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# Appendix 4D Half Year Report Ended

31 December 2023

Arovella Therapeutics Limited  
ABN 35 090 987 250

**Arovella Therapeutics Limited**  
**Appendix 4D**  
**Half-year report**

**1. Company details**

Name of entity:	Arovella Therapeutics Limited
ABN:	35 090 987 250
Reporting period:	Half-year Ended 31 December 2023
Previous period:	Half-year Ended 31 December 2022

**2. Results for announcement to the market**

			\$
Revenues from ordinary activities and other income	up	40.9% to	2,029,825
Loss from continuing operations from ordinary activities after tax attributable to the owners of Arovella Therapeutics Limited	up	1.2% to	(3,945,770)
Loss from continuing operations for the half-year attributable to the owners of Arovella Therapeutics Limited	up	1.2% to	(3,945,770)

*Dividends*

There were no dividends paid, recommended or declared during the current financial period.

*Comments*

The loss from continuing operations for the company after providing for income tax amounted to \$3,945,770 (31 December 2022: \$3,899,162).

**3. Net tangible assets**

	Reporting period Cents	Previous period Cents
Net tangible assets per ordinary security	0.34	0.39

**4. Control gained over entities**

Not applicable.

**5. Loss of control over entities**

Not applicable.

**6. Dividends**

*Current period*

There were no dividends paid, recommended or declared during the current financial period.

*Previous period*

There were no dividends paid, recommended or declared during the previous financial period.

**7. Dividend reinvestment plans**

Not applicable.

**8. Details of associates and joint venture entities**

Not applicable.

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**9. Foreign entities**

*Details of origin of accounting standards used in compiling the report:*

Not applicable.

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**10. Audit qualification or review**

*Details of audit/review dispute or qualification (if any):*

The financial statements were subject to a review by the auditors and the review report is attached as part of the Interim financial report for the half-year ended.

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**11. Attachments**

*Details of attachments (if any):*

The Interim financial report for the half-year ended of Arovella Therapeutics Limited for the half-year ended 31 December 2023 is attached.

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**12. Signed**

Signed



Thomas Duthy  
Chair

Date: 28 February 2024

# **Arovella Therapeutics Limited**

**ABN 35 090 987 250**

**Interim financial report for the half-year ended - 31 December  
2023**



**Arovella Therapeutics Limited**  
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**31 December 2023**

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**Arovella Therapeutics Limited**  
**Corporate directory**  
**31 December 2023**

**Directors**

Dr. Thomas Duthy  
*Non-Executive Chair*

Dr. Elizabeth Stoner  
*Non-Executive Director*

Dr. Michael Baker  
*CEO and Managing Director*

Dr. Debora Barton  
*Non-Executive Director*

Mr. Gary Phillips  
*Non-Executive Director*

Mr. David Simmonds (Resigned 7 September 2023)  
*Non-Executive Director*

**Company secretary**

Mr. Tim Luscombe (Appointed 1 December 2023)

**Registered office**

84 Hotham Street  
Preston VIC 3072

**Share registry**

Automic Pty Ltd  
Level 35 477 Collins Street  
Melbourne VIC 3000  
1300 288 664

**Auditor**

HLB Mann Judd (WA Partnership)  
Level 4, 130 Stirling Street  
Perth WA 6000

**Bankers**

National Australia Bank  
330 Collins Street  
Melbourne VIC 3000

**Stock exchange listing**

Australian Securities Exchange Ltd  
Level 50, South Tower, Rialto,  
525 Collins St, Melbourne VIC 3000  
Listing Codes: Ordinary Shares  
ALA

**Website**

[www.arovella.com](http://www.arovella.com)

**Arovella Therapeutics Limited**  
**Directors' report**  
**31 December 2023**

The Directors present their report on Arovella Therapeutics Limited (thereafter referred to "Arovella" or "the Company") "for the half-year ended 31 December 2023.

**Directors**

The following persons were directors of the company during the whole of the financial half-year and up to the date of this report, unless otherwise stated:

Dr. Thomas Duthy - Non-Executive Chair  
Dr. Michael Baker - CEO and Managing Director  
Dr. Elizabeth Stoner - Non-Executive Director  
Dr. Debora Barton - Non-Executive Director  
Mr. Gary Phillips - Non-Executive Director  
Mr. David Simmonds- Non-Executive Director (Resigned 7 September 2023)

**Significant changes in the state of affairs**

The following occurred during the period:

On 12 July 2023, a total of 49,241,018 shares were issued at \$0.045 each as part of a share purchase plan.

On 1 August 2023, the cashless exercise facility was utilised to convert 1,900,000 options into 565,105 shares, and a further 500,000 options cancelled.

On 24 August 2023, 2,250,000 ordinary shares were issued at \$0.04 each; 3,043,478 unlisted options were issued with an exercise price of \$0.04 each expiring 22 August 2028; and 3,478,261 unlisted options were issued with an exercise price of \$0.032 each expiring 22 August 2028, to Dr Thomas Duthy as approved by shareholders at the Extraordinary General Meeting ("EGM") on 23 August 2023.

On 25 October 2023, 4,347,826 shares were issued in lieu of cash for the upfront fee from the license agreement with Sparx Group announced 12 October 2023.

In November 2023 a total of 2,342,290 options were exercised with an exercise price of \$0.076.

On 17 November 2023 260,319 share were issued in lieu of cash for services to a consultant valued at \$15,000.

On 29 November 2023, 125,000 options were exercised with an exercise price of \$0.0675.

On 29 December 2023, the cashless exercise facility was utilised to convert 2,800,000 options into 587,824 shares.

There were no other significant changes in the state of affairs of the company during the financial half-year.

**Review of operations**

The loss from continuing operations for the company after providing for income tax amounted to \$3,945,770 (31 December 2022: \$3,899,162).

