8	Other (GST)	110	269
1.9	**Net cash from / (used in) operating activities**	**(2,453)**	**(5,085)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(89)	(124)
	(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)		(50)
2.6	**Net cash from / (used in) investing activities**	**(89)**	**(174)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	2,216
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	594	780
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(11)	(132)
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 (Placement funds received, shares issued in April 2024)	615	615
3.10	**Net cash from / (used in) financing activities**	**1,198**	**3,479**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	4,763	5,175
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,453)	(5,085)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(89)	(174)

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)	1,198	3,479
4.5	Effect of movement in exchange rates on cash held	1	25
4.6	**Cash and cash equivalents at end of period**	**3,420**	**3,420**

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	1,351	483
5.2	Call deposits	2,069	4,280
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)**	**3,420**	**4,763**

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	140
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.

The amount at 6.1 includes Director fees and salary (including superannuation) for the CEO and Managing Director and Non-Executive Directors.

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.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,453)
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,420
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	3,420
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.4

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: Arovella Therapeutics Limited will be able to continue the current level of net operating cash flows due to completion of $12.5M Placement (before costs) announced to the market on 26 March 2024 and shares issued 4 April 2024.

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: Arovella Therapeutics Limited has successfully completed a $12.5M (before costs) Placement to fund the Company to Phase 1 data read-out which was announced to the market on 26 March 2024. $615K was received prior to 31 March 2024 with the remaining funds fully received in April 2024.

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:	Arovella Therapeutics Limited expects to continue operations and meet business objectives due to the successful $12.5M Placement (before costs) completed and received in April 2024.

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: 30 April 2024

Authorised by: 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.