



# Appendix 4D

## Half Year Report Ended

### 31 December 2021

Arovella Therapeutics Limited  
ABN 35 090 987 250

# Arovella Therapeutics Limited

(Formerly known as Suda Pharmaceuticals Limited)

## Appendix 4D

### Half-year Ended 31 December 2021

Name of entity:	Arovella Therapeutics Limited
ABN:	35 090 987 250
Half-year ended:	31 December 2021
Previous period:	31 December 2020

#### Results for announcement to the market

				\$
Revenue from ordinary activities	Down	(90.7)%	to	22,591
Loss from ordinary activities after tax	Up	126.1%	to	(3,949,987)
Net loss for the period attributable to members	Up	126.1%	to	(3,949,987)

#### Net tangible assets per security

	31 December 2021 Cents	31 December 2020 Cents
Net tangible asset backing (per share)	0.41	1.19

#### Explanation of results

An explanation of the key financial elements contributing to the revenue and result above can be found in the review of operations included within the Directors' report.

#### Distributions

No dividends have been paid or declared by the Company for the current financial period. No dividends were paid for the previous financial period.

#### Changes in controlled entities

There have been no changes in controlled entities during the half-year ended 31 December 2021.

#### Other information required by Listing Rule 4.2A

N/A



**(Formerly known as Suda Pharmaceuticals Limited)**

ABN 35 090 987 250

**Interim financial report  
for the half-year ended 31 December  
2021**

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**Arovella Therapeutics Limited**  
**(Formerly know as Suda Pharmaceuticals Limited)**  
**Corporate Directory**

**Directors**

Mr. Paul Hopper  
*Non-Executive Chairman*

Mr. David Simmonds  
*Non-Executive Director*

Mr. David Phillips (resigned 14 January 2022)  
*Executive Director*

Dr. Michael Baker  
*CEO and Managing Director*

Dr. Debora Barton (appointed 10 August 2021)  
*Non-Executive Director*

Dr. Elizabeth Stoner (appointed 10 November 2021)  
*Non-Executive Director*

**Secretary**

Mr. Phillip Hains

**Principal registered office in Australia**

Level 3  
62 Lygon Street  
Carlton VIC 3053  
Australia  
03 9824 5254

**Share and debenture register**

Advanced Share Registry Ltd  
110 Stirling Highway  
Nedlands WA 6009  
+61 8 9389 8033

**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  
Exchange Plaza  
2 The Esplanade  
Perth, WA 6000

Listing code:  
Ordinary Shares ALA  
Listed Options ALAOE

**Website**

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

The Directors present their report on Arovella Therapeutics Limited (thereafter referred to "Arovella" or "the Company") for the half-year ended 31 December 2021.

The Directors were in office for the entire period and up to the date of this report.

## **Directors**

Mr. Paul Hopper - Non-Executive Chairman  
Dr. Michael Baker - CEO and Managing Director  
Dr. Debora Barton - Non-Executive Director (Appointed 10 August 2021)  
Dr. Elizabeth Stoner - Non-Executive Director (Appointed 10 November 2021)  
Mr. David Simmonds - Non-Executive Director  
Mr. David Phillips - Executive Director (resigned 14 January 2022)

## **Review and results of operations**

The loss from ordinary activities for the half-year ended 31 December 2021 was \$3,949,987, an increase of 126.1% compared to last year (31 December 2020: \$1,747,374).

Cash at bank as at 31 December 2021 is \$4,385,926 (30 June 2021: \$6,717,198) and the Company finalised successful capital raises post half-year ended 31 December 2021 of \$4,568,748 from sophisticated and new investors, including well known life sciences investor, Merchant. The funds raised will be used to support ongoing development of the iNKT cell therapy technologies and working capital. The funds will also be used to support potential acquisitions of new technologies in the fields of oncology.