The loss from ordinary activities for the half-year ended 31 December 2023 was \$3,945,770, an increase of 1.2% compared to the last year (31 December 2022:\$3,899,162). Cash at bank as at 31 December 2023 is \$4,763,425(30 June 2023: \$5,175,338).

During the reporting period, Arovella continued to advance its lead asset, ALA-101, towards the clinic, while also significantly strengthening its pipeline for solid tumours.

During the half-year ended 31 December 2023, Arovella:

- Advanced its manufacturing activities through a new partnership with Cell Therapies Pty Ltd (CTPL) in readiness to manufacture ALA-101 for clinical trials in the first half of CY24.
- Completed GMP manufacturing of its lentiviral vector for ALA-101, a critical component required for GMP manufacturing for clinical trials.
- Progressed its solid tumour strategy by signing an exclusive license with Sparx Group to develop a world-first CAR-iNKT cell therapy targeting a validated target, Claudin 18.2 (CLDN18.2), which is expressed in gastric cancer (GC), gastroesophageal junction cancer (GEJC) and pancreatic cancer (PC).
- Received positive data demonstrating that the cytokine technology under option from the University of North Carolina can increase the persistence of iNKT cells and enhances their anti-tumour effect in a mouse solid tumour model which led to Arovella entering an exclusive, worldwide licence for the technology.
- Completed an oversubscribed SPP to raise a total of \$2.2 million and received its FY23 R&D tax credit of \$1.9 million, providing a strong cash position as at 31 December 2023.

### *PROGRESSING ALA-101 TOWARDS THE CLINIC*

Arovella is developing ALA-101 to treat CD19+ lymphomas and leukemias. A key requirement for the development of an iNKT cell therapy product is the establishment of the manufacturing process under GMP conditions. During the reporting period, Arovella continued to make important progress optimizing and scaling-up its manufacturing process for ALA-101. Importantly, this included the manufacture and release testing of its GMP-grade lentiviral vector. The GMP lentiviral vector, which carries the genetic material to program iNKT cells to target and eliminate cancer cells, is a critical component required for GMP manufacture of ALA-101 in preparation for phase 1 clinical trials.

Arovella also partnered with CTPL to conduct process optimization and scale-up activities for the ALA-101 manufacturing process. CTPL has over 20 years of experience delivering cellular therapy products to patients around the world and is embedded within Melbourne's Peter MacCallum Cancer Centre. Its GMP manufacturing facility holds licenses and accreditation from Australia's TGA and Japan's MHLW, with increased capacity courtesy of its new commercial-scale expansion that was opened in July 2023. CTPL has the expertise to support Arovella's products as we progress from concept to commercialization and is an ideal partner for Arovella.

### *ENTERING A NEW PHASE FOR SOLID TUMOURS*

During the reporting period, Arovella made several key steps in advancing its strategy to expand the CAR-iNKT platform into solid tumours. The first of these was entering into an exclusive licence agreement with Sparx Group to utilize their novel monoclonal antibody (mAb) that targets CLDN18.2 (SPX-101) in cell therapies.

Arovella's iNKT cell therapy platform has several advantages over existing CAR-T treatments, particularly for solid tumours. iNKT cells:

- Can be taken from a healthy donor and given to patients without causing graft versus host disease (GvHD).
- Contain an invariant T cell receptor (iTCR) that targets lipid-bound CD1d, present on several tumour types.
- Can be modified to produce a chimeric antigen receptor (CAR) to target specific tumours, making them dual-targeting for tumours that express the target antigen and CD1d.
- Can be expanded >5,000 fold to generate a significant number of doses from a single manufacturing batch.
- Naturally fight solid tumours as shown through the correlation between the natural level of iNKT cells in a cancer patient and improved prognosis in several solid tumour types, including head and neck and colorectal cancer.
- Can modify the tumour microenvironment and kill pro-tumour cells such as myeloid-derived suppressor cells (MDSCs) and tumour associated macrophages (TAMs).
- Can recruit other immune cells to aid in tumour destruction.

CLDN18.2 is a high-priority target for new cancer therapies which is expressed in gastric cancer (GC), gastroesophageal junction cancers (GEJC) and pancreatic cancer (PC). It is normally expressed in the tight junctions between cells and is not surface-exposed. However, in several tumour types (gastric, esophageal, pancreatic cancer and subsets of lung and ovarian cancer), CLDN18.2 becomes exposed as the tumour cells grow and lose their normal tissue structure. This makes CLDN18.2 an attractive target for a CAR expressed on a cytotoxic cell therapy which will target the cytotoxic cells to the tumor.

**Arovella Therapeutics Limited**  
**Directors' report**  
**31 December 2023**

The SPX-101 antibody has completed all preclinical proof-of-concept, safety and specificity studies and toxicology studies required to commence a phase 1 trial to treat gastric cancers and has improved affinity and selectivity for CLDN18.2 relative to zolbetuximab, a mAb that has recently shown a survival benefit in phase 3 studies in HER2-negative gastric cancer and was acquired by Astellas Pharma during its takeover of Ganymed Pharmaceuticals in 2016 for €422 million up-front and the potential for €860 million in milestones. Zolbetuximab is expected to be approved by the FDA in 2024.

Arovella will use the SPX-101 sequence to generate CAR-iNKT cells targeting CLDN18.2. Arovella's CLDN18.2-iNKT cells will be the only CAR-iNKT product in development and initial proof-of-concept data to demonstrate the potential of this approach is expected to be available in H1 CY24.

In addition to the SPX-101 licence, Arovella also received additional positive data for its cytokine technology, which was under option from the University of North Carolina. The data demonstrated that CAR-iNKT cells producing a modified version of interleukin 12 (IL-12-TM), which remains anchored to the iNKT cell surface, were able to proliferate better and survive longer, leading to higher number of CAR-iNKT cells. This resulted in substantially better antitumour activity in mouse models, particularly for solid tumours.

This data precipitated Arovella to enter into an exclusive worldwide licence for the IL-12-TM technology, which was finalized in January 2024. Arovella intends to combine the IL-12-TM technology with the CLDN18.2-targeting technology which is expected to enhance activity *in vivo*. Arovella will be the only CAR-iNKT cell company developing CAR-iNKT products incorporating this cytokine.

## **CORPORATE OVERVIEW**

In July 2023, Arovella completed an oversubscribed SPP to raise \$2.2 million. This followed a successful oversubscribed Placement which raised \$4.1 million to bring the total amount raised to \$6.3 million. In November, Arovella also received its FY23 R&D Tax Incentive rebate of \$1.9 million, providing a strong cash position at the end of the period of \$4.7 million.

On 1 December 2023, Arovella appointed Tim Luscombe as Chief Financial Officer (CFO) and Company Secretary. Tim is a Director at Bio101 Financial Advisory (Bio101), a financial services firm providing outsourced CFO, taxation and company secretarial solutions to the Healthcare sector. Tim has more than 10 years of finance and commercial experience working with public and private companies in Australia and abroad. He currently serves as a CFO and Company Secretary for several ASX listed, public unlisted and private Healthcare companies. Tim holds a Bachelor of Commerce from the University of Melbourne and a Certificate in Governance Practice from the Governance Institute of Australia and is a qualified Chartered Accountant.

### **Matters subsequent to the end of the financial half-year**

On 4 January 2024, 2,873,128 options were exercised with exercise prices of \$0.074 and \$0.041.

On 10 January 2024, 413,379 Ordinary Shares were issued for the provision of services in lieu of cash.

On 10 January 2024, 4,125,000 options were exercised. 4,000,000 options were exercised at \$0.025 and 125,000 options exercised at \$0.057.

On 16 January 2024, 1,183,334 options were exercised at \$0.0675.

On 17 January 2024, 125,000 options were exercised at \$0.0675.

On 30 January 2024 entered into a global, exclusive license with University of North Carolina Lineberger Comprehensive Cancer Center to incorporate a novel armoured cytokine technology (IL-12-TM) for its CAR-iNKT cell platform. The license has no immediate material financial impact on the Company as a result of signing the agreement. There is no upfront fee payable for the license, and future licensing fees will include annual license maintenance fees, stage-gated, industry-standard development milestones for the first patient dosed in a pivotal clinical trial and marketing approval. The Licence also includes a low single-digit royalty on future sales.

On 31 January 2024, 75,000 options were exercised at \$0.057.

On 14 February 2024, the company issued 2,000,000 options with an exercise price of \$0.1807 and an expiry of 14 February 2026, for the provision of corporate advisory services in lieu of cash.

On 20 February 2024, 5,481,482 options were exercised. 2,000,000 options were exercised at \$0.075, 2,000,000 options were exercised at \$0.030 and 1,481,482 were exercised at \$0.0675.

No other matter or circumstance has arisen since 31 December 2023 that has significantly affected, or may significantly affect the company's operations, the results of those operations, or the company's state of affairs in future financial years.

## **Business Risks**

### **1. Company and Industry risks**

The risks outlined below are specific to the Company's operations.

#### **1.1 Dependency upon licence agreements**

Access to the intellectual property rights to develop and commercialise CAR-iNKT cells in the field of oncology is predicated on the continuing operation of the license agreements in place between the Company and its licensors. Arovella is reliant on its licensors to have in place the relevant protection and rights to the technology as well as the authority to enter into the license agreements. Failure of a licensor or Arovella to comply with the terms of the licence agreements without an appropriate countermeasure could have a material adverse on Arovella's business, financial condition, operations or prospects.

#### **1.2 Product development and regulatory risk**

Arovella's ability to commercialise its intellectual property is reliant on its ability to generate preclinical and clinical data, including in respect of the new therapies using CAR-iNKT cells, which the Company is developing. These new therapies must undergo further clinical studies and those tests and trials may show that the product does not work in a safe and effective manner. There can be no guarantee that relevant regulatory agencies will allow Arovella to undertake such trials. The development and approval process for any new products or applications of existing products may take longer and/or cost more than expected and may result in the Company not producing a viable product. Drug development is a highly risky business with a high rate of failure, including due to potential low therapeutic benefit and unacceptable toxicity.

While the Company will conduct its clinical programs on the advice of consultants experienced in clinical trial design and regulatory affairs, there is no certainty that the trial design will provide appropriate data or that the data will meet the regulator's benchmark. This may require the Company to conduct further clinical studies, resulting in significant additional cost and delay. From the commencement of the clinical trial phase, the final drug development path typically takes between 7 to 11 years, depending on the indication.

#### **1.3 Product manufacturing risk**

Cell therapies, like Arovella's CAR-iNKT cell products, are complex therapeutics that rely on the use of a viral vector and human immune cells. The use of human immune cells as a raw material and the generation of a living therapeutic introduces the risk of variability between manufacturing runs. Arovella relies on the input of world-class consultants, advisors and team members to manufacture its CAR-iNKT cell products and to prepare the documentation to support regulatory filings. Notwithstanding, there is no guarantee that Arovella will not require additional time and incur additional costs to define a manufacturing process, and collect the relevant documentation, that appeases regulators such as the FDA and support the use of the material in clinical trials and for commercialisation.

#### **1.4 Pipeline product in development and not approved for commercial sale**

Arovella's ability to achieve profitability is dependent on several factors, including its ability to initiate and complete successful clinical trials, obtain regulatory approval for its CAR-iNKT technology and successfully commercialise its products. There is no guarantee that Arovella's products will be commercially successful.

#### **1.5 Regulatory and reimbursement approvals**

The research, development, manufacture, marketing and sale of products using Arovella's technology are subject to varying degrees of regulation by a number of government authorities in Australia and overseas. Products developed using Arovella's technology must undergo a comprehensive and highly regulated development and review process before receiving approval for marketing. Products may also be submitted for reimbursement approval. The availability and timing of reimbursement approval may not be forthcoming and if it does, it may have an impact on the uptake and profitability of products in some territories.