The notable events during the half-year ended 31 December 2021 were:

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

On 13 December 2021, the Company announced that it signed a global, exclusive licence agreement with The University of Texas MD Anderson Cancer Center for the patent rights to a novel monoclonal antibody (mAb) developed for cancer treatment. This is the first mAb directed against a DKK1 peptide (DKK1) found linked by the HLA-A2 protein to the surface of cancer cells. The target is found in many cancer types, including blood cancers and solid tumours and 40-50% of the population is HLA-A2 positive, meaning that this technology may be applicable across a wide spectrum of cancers that affect a significant proportion of the population. Higher levels of DKK1 in cancer patients may serve as a prognostic biomarker for cancers such as Multiple Myeloma, Head and Neck Squamous Cell Carcinoma (HNSCC), Pancreatic Adenocarcinoma (PAAD), and Lung Squamous Cell Carcinoma (LUSC). Higher DKK1 production has been observed in bladder cancer and increased production of DKK1 may assist Non-small Cell Lung Carcinoma (NSCLC) cell invasion and migration. It has also been suggested that increased DKK1 levels may cause resistance to chemotherapy in cancers such as ovarian cancer.

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

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

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

## **Review and results of operations (continued)**

### *Arovella entered into a Collaborative Research Agreement (CRA) with Imperial College London*

On 16 August 2021, Arovella entered into a Collaborative Research Agreement (CRA) with Imperial College London and the laboratory of Professor Karadimitris. Under the CRA, Arovella will fund ongoing research in the laboratory of Professor Karadimitris, which will focus on creating additional intellectual property for its iNKT cell therapy platform. The initial focus of the platform is for the treatment of blood cancers and the research will enable Arovella to optimise the therapy and to expand into additional cancers of unmet need, creating additional intellectual property for the platform. The research agreement is for a period of two years and is extendable by mutual agreement from each party.

### *Arovella enhanced its management team for its iNKT cell therapy platform*

On 2 August 2021, Arovella appointed Dr. Sandhya Buchanan as its VP of Manufacturing and Quality for its newly acquired iNKT cell therapy platform. Dr. Buchanan joined Arovella from Atara Biotherapeutics, a biotechnology company pioneering off-the-shelf cell therapies for treating cancer and autoimmune disease. During her time at Atara Biotherapeutics, Dr. Buchanan served as the chemistry manufacturing and control technical lead for autologous CAR-T programs and head of Viral Vector Development; managing both internal and external collaborations. Prior to Atara Biotherapeutics, Dr. Buchanan held senior roles at Torque Therapeutics (now Repertoire Immune Medicines), FujiFilm Diosynth Biotechnologies, Penn Medicine, a world-renowned academic medical centre in Philadelphia, and Novartis. Dr. Buchanan has more than 20 years' experience working in cell & gene therapy and vaccine development.

On 25 January 2022, Arovella appointed Dr. Mini Bharathan as its VP of Development and Translational Medicine. Dr. Bharathan joins Arovella from Cellectis, a biotechnology company that is using its pioneering gene editing platform to develop allogenic cell therapies. During her time at Cellectis, Dr. Bharathan served as the Director of Translational Medicine and Clinical Development where she coordinated the development programs for key products, recommended patient stratification and biomarker strategies and oversaw the development and validation of novel clinical stage assay methodologies, patient selection markers and biomarkers for multiple global allogenic CAR-T clinical trials. Dr. Bharathan also held senior roles at Celgene, Celularity and Immatics, all focused on the development of cell therapies. Dr. Bharathan has more than 15 years' experience in the field of immunology with more than 12 years focused on the development of cell therapies.

### *Arovella strengthened its Board of Directors*

On 10 August 2021, Arovella appointed Dr. Debora Barton, M.D., as an independent Non-Executive Director. Dr. Barton has over 20 years' experience in the field of oncology. After practicing oncology as a physician and clinical trial investigator, she spent five years at Novartis and five years at Celgene in roles of increasing responsibilities in Medical Affairs and Clinical Development. Dr. Barton has extensive experience working with cell therapy products, formerly as the Senior Vice President, Clinical and Head of Safety, of the clinical stage company, Iovance, who are developing T cell therapies for cancer treatment. Dr. Barton is currently the Chief Medical Officer of Carisma Therapeutics, a clinical stage biopharmaceutical company, developing innovative immunotherapies including the first in class chimeric antigen receptor (CAR) macrophages for the treatment of certain cancers. Dr. Barton is a member of the Manhattan Board of Directors for the American Cancer Society and is also a member of the Medical Advisory Board of the Tigerlily Foundation, a national breast cancer foundation providing education, awareness, advocacy and hands-on support to young women before, during and after breast cancer.