#### **1.6 Intellectual Property**

Arovella's ability to leverage its innovation and expertise depends on its ability to secure and protect its intellectual property and any improvements to it. The intellectual property may not be capable of being legally protected, it may be the subject of



unauthorised disclosure or be unlawfully infringed, or the Company may incur substantial costs in asserting or defending its intellectual property rights. This includes Arovella's ability to obtain commercially valuable patent claims. Aside from the territories in which patents are currently granted, the patent applications are still pending, and additional patents are likely to be filed to provide for extensive protection.

### **1.7 Dependence upon key personnel**

Arovella depends on the talent and experience of its personnel, and it may be difficult to replace them, or to do so in a timely manner or at comparable expense. The loss of services of one or more senior executives may have an adverse effect on the Company's operations.

### **1.8 Risk of delay and continuity of operations**

Arovella may experience delay in achieving a number of critical milestones, including, completion of clinical trials, obtaining regulatory approvals, manufacturing, and securing commercial partners. Any material delays may impact adversely upon the Company, including the timing of results and the initiation and completion of clinical trials.

### **1.9 Future capital requirements**

Arovella is generally loss making and the Company will require substantial additional financing in the future to sufficiently fund its operations, research and development, manufacturing and clinical trials. Any additional equity financing may be dilutive to shareholders (who may not have the opportunity to participate in that raising), and may be undertaken at lower prices than any prior offer prices.

Should the Company require additional funding, there can be no assurance that additional financing will be available on acceptable terms or at all. Any inability to obtain additional financing, if required, would have a material adverse effect on the Company's business, financial condition and results of operations. The Company's actual cash requirements may vary from those now planned and will depend upon many factors, including the continued progress of its research and development programs, the timing, costs and results of clinical trials, the cost, timing and outcome of submissions for regulatory approval and the status and timing of competitive developments.

### **1.10 Contractual risk**

Any dispute or breakdown in the relationship between the Company and counterparties to its contracts including the licensors for its technologies, could adversely impact the business if the Company is in breach of any of its agreements and its counterparties seek to pursue the Company for breach of contract or enforce security interests against the Company's assets (and conversely the Company depends on such counterparties performing their obligations under such agreement).

## **2. General Risks**

The future prospects of the Company's business may be affected by circumstances and external factors beyond the Company's control. Financial performance of the Company may be affected by a number of business risks that apply to companies generally and may include economic, financial, market or regulatory conditions.

### **2.1 Economic risks**

The operating and financial performance of the Company is influenced by a variety of general economic and business conditions, including levels of consumer spending, inflation, interest rates, access to debt and capital markets, international economic conditions, significant acts of terrorism, hostilities or war or natural disasters, and government fiscal, monetary and regulatory policies. Prolonged deterioration in general economic conditions may have an adverse impact on the Company's business or financial condition. No guarantee can be made that the Company's market performance will not be adversely affected by any such market fluctuations or factors.

### **2.2 Market conditions**

An investment in the Company's Shares has the general risks associated with any investment in the share market. Returns from an investment in Shares will depend on general stock market conditions as well as the performance of the Company. The market price of the Company's Shares can fall as well as rise and may be subject to varied and unpredictable influences on the market for equities in general. The trading price of the Company's Shares may be subject to fluctuations in response to factors such as actual or anticipated variations in the Company's operating results, announcements of new contracts by the Company or its competitors, announcements by the Company or its competitors of significant acquisitions, technological

developments, capital commitments, additions or departures of key personnel and other events or factors, many of which are beyond the Company's control.

Further, general share market conditions may affect the value of the Company's quoted securities regardless of the Company's operating performance. Share market conditions are affected by many factors such as: general economic outlook; interest rates and inflation rates; currency fluctuations; changes in investor sentiment; the demand for, and supply of, capital; and terrorism or other hostilities. Neither the Company nor the Directors warrant the future performance of the Company or any return on an investment in the Company.

### **2.3 Liquidity risk**

The market for the Company's Shares may be illiquid. As a consequence, investors may be unable to readily exit or realise their investment.

### **2.4 Force majeure**

The Company's contracts now or in the future may be adversely affected by risks outside the control of the Company including labour unrest, civil disorder, war, subversive activities or sabotage, fires, floods, explosions or other catastrophes, pandemics, epidemics or quarantine restrictions.

### **2.5 Taxation and government regulations**

Changes in taxation and government legislation in a range of areas (for example, the Corporations Act, accounting standards, and taxation law) can have a significant influence on the outlook for companies and the returns to investors. The recoupment of taxation losses accrued by the Company from any future revenues is subject to the satisfaction of tests outlined in taxation legislation or regulations in the jurisdictions in which the Company operates. There is no guarantee that the Company will satisfy all of these requirements at the time it seeks to recoup its tax losses which may impact on the financial performance and cash flows of the Company.

### **2.6 Litigation risk**

The Company is not currently engaged in any litigation. However, the Company is exposed to the risk of actual or threatened litigation or legal disputes in the form of customer claims, intellectual property claims, personal injury claims, employee claims and other litigation and disputes. If any claim was successfully pursued it may adversely impact the financial performance, financial position, cash flow, share price and/or industry standing of the Company.

### **2.7 Insurance risk**

The Company intends to insure its operations in accordance with industry practice. However, in certain circumstances, the Company's insurance may not be of a nature or level to provide adequate insurance cover. The occurrence of an event that is not covered or fully covered by insurance could have a material adverse effect on the business, financial condition and results of the Company.

## **3. Concluding Comment**

The above list of risk factors ought not to be taken as an exhaustive one of the risks faced by Arovella or by investors in the Company. The above factors, and others not specifically referred to above, may in the future materially affect the financial performance of Arovella.

### **Auditor's independence declaration**

A copy of the auditor's independence declaration as required under section 307C of the Corporations Act 2001 is set out on page 6.

**Arovella Therapeutics Limited**  
**Directors' report**  
**31 December 2023**

This report is made in accordance with a resolution of directors, pursuant to section 306(3)(a) of the Corporations Act 2001.

On behalf of the directors



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Thomas Duthy  
Chair

28 February 2024

## AUDITOR'S INDEPENDENCE DECLARATION

As lead auditor for the review of the financial report of Arovella Therapeutics Limited for the half-year ended 31 December 2023, I declare that to the best of my knowledge and belief, there have been no contraventions of:

- a) the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
- b) any applicable code of professional conduct in relation to the review.



Perth, Western Australia  
28 February 2024

**B G McVeigh**  
Partner

**hlb.com.au**

**HLB Mann Judd (WA Partnership) ABN 22 193 232 714**

Level 4, 130 Stirling Street, Perth WA 6000 / PO Box 8124 Perth BC WA 6849

**T:** +61 (0)8 9227 7500 **E:** mailbox@hlbwa.com.au

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HLB Mann Judd (WA Partnership) is a member of HLB International, the global advisory and accounting network.

**Arovella Therapeutics Limited**  
**Statement of profit or loss and other comprehensive income**  
**For the half-year ended 31 December 2023**

	Note	31 December 2023 \$	31 December 2022 \$
<b>Revenue and other income</b>			
Revenue from contracts with customers	4	8,500	379,588
Other income	5	1,935,122	1,048,763
Interest income		86,203	12,015
		<u>2,029,825</u>	<u>1,440,366</u>
<b>Expenses</b>			
Amortisation of intangible assets		-	(640,024)
Depreciation of non-current assets		(22,817)	(85,102)
Employee benefits expenses		(665,482)	(565,732)
Finance costs		(8,631)	(34,275)
License Fee		(245,033)	(94,169)
Manufacturing costs		-	(180,656)
Other expenses		(835,582)	(1,639,641)
Research expenses		(3,659,121)	(1,662,466)
Shared-based payment expenses		(538,929)	(437,463)
Total expenses		<u>(5,975,595)</u>	<u>(5,339,528)</u>
<b>Loss from continuing operations before income tax expense</b>		<u>(3,945,770)</u>	<u>(3,899,162)</u>
Income tax expense		-	-
<b>Loss from continuing operations after income tax expense for the half-year attributable to the owners of Arovella Therapeutics Limited</b>		<u>(3,945,770)</u>	<u>(3,899,162)</u>
Other comprehensive income for the half-year, net of tax		-	-
<b>Total comprehensive income for the half-year attributable to the owners of Arovella Therapeutics Limited</b>		<u><u>(3,945,770)</u></u>	<u><u>(3,899,162)</u></u>
		<b>Cents</b>	<b>Cents</b>
Basic loss per share	3	(0.44)	(0.58)
Diluted loss per share	3	(0.44)	(0.58)

*The above statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes*

**Arovella Therapeutics Limited**  
**Statement of financial position**  
**As at 31 December 2023**

	Note	31 December 2023 \$	30 June 2023 \$
<b>Assets</b>			
<b>Current assets</b>			
Cash and cash equivalents		4,763,425	5,175,338
Trade and other receivables	6	111,449	10,241
Other current assets		302,442	235,516
Total current assets		<u>5,177,316</u>	<u>5,421,095</u>
<b>Non-current assets</b>			
Property, plant and equipment		150,867	49,864
Total non-current assets		<u>150,867</u>	<u>49,864</u>
<b>Total assets</b>		<u>5,328,183</u>	<u>5,470,959</u>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	7	1,973,955	1,225,514
Contract liabilities		144,500	153,000
Provisions		65,851	303,134
Total current liabilities		<u>2,184,306</u>	<u>1,681,648</u>
<b>Non-current liabilities</b>			
Provisions		10,564	9,220
Total non-current liabilities		<u>10,564</u>	<u>9,220</u>
<b>Total liabilities</b>		<u>2,194,870</u>	<u>1,690,868</u>
<b>Net assets</b>		<u>3,133,313</u>	<u>3,780,091</u>
<b>Equity</b>			
Equity securities issued	8	91,778,929	88,871,656
Reserves		2,102,550	1,963,833
Accumulated losses		(90,748,166)	(87,055,398)
<b>Total equity</b>		<u>3,133,313</u>	<u>3,780,091</u>

*The above statement of financial position should be read in conjunction with the notes*



**Arovella Therapeutics Limited**  
**Statement of changes in equity**  
**For the half-year ended 31 December 2023**

	<b>Issue capital</b> \$	<b>Share-based Payment Reserves</b> \$	<b>Accumulated Losses</b> \$	<b>Total</b> \$
<b>Balance at 1 July 2022</b>	83,536,397	1,105,097	(77,024,513)	7,616,981
Loss from continuing operations after income tax expense for the half-year	-	-	(3,899,162)	(3,899,162)
Other comprehensive income for the half-year, net of tax	-	-	-	-
Total comprehensive income for the half-year	-	-	(3,899,162)	(3,899,162)
Share issued during the period	111,289	-	-	111,289
Share issue costs	(12,500)	-	-	(12,500)
Options issued/expensed	-	437,464	-	437,464
Options lapsed during the period	-	(108,452)	108,452	-
Options exercised	4,260	-	-	4,260
<b>Balance at 31 December 2022</b>	<u>83,639,446</u>	<u>1,434,109</u>	<u>(80,815,223)</u>	<u>4,258,332</u>
	<b>Issued capital</b> \$	<b>Share-based Payment Reserves</b> \$	<b>Accumulated Losses</b> \$	<b>Total equity</b> \$
<b>Balance at 1 July 2023</b>	88,871,656	1,963,833	(87,055,398)	3,780,091
Loss from continuing operations after income tax expense for the half-year	-	-	(3,945,770)	(3,945,770)
Other comprehensive income for the half-year, net of tax	-	-	-	-
Total comprehensive income for the half-year	-	-	(3,945,770)	(3,945,770)
Shares issued during the period	2,620,850	-	-	2,620,850
Share issue costs	(47,268)	-	-	(47,268)
Options issued/expensed	-	538,929	-	538,929
Options lapsed during period	-	(253,002)	253,002	-
Options exercised	333,691	(147,210)	-	186,481
<b>Balance at 31 December 2023</b>	<u>91,778,929</u>	<u>2,102,550</u>	<u>(90,748,166)</u>	<u>3,133,313</u>