On 10 November 2021, the Company appointed Dr. Elizabeth Stoner, M.S. M.D., as an independent Non-Executive Director. Dr. Stoner, based in Boston, has over 30 years' experience in the life-sciences sector, spanning early-stage research, drug development and venture investing. She is currently Executive Partner at MPM Capital, a leading US healthcare investment firm, with over two decades of experience founding and investing in life-sciences companies that seek to translate scientific innovations into cures for major diseases. Dr. Stoner served as the interim CEO of the cell therapy biotechnology company, Semma Therapeutics, which was acquired by Vertex in 2019 for US\$950 million. Dr. Stoner received her M.D. from the Albert Einstein College of Medicine and prior to joining the biopharma industry, she was an Assistant Professor of Paediatrics at Cornell University Medical College.

## **Review and results of operations (continued)**

### *Arovella assembled a world class Scientific Advisory Board for its iNKT cell therapy platform*

Professor Tassos Karadimitris was appointed as the Chair of Arovella's Scientific Advisory Board for its iNKT cell therapy platform. Professor Karadimitris' research group was the first to demonstrate that iNKT cells are protective against graft versus host disease (GVHD). The iNKT cell platform has a critical advantage, that it may be used "off-the-shelf", meaning that the cells can be isolated from a healthy donor, modified to enhance their activity against cancer and stored frozen, ready to be administered to cancer patients as needed. Two world renowned experts joined Arovella's Scientific Advisory Board, Dr. Reuben Benjamin and Dr. John Maher. Dr. Benjamin is an internationally recognised expert in the field of cellular immunotherapies for the treatment of blood cancer. Dr. Benjamin was the Chief Investigator of the CALM clinical trial, the first allogeneic (off-the-shelf) CAR-T cell study for relapsed adult B-cell acute lymphoblastic leukemia (B-ALL). Dr. Maher is an internationally recognised clinical immunologist, focused on the development of CAR-T cell therapies. Dr. Maher played a key role in the early development of second-generation CAR technology while a visiting fellow at Memorial Sloan Kettering Cancer Center in the US. Dr. Maher is the scientific founder and Chief Scientific Officer of Leucid Bio, a clinical stage cell therapy company with a pipeline of novel CAR-T cell therapies developed using its proprietary engine.

### *Arovella completed its name change and rebranding*

The company completed its name change and rebranding to introduce Arovella Therapeutics Limited. On 14 October 2021, shareholders voted to approve the resolution to change the name of the Company to Arovella Therapeutics Limited. On 25 October 2021, the Company began trading under the new ticker ALA. The name change reflects the acquisition of the Company's iNKT cell therapy platform for cancer treatment and the strategic direction of working with new therapeutic platforms to impact human health positively. The new name better reflects that the Company has broadened its strategy to include multiple therapeutic platforms. The Company focuses on specific disease areas, oncology and conditions that affect the central nervous system. Arovella is a combination of two essential words in the arena of Drug discovery; arrow, which references the targeting of specific diseases and novella, which has the meaning of "new" in Italian (the feminine version of novello). The combined name, Arovella Therapeutics, encompasses the Company's strategic goal to target specific disease areas using novel platforms.

### *Commercial milestones achieved for ZolpiMist*

On 24 August 2021, Arovella entered into an exclusive License and Distribution Agreement for ZolpiMist® in Australia with STADA Pharmaceuticals Australia Pty Ltd, a member of the global, German-based STADA Group. Arovella will submit a further application to the Therapeutics Goods Administration (TGA) for a modification to the current spray unit, incorporating in the application a more economical, elegant, and user-friendly Child Resistant Lock (CRL). It is anticipated that the new CRL will be implemented from the second batch of product produced for STADA onward.

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

## **Significant changes in the state of affairs**

There were no significant changes in the state of the affairs of the Company during the period.

## **Events since the end of the reporting period**

On 1 February 2022, the Company issued 120,230,220 new ordinary shares at \$0.038 per share to new and existing institutional and sophisticated investors, including well known cornerstone participation by specialist life sciences investor, Merchant, to fund ongoing development of the iNKT cell therapy technologies and working capital. The funds will also be used to support potential acquisitions of new technologies in the fields of oncology.