*The above statement of changes in equity should be read in conjunction with the accompanying notes*

**Arovella Therapeutics Limited**  
**Statement of cash flows**  
**For the half-year ended 31 December 2023**

	Note	31 December 2023 \$	31 December 2022 \$
<b>Cash flows from operating activities</b>			
Receipts from customers		-	207,904
Payments to suppliers and employees		(4,649,280)	(3,861,636)
Receipts from Government grants and tax incentives		1,935,122	1,048,763
Interest received		74,602	12,015
Interest paid		-	(5,924)
Finance cost		-	(28,351)
Net cash used in operating activities		<u>(2,639,556)</u>	<u>(2,627,229)</u>
<b>Cash flows from investing activities</b>			
Payments for property, plant and equipment		(34,649)	-
Payments for other assets		<u>(50,000)</u>	<u>-</u>
Net cash used in investing activities		<u>(84,649)</u>	<u>-</u>
<b>Cash flows from financing activities</b>			
Proceeds from issues of shares and other equity securities	8	2,402,338	103,049
Costs associated with issuance of shares and other securities	8	(112,441)	-
Principal elements of lease payments		<u>-</u>	<u>(35,046)</u>
Net cash from financing activities		<u>2,289,897</u>	<u>68,003</u>
Net decrease in cash and cash equivalents		(434,308)	(2,559,226)
Cash and cash equivalents at the beginning of the financial half-year		5,175,338	6,070,967
Effects of exchange rate changes on cash and cash equivalents		<u>22,395</u>	<u>-</u>
Cash and cash equivalents at the end of the financial half-year		<u><u>4,763,425</u></u>	<u><u>3,511,741</u></u>

*The above statement of cash flows should be read in conjunction with the accompanying notes*

## **1. Summary of accounting policies**

### **(a) Basis of preparation**

These condensed interim financial statements are general purpose financial statements and have been prepared in accordance with the requirements of the *Corporations Act 2001*, Australian Accounting Standards including AASB 134: *Interim Financial Reporting*, Accounting Interpretations and other authoritative pronouncements of the Australian Accounting Standards Board.

The financial statements comprise the condensed interim financial statements for the Company. For the purposes of preparing the financial statements, the Company is a for profit entity.

The interim financial statements do not include full disclosures of the type normally included in the full financial report. Therefore, it cannot be expected to provide as full an understanding of the financial performance, financial position and cash flows of the Company as the full financial report. It is recommended these interim financial statements be read in conjunction with the full financial report for the year ended 30 June 2023 and any public announcements made by Arovella Therapeutics Limited during the half-year in accordance with continuous disclosure requirements arising under the *Corporations Act 2001* and ASX Listing Rules.

The accounting policies and methods of computation adopted are consistent with those of the previous financial year and corresponding half-year, except for the impact of the new Standards and Interpretations described in Note 1(c) below. These accounting policies are consistent with Australian Accounting Standards and with international Financial Reporting Standards.

The interim financial report has been prepared on an historical cost basis. Cost is based on the fair value of the consideration given in exchange for assets.

The company is domiciled in Australia and all amounts are presented in Australian dollars, unless otherwise noted.

For the purpose of preparing the interim financial statements, the half-year has been treated as a discrete reporting period.

### **(b) Statement of compliance**

The interim financial report was authorised for issue on 28 February 2024.

The interim financial report complies with Australian Accounting Standards, which include Australian equivalents to international Financial Reporting Standards (AIFRS). Compliance with AIFRS ensures that the financial report, comprising the interim financial report and notes thereto, complies with International Financial Reporting Standards (IFRS).

### **(c) New or amended Accounting Standards and Interpretations adopted**

The company has adopted all of the new or amended Accounting Standards and Interpretations issued by the Australian Accounting Standards Board ('AASB') that are mandatory for the current reporting period.

The adoption of these standards has not had any impact on the disclosures or amounts reported in these financial statements.

### **(d) New Standards and Interpretations in issue not yet adopted**

The Directors have also reviewed all of the new Standards and Interpretations in issue not yet adopted for the period ended 31 December 2023. As a result of this review, the Directors have determined that there is no material impact of the standards and Interpretations in issue not yet adopted on the Company and, therefore, no change is necessary to Company accounting policies.

### **(e) Going concern**

The financial statements have been prepared on the going concern basis, which contemplates continuity of normal business activities and the realization of assets and settlement of liabilities in the normal course of business. This includes the continued development and commercialization of the Company's current project.

As disclosed in the financial statements, the Company incurred an operating loss of \$3,945,770 and a net cash outflow from operating activities amount to \$2,639,556 for the period ended 31 December 2023. As at 31 December 2023, the company held cash and cash equivalents of \$4,763,425. The Directors are of the opinion that the Company is a going concern for the following reasons:

- The Directors anticipate that an equity raising will be completed in FY24,
- Based on prior experience, the Directors are confident that they can raise additional capital if and when required.