Furthermore, the Company launched a Share Purchase Plan ("SPP") to raise up to \$2 million for eligible existing shareholders on 24 January 2022 and the expected closing date of SPP is on 9 March 2022.

Subject to shareholder approval in the upcoming General Meeting, the Company granted 4,854,999 unlisted options with an exercise price of \$0.057 each option expiring 31 January 2025 to an external consulting firm, Baker Young for professional service rendered. In addition, the Directors intend to participate up to 4,210,526 new ordinary shares at \$0.038 per share amounting to \$160,000 before costs.



**Auditor's independence declaration**

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

This report is signed in accordance with a resolution of Directors made pursuant to s.306(3) of the *Corporations Act 2001*.



Mr. Paul Hopper  
Non-Executive Chairman

Sydney  
28 February 2022

## AUDITOR'S INDEPENDENCE DECLARATION

As lead auditor for the review of the consolidated financial report of Arovella Therapeutics Limited for the half-year ended 31 December 2021, 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 2022



**L Di Giallonardo**  
Partner

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**Arovella Therapeutics Limited**  
**(Formerly known as Suda Pharmaceuticals Limited)**  
**Condensed statement of profit or loss and other comprehensive income**  
**For the half-year ended 31 December 2021**

	Notes	31 December 2021 \$	31 December 2020 \$
Revenue from contracts with customers	2	22,591	242,541
Other income	3	-	222,198
Interest income		1,584	3,528
Manufacturing costs		(106,594)	(116,375)
Employee benefits expenses		(630,420)	(649,712)
Depreciation of non-current assets		(103,468)	(95,638)
Amortisation of intangible assets		(177,817)	(219,707)
Finance costs		(183,152)	(25,401)
Licence fee		(482,752)	(21,710)
Research costs		(722,256)	(229,779)
Share-based payment expense		(250,364)	(15,111)
Other		(1,317,339)	(842,208)
<b>Loss before income tax</b>		<b>(3,949,987)</b>	<b>(1,747,374)</b>
<b>Income tax benefit</b>		<b>-</b>	<b>-</b>
<b>Loss after tax from continuing operations</b>		<b>(3,949,987)</b>	<b>(1,747,374)</b>
<b>Net loss for the period</b>		<b>(3,949,987)</b>	<b>(1,747,374)</b>
<b>Other comprehensive income</b>		<b>-</b>	<b>-</b>
<b>Total comprehensive loss for the period</b>		<b>(3,949,987)</b>	<b>(1,747,374)</b>
		<b>Cents</b>	<b>Cents</b>
<b>Loss per share for loss from continuing operations attributable to the ordinary equity holders of the Company:</b>			
Basic loss per share	5(a)	(0.82)	(0.63)
Diluted loss per share	5(a)	(0.82)	(0.63)

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

**Arovella Therapeutics Limited**  
**(Formerly known as Suda Pharmaceuticals Limited)**  
**Condensed statement of financial position**  
**As at 31 December 2021**

	Notes	31 December 2021 \$	30 June 2021 \$
<b>ASSETS</b>			
<b>Current assets</b>			
Cash and cash equivalents		4,385,926	6,717,198
Trade and other receivables	7(a)	22,452	533,637
Other current assets		361,799	92,309
<b>Total current assets</b>		<b>4,770,177</b>	<b>7,343,144</b>
<b>Non-current assets</b>			
Property, plant and equipment		325,683	380,903
Right-of-use assets		135,532	52,037
Intangible assets	8	3,189,361	2,911,206
<b>Total non-current assets</b>		<b>3,650,576</b>	<b>3,344,146</b>
<b>Total assets</b>		<b>8,420,753</b>	<b>10,687,290</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Trade and other payables	7(b)	2,335,370	1,226,899
Contract liabilities		470,000	200,000
Borrowings		1,918	5,721
Provisions		113,400	191,565
Lease liabilities		61,075	70,772
<b>Total current liabilities</b>		<b>2,981,763</b>	<b>1,694,957</b>
<b>Non-current liabilities</b>			
Borrowings		-	2,742
Provisions		6,692	7,908
Lease liabilities		111,794	-
<b>Total non-current liabilities</b>		<b>118,486</b>	<b>10,650</b>
<b>Total liabilities</b>		<b>3,100,249</b>	<b>1,705,607</b>
<b>Net assets</b>		<b>5,320,504</b>	<b>8,981,683</b>
<b>EQUITY</b>			
Issued capital	9(a)	77,041,791	77,003,347
Reserves		701,050	450,686
Accumulated losses		(72,422,337)	(68,472,350)
<b>Total equity</b>		<b>5,320,504</b>	<b>8,981,683</b>