## **1. Summary of accounting policies (continued)**

If the raising of additional capital cannot be completed, there is a material uncertainty that may cast significant doubt as to whether the Company will continue as a going concern and whether it will be able to realize its assets and extinguish its liabilities in the normal course of business. Despite these uncertainties, the Directors are of the view that the Company will be successful in the above matter and accordingly have adopted the going concern basis of the preparation of the financial report.

### **(f) Significant accounting estimates and judgements**

The preparation of the interim financial statements requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates.

The judgements, estimates and assumptions applied in the interim financial statements, including the key sources of estimation uncertainty were the same as those applied in the Company's last annual financial statements for the year ended 30 June 2023.

## **2. Segment information**

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. The chief operating decision maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Managing Director of Arovella. The Company has identified one reportable segment, that was development of 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.

## **3. Loss per share**

### **(a) Basic and diluted loss per share**

	<b>31 December 2023</b>	<b>31 December 2022</b>
	<b>\$</b>	<b>\$</b>
Loss from continuing operations after income tax attributable to the owners of Arovella Therapeutics Limited	<u>(3,945,770)</u>	<u>(3,899,162)</u>
	<b>Number</b>	<b>Number</b>
Weighted average number of ordinary shares used in calculating basic loss per share	<u>900,514,667</u>	<u>670,784,589</u>
Weighted average number of ordinary shares used in calculating diluted loss per share	<u>900,514,667</u>	<u>670,784,589</u>
	<b>Cents</b>	<b>Cents</b>
Basic loss per share	(0.44)	(0.58)
Diluted loss per share	(0.44)	(0.58)

## **4. Revenue from contracts with customers**

The Company derives its revenue from the sale or license of goods and the provision of services at a point in time and over time in the timing of transfer of goods or services (for example, revenue from goods or services transferred to customers at a point in time and revenue from goods and services transferred over time).

**4. Revenue from contracts with customers (continued)**

	31 December 2023 \$	31 December 2022 \$
Sale or license of goods - At a point in time	-	207,904
Co-development revenue - Over time	8,500	171,684
Total revenue from contracts with customers	<u>8,500</u>	<u>379,588</u>

**5. Other income**

	31 December 2023 \$	31 December 2022 \$
R&D tax incentive income	<u>1,935,122</u>	<u>1,048,763</u>

In the half-year ended 31 December 2023, the Company recognized an R&D tax incentive income of \$1,935,122 related to the year ended 30 June 2023.

**6. Trade and other receivables**

	31 December 2023 \$	30 June 2023 \$
<i>Trade Receivables</i>		
Trade receivables	10,241	10,241
Less: Allowance for expected credit losses	(10,241)	-
	<u>-</u>	<u>10,241</u>
Other Receivables	<u>111,449</u>	<u>-</u>
	<u>111,449</u>	<u>10,241</u>

**7. Trade and other payables**

	31 December 2023 \$	30 June 2023 \$
<i>Current liabilities</i>		
Account Payable	1,611,117	772,971
Sundry payables and accrued expenses	362,838	452,543
	<u>1,973,955</u>	<u>1,225,514</u>

**8. Equity securities issued**

	31 December 2023 Shares	30 June 2023 Shares	31 December 2023 \$	30 June 2023 \$
Issued Capital - Ordinary shares	<u>909,628,062</u>	<u>849,908,680</u>	<u>91,778,929</u>	<u>88,871,656</u>

## 8. Equity securities issued (continued)

### *Movements in ordinary share capital*

	31 December 2023 Shares	30 June 2023 Shares	31 December 2023 \$	30 June 2023 \$
Balance brought forward as at 1 July	849,908,680	669,835,226	88,871,656	83,536,397
Issue of shares from placements/services provided	56,099,163	179,073,454	2,620,850	5,915,937
Issue of shares from exercise of options	3,620,219	1,000,000	333,691	25,000
Transaction costs relating to placements	-	-	(47,268)	(605,678)
	<u>909,628,062</u>	<u>849,908,680</u>	<u>91,778,929</u>	<u>88,871,656</u>

### *Movements in options on issue*

	31 December 2023 Options	30 June 2023 Options
Balance brought forward as at 1 July	84,173,380	98,376,136
Exercise of options	(8,248,385)	(1,085,204)
Expiration of options	(3,000,000)	(53,532,498)
Issuance of options	16,928,058	40,419,946
	<u>89,853,053</u>	<u>84,178,380</u>

### *Fair value of options granted*

The assessed fair value of options at grant date was determined using the Black-Scholes option pricing model that takes into account the exercise price, term of the option, security price at grant date and expected price volatility of the underlying security, the expected dividend yield, the risk-free interest rate for the term of the security and certain probability assumptions.

The model inputs for options granted during the half-year 31 December 2023 included:

Grant date	Expiry date	Exercise price	Number of options	Share price at grant date	Expected volatility	Dividend yield	Risk-free interest rate	Fair value at grant date
		\$		\$	%	%	%	\$
01/07/2023	01/07/2026	\$0.0740	6,054,788	\$0.0500	86.62%	-	4.03%	\$0.0240
23/08/2023	23/08/2028	\$0.0400	3,043,478	\$0.0320	100.00%	-	3.40%	\$0.0358
23/08/2023	23/08/2027	\$0.0320	3,478,261	\$0.0320	100.00%	-	3.40%	\$0.0317
10/11/2023	30/06/2027	\$0.0750	2,178,531	\$0.0980	86.62%	-	4.31%	\$0.0681
10/11/2023	10/11/2028	\$0.1267	2,173,000	\$0.0980	86.62%	-	4.31%	\$0.0650

## 9. Fair value measurement

The Directors consider that the carrying amount of financial assets and financial liabilities, as recorded in the financial statements, represent or approximate their respective fair values. The Group's financial assets and liabilities are measured at amortised cost. Therefore, the disclosures required by AASB13: Fair Value Measurement, of the fair value measurement hierarchy have not been made.