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

**Arovella Therapeutics Limited**  
**(Formerly known as Suda Pharmaceuticals Limited)**  
**Condensed statement of changes in equity**  
**For the half-year ended 31 December 2021**

	Notes	Attributable to owners of Arovella Therapeutics Limited				Total \$
		Issue Capital \$	Accumulated Losses \$	Share-based Payment Reserve \$	Minority Interest Acquisition (i) \$	
<b>Balance at 1 July 2020</b>		67,385,981	(64,880,540)	225,712	1,404,267	4,135,420
Loss for the period		-	(1,747,374)	-	-	(1,747,374)
<b>Total comprehensive loss for the period</b>		-	<b>(1,747,374)</b>	-	-	<b>(1,747,374)</b>
<b>Transactions with owners in their capacity as owners:</b>						
Shares issued during the period		6,886,648	-	-	-	6,886,648
Share issue costs		(572,360)	-	-	-	(572,360)
Equity settled share-based payments		-	-	143,407	-	143,407
Options lapsed during the period		-	51,388	(51,388)	-	-
		6,314,288	51,388	92,019	-	6,457,695
<b>Balance at 31 December 2020</b>		<b>73,700,269</b>	<b>(66,576,526)</b>	<b>317,731</b>	<b>1,404,267</b>	<b>8,845,741</b>
<b>Balance as at 1 July 2021</b>		<b>77,003,347</b>	<b>(68,472,350)</b>	<b>450,686</b>	<b>-</b>	<b>8,981,683</b>
Loss for the period		-	(3,949,987)	-	-	(3,949,987)
Other comprehensive income		-	-	-	-	-
<b>Total comprehensive loss for the period</b>		-	<b>(3,949,987)</b>	-	-	<b>(3,949,987)</b>
Shares issued during the period	9(a)	5,044	-	-	-	5,044
Share issue costs (ii)	9(a)	33,400	-	-	-	33,400
Equity settled share-based payments		-	-	250,364	-	250,364
<b>Balance at 31 December 2021</b>		<b>77,041,791</b>	<b>(72,422,337)</b>	<b>701,050</b>	<b>-</b>	<b>5,320,504</b>

(i) Minority Interest Acquisition reserve was reclassified to Accumulated Losses as at 30 June 2021.

(ii) The positive share issue costs at half-year end is due to an over accrual of capital raising costs during the year ended 30 June 2021.

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

**Arovella Therapeutics Limited**  
**(Formerly known as Suda Pharmaceuticals Limited)**  
**Condensed statement of cash flows**  
**For the half-year ended 31 December 2021**

	<b>31 December 2021</b>	31 December 2020
	\$	\$
<b>Cash flows from operating activities</b>		
Receipts from customers	279,734	247,882
Payments to suppliers and employees	(3,062,125)	(3,001,161)
Receipts from Government grants and tax incentives	524,042	888,610
Interest received	1,584	3,528
Interest paid	(3,823)	(8,715)
<b>Net cash (outflow) from operating activities</b>	<u>(2,260,588)</u>	<u>(1,869,856)</u>
<b>Cash flows from investing activities</b>		
Payments for development of products	-	(176,746)
Payments for property, plant and equipment	(32,381)	(65,076)
<b>Net cash (outflow) from investing activities</b>	<u>(32,381)</u>	<u>(241,822)</u>
<b>Cash flows from financing activities</b>		
Proceeds from issues of shares and other equity securities	5,044	6,851,337
Share issue costs	-	(197,511)
Principal elements of lease payments	(42,740)	(31,246)
<b>Net cash (outflow)/inflow from financing activities</b>	<u>(37,696)</u>	<u>6,622,580</u>
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>(2,330,665)</b>	4,510,902
Cash and cash equivalents at the beginning of the financial year	6,717,198	977,472
Effects of exchange rate changes on cash and cash equivalents	(607)	(19,237)
<b>Cash and cash equivalents at end of the period</b>	<u><b>4,385,926</b></u>	<u>5,469,137</u>

*The above condensed 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 2021 and any public announcements made by Suda Pharmaceuticals Ltd and its subsidiaries during the half-year in accordance with continuous disclosure requirements arising under the *Corporations Act 2001* and the 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 2022.