## **10. Dividends**

The Board of Directors of Arovella Therapeutics Ltd does not recommend the payment of an interim dividend for the period ended 31 December 2023.

## **11. Related party transactions**

A total of 6,521,739 options were issued to Directors as approved by Shareholders at the EGM.

A total of 4,351,531 options were issued to Directors as approved by Shareholders at the AGM.

There are no other related party transactions other than those related to Director and key management personnel remuneration and transactions by the Company.

## **12. Contingent liabilities**

In the ordinary course of business, the Group may be exposed to contingent liabilities related to litigation for breach of contract and other claims. Contingent liabilities occur when the possibility of a future settlement of economic benefits is considered to be less than probable but more likely than remote. If the expected settlement of the liability becomes probable, a provision is recognised. Individually significant matters, including narrative on potential future exposures incapable of reliable measurement, are disclosed below, to the extent that disclosure does not prejudice the Group.

### *Disputes*

As previously disclosed to the market, the Company has shifted its operational focus away from OroMist activities in order to concentrate entirely on the development of its iNKT cell therapy platform, and has been in the process of reviewing its contractual arrangements relating to its ZolpiMist product. Relatedly, the Company and the counterparty to a license and supply agreement for the ZolpiMist product, have been in discussions regarding termination of the agreement. As part of these discussions, allegations of breach under the agreement have been made by both parties. The Company disputes any allegations that it has breached the agreement, and/or any entitlement of the counterparty to damages for breach alleged against it. No proceedings have been commenced by either party to the agreement, and the parties are continuing commercial negotiations. The outcome of these discussions is, by its nature, uncertain, and it is not currently possible for the Company to provide a reliable estimate or timing of any liability or contingent liability that may arise.

## **13. Events after the reporting period**

On 4 January 2024, 2,873,128 options were exercised with exercise prices of \$0.074 and \$0.041.

On 10 January 2024, 413,379 Ordinary Shares were issued for the provision of services in lieu of cash.

On 10 January 2024, 4,125,000 options were exercised. 4,000,000 options were exercised at \$0.025 and 125,000 options exercised at \$0.057.

On 16 January 2024, 1,183,334 options were exercised at \$0.0675.

On 17 January 2024, 125,000 options were exercised at \$0.0675.

On 30 January 2024 entered into a global, exclusive license with University of North Carolina Lineberger Comprehensive Cancer Center to incorporate a novel armoured cytokine technology (IL-12-TM) for its CAR-iNKT cell platform. The license has no immediate material financial impact on the Company as a result of signing the agreement. There is no upfront fee payable for the license, and future licensing fees will include annual license maintenance fees, stage-gated, industry-standard development milestones for the first patient dosed in a pivotal clinical trial and marketing approval. The Licence also includes a low single-digit royalty on future sales.

On 31 January 2024, 75,000 options were exercised at \$0.057.

On 14 February 2024, the company issued 2,000,000 options with an exercise price of \$0.1807 and an expiry of 14 February 2026, for the provision of corporate advisory services in lieu of cash.

**13. Events after the reporting period (continued)**

On 20 February 2024, 5,481,482 options were exercised. 2,000,000 options were exercised at \$0.075, 2,000,000 options were exercised at \$0.030 and 1,481,482 were exercised at \$0.0675.

No other matter or circumstance has arisen since 31 December 2023 that has significantly affected, or may significantly affect the company's operations, the results of those operations, or the company's state of affairs in future financial years.

**Arovella Therapeutics Limited**  
**Directors' declaration**  
**31 December 2023**

In the directors' opinion:

- the attached financial statements and notes comply with the Corporations Act 2001, Australian Accounting Standard AASB 134 'Interim Financial Reporting', the Corporations Regulations 2001 and other mandatory professional reporting requirements;
- the attached financial statements and notes give a true and fair view of the company's financial position as at 31 December 2023 and of its performance for the financial half-year ended on that date; and
- there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of directors made pursuant to section 303(5)(a) of the Corporations Act 2001.

On behalf of the directors



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Thomas Duthy  
Chair

28 February 2024

**INDEPENDENT AUDITOR'S REVIEW REPORT**

To the Members of Arovella Therapeutics Limited

**Report on the Condensed Half-Year Financial Report***Conclusion*

We have reviewed the half-year financial report of Arovella Therapeutics Limited ("the Company"), which comprises the condensed statement of financial position as at 31 December 2023, the condensed statement of profit or loss and other comprehensive income, the condensed statement of changes in equity and the condensed statement of cash flows for the half-year ended on that date, selected explanatory notes, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of Arovella Therapeutics Limited does not comply with the *Corporations Act 2001* including:

- (a) giving a true and fair view of the Company's financial position as at 31 December 2023 and of its performance for the half-year ended on that date; and
- (b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

*Basis for Conclusion*

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*. Our responsibilities are further described in the *Auditor's Responsibilities for the Review of the Financial Report* section of our report. We are independent of the company in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

*Material Uncertainty Related to Going Concern*

We draw attention to Note 1(e) in the financial report, which indicates that a material uncertainty exists that may cast significant doubt on the Company's ability to continue as a going concern. Our conclusion is not modified in respect of this matter.

*Responsibility of the Directors for the Financial Report*

The directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

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**HLB Mann Judd (WA Partnership) ABN 22 193 232 714**

Level 4, 130 Stirling Street, Perth WA 6000 / PO Box 8124 Perth BC WA 6849

**T:** +61 (0)8 9227 7500 **E:** mailbox@hlbwa.com.au

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*Auditor's Responsibility for the Review of the Financial Report*

Our responsibility is to express a conclusion on the half-year financial report based on our review. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Company's financial position as at 31 December 2023 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

*Independence*

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001*.

*HLB Mann Judd*  
**HLB Mann Judd**  
**Chartered Accountants**

**Perth, Western Australia**  
**28 February 2024**

*B G McVeigh*  
**B G McVeigh**  
**Partner**