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 and amended standards adopted by the Company**

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 2021. 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 realisation of assets and settlement of liabilities in the normal course of business. This includes the continued development and commercialisation of the Company's current projects.

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

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

As disclosed in the financial statements, the Company incurred an operating loss of \$3,949,987 and a net cash outflow from operating activities amounting to \$2,260,588 for the period ended 31 December 2021. As at 31 December 2021, the Company held cash and cash equivalents of \$4,385,926. The Directors are of the opinion that the Company is a going concern for the following reasons:

- On 1 February 2022, the Company issued 120,230,220 new ordinary shares at \$0.038 per share to new and existing institutional and sophisticated investors, including well known cornerstone participation by specialist life sciences investor, Merchant, to fund ongoing development of the iNKT cell therapy technologies and working capital. The funds will also be used to support potential acquisitions of new technologies in the fields of oncology.
- Furthermore, the Company launched a Share Purchase Plan ("SPP") to raise up to \$2 million for eligible existing shareholders on 24 January 2022 and the expected closing date of SPP is on 9 March 2022.
- In addition, the Directors intend to participate in up to 4,210,526 of new ordinary shares at \$0.038 per share amounting to \$160,000 before costs.
- The Directors anticipate that a further equity raising will be required and will be completed in FY2023.
- Based on prior experience, the Directors are confident that they can raise additional capital if and when required.

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 realise 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.

COVID-19 has led to widespread restrictions on both national and international travel. To date, the Company's supply chain has not been affected. Nevertheless, the risk that COVID-19 poses in terms of overwhelming health care systems must be taken into account when factoring in programs that are at the clinical stage.

As a result of the COVID-19 outbreak, or similar pandemics, the Company may experience disruptions that could severely impact the business in the following ways:

- delays or disruptions in supply chain for materials required for research and/or clinical trials;
- delays in the completion of research due to infection of key research personnel;
- delays enrolling patients into clinical trials;
- interruption or delays in the operations of regulatory bodies, including the U.S. Food and Drug Administration or Therapeutics Goods Administration, which may impact approval timelines;
- reduced ability to engage with the medical, pharmaceutical industry and investor communities due to the cancellation of conferences and travel bans, which may impact the ability to attract collaborators, potential industry partners and investors.

### **(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 expense. 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 2021.



## 2 Revenue from contracts with customers

The Company derives its revenue from the sale or licence of goods and the provision of services at a point in time and over time in the timing of transfer of goods or service (for example, revenue from goods or services transferred to customers at a point in time and revenue from goods or services transferred over time). This is consistent with the revenue information that is disclosed for each reportable segment under AASB 8 (see note 4).

	<b>31 December 2021</b>	31 December 2020
	\$	\$
<b>At a point in time</b>		
Sale or license of goods	<b>22,591</b>	109,539
<b>Over time</b>		
Co-development revenue	-	133,002
	<hr/>	<hr/>
Total revenue	<b>22,591</b>	242,541

## 3 Other income

	<b>31 December 2021</b>	31 December 2020
	\$	\$
Export manufactures development grant (i)	-	100,000
COVID-19 assistance (ii)	-	113,100
R&D tax incentive income (iii)	-	9,098
	<hr/>	<hr/>
	-	222,198

(i) The Company recognised \$100,000 Export Market Development Grant (EMDG) in the half-year ended 31 December 2020. This is a key Australian Government financial assistance program for aspiring current exporters.

(ii) No COVID-19 assistance was obtained in the half-year ended 31 December 2021. COVID-19 assistance received in the half-year ended 31 December 2020 consisted of Jobkeeper payment of \$75,600 and "Cashflow boost for employers" of \$37,500 received as part of the COVID-19 relief announced by the Australian Government.

(iii) In the half-year ended 31 December 2020, the Company recognised an R&D tax incentive income of \$9,098 due to an under accrual on R&D tax incentive income for the year ended 30 June 2020.

## 4 Segment information

### (a) Accounting policy

#### *Accounting policy*

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 Board of Directors of Arovella.

In 2020, the Company has identified two segments, which are Suda and MRC. MRC had a segment net operating loss after tax of \$5,704,410 that mainly made up of impairment expense of \$5,669,088, nil segment asset and \$254 segment liabilities. The rest of the segment net operating losses; segment assets and segment liabilities were from Arovella standalone.

As of 30 June 2021, the Company has filed company deregistration for Malaria Research Company Pty Ltd, Eastland CN Nominees Pty Ltd and SUD 18 Pty Ltd. Therefore, these entities had been accounted for as discontinued operations in the year ended 30 June 2021 and Malaria Research Company Pty Ltd is no longer presented in the segment note. The Company has identified one reportable segment as a whole. The principal activity of the segment during the year was pharmaceutical development and to acquire new platforms that align with the Company's two focus areas, oncology and conditions that affect the central nervous system.

## 5 Loss per share

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

	31 December 2021 Cents per share	31 December 2020 Cents per share
Basic loss per share	(0.82)	(0.63)
Diluted loss per share	(0.82)	(0.63)

### (b) Reconciliation of loss used in calculating loss per share

	31 December 2021 \$	31 December 2020 \$
Loss attributable to the ordinary equity holders of the Company used in calculating basic and diluted loss per share	<u>(3,949,987)</u>	<u>(1,747,374)</u>

### (c) Weighted average number of shares

The weighted average number of ordinary shares used in the calculation of basic and diluted loss per share is as follows:

	31 December 2021 Number	31 December 2020 Number
Weighted average number of ordinary shares for the purpose of basic/diluted loss per share	<u>480,847,951</u>	<u>277,768,326</u>

## 6 Dividends

The Board of Directors of Arovella Therapeutics Ltd does not recommend the payment of an interim dividend for the period ended 31 December 2021.

## 7 Financial assets and financial liabilities

### (a) Trade and other receivables

	31 December 2021			30 June 2021		
	Current	Non-current	Total	Current	Non-current	Total
	\$	\$	\$	\$	\$	\$
Trade and other receivables	22,452	-	22,452	9,595	-	9,595
R&D tax incentive receivable	-	-	-	524,042	-	524,042
	<b>22,452</b>	<b>-</b>	<b>22,452</b>	<b>533,637</b>	<b>-</b>	<b>533,637</b>

### (b) Trade and other payables

	31 December 2021	30 June 2021
	\$	\$
<b>Current liabilities</b>		
Trade payables	696,313	227,459
Payroll tax and other statutory liabilities	-	4,412
Sundry payables and accrued expenses	954,855	472,876
Legal settlement (Note 11)	684,202	522,152
	<b>2,335,370</b>	<b>1,226,899</b>

## 8 Intangible assets

	Patents \$	Development costs \$	Total \$
<b>Year ended 30 June 2021</b>			
Opening carrying value	132,358	4,118,864	4,251,222
Additions	-	348,447	348,447
Amortisation	-	(448,996)	(448,996)
Impairment (i)	-	(1,239,467)	(1,239,467)
Closing net book amount	132,358	2,778,848	2,911,206
<b>Period ended 31 December 2021</b>			
Opening carrying value	132,358	2,778,848	2,911,206
Additions	-	455,972	455,972
Amortisation	-	(177,817)	(177,817)
Closing net book amount	132,358	3,057,003	3,189,361

- (i) In the prior year, the Company decided not to commit further resources to the Sildenafil and Duromist projects as these projects were put on hold since the prior year and there were no suitable co-development opportunities. The carrying value of Sildenafil and Duromist projects at reporting date has been fully impaired resulting in an impairment expense of \$1,239,467 recognised in the statement of profit or loss and other comprehensive income in the year ended 30 June 2021.

## 9 Equity securities issued

### (a) Ordinary shares

	31 December 2021 Shares	30 June 2021 Shares	31 December 2021 \$	30 June 2021 \$
<b>Ordinary shares</b>				
Fully paid	480,920,880	480,819,986	77,041,791	77,003,347
	480,920,880	480,819,986	77,041,791	77,003,347

## 9 Equity securities issued (continued)

### (a) Ordinary shares (continued)

#### (i) Movements in ordinary shares:

Details	Number of shares	Total \$
<b>Opening balance 1 July 2020</b>	142,254,865	67,385,981
Share consolidation adjustment	(468)	-
Rights issue (August 2020)	142,254,397	3,556,360
Shares issue (August 2020)	21,338,159	533,455
Shares issue in lieu of cash (October 2020)	988,949	35,310
Shares issue (December 2020)	76,708,975	2,761,523
Shares issue (February 2021)	1,111,112	40,000
Shares issue (June 2021)	96,163,997	3,654,232
Less: Capital raising costs	-	(963,514)
Balance 30 June 2021	480,819,986	77,003,347
Exercise of listed options (November 2021) (i)	100,894	5,044
Less: Capital raising costs (ii)	-	33,400
	480,920,880	77,041,791
Balance 31 December 2021	480,920,880	77,041,791

- (i) 100,894 options were exercised on 11 November 2021 with cash consideration, resulting in an issue of shares at 1:1.
- (ii) The positive capital raising costs at half-year end is due to an over accrual of capital raising costs during the year ended 30 June 2021.

## 9 Equity securities issued (continued)

### (b) Share-based payment reserve

	31 December 2021 \$	30 June 2021 \$
Share-based payment reserve	<u>701,050</u>	450,686

#### (i) Movement in share-based payment reserve

Details	Number of options	\$
Balance at 1 July 2020	53,744,337	225,712
Unlisted options lapsed during the period	(460,000)	(51,388)
Listed options SUDOE issued	47,418,378	-
Listed options SUDOC expired	(48,644,337)	-
Unlisted options issued for professional service rendered	6,209,218	241,217
Share based payment expense for previously issued unlisted options	-	35,145
Balance at 30 June 2021	<u>58,267,596</u>	450,686

Unlisted options issued during the year (i)	<u>28,583,385</u>	210,486
Exercise of options during the period	(100,894)	-
Share based payment expense for previously issued unlisted options	-	39,878
Balance at 31 December 2021	<u>86,750,087</u>	701,050

- (i) 3,860,000 unlisted options were issued to an external consultant under the Company's ESOP on 13 July 2021. These options were granted in June 2021.

3,000,000 unlisted options were issued to an external consultant, under the Company's ESOP pursuant to commencement at the Company on 2 August 2021.

2,923,385 unlisted options were granted in June 2021 to external corporate advisory group Baker Young Stockbrokers for professional services rendered and were issued upon shareholders approval at the general meeting held on 14 October 2021.

8,000,000 unlisted options were issued to Dr Michael Baker, CEO and Managing Director, under the Company's ESOP pursuant to resolution of shareholders at the General Meeting held on 14 October 2021.

2,400,000 unlisted options were issued to Dr Elizabeth Stoner, Non-Executive Director, under the Company's ESOP pursuant to resolution of shareholders at the Annual General Meeting held on 16 December 2021.

2,400,000 unlisted options were issued to Dr Debora Barton, Non-Executive Director, under the Company's ESOP pursuant to resolution of shareholders at the Annual General Meeting held on 16 December 2021.

6,000,000 unlisted options were issued to Mr Paul Hopper, Non-Executive Chairman, under the Company's ESOP pursuant to resolution of shareholders at the Annual General Meeting held on 16 December 2021.

## 9 Equity securities issued (continued)

### (b) Share-based payment reserve (continued)

#### (i) Movement in share-based payment reserve

Options to Baker Young

There were 2,923,385 unlisted options granted in June 2021 but issued in November 2021 after shareholders' approval at the General Meeting.

The fair value of the equity-settled share options at grant date was derived using the Black-Scholes model based on the terms of the options above and the following inputs:

#### Options issued during the period

31 December 2021	Dr Michael Baker	Dr Debora Barton	Mr Paul Hopper	Dr Elizabeth Stoner
Number of options	8,000,000	2,400,000	6,000,000	2,400,000
Grant date	14 Oct 2021	16 Dec 2021	16 Dec 2021	16 Dec 2021
Dividend yield (%)	0.00%	0.00%	0.00%	0.00%
Expected volatility (%)	143.45%	142.89%	142.89%	142.89%
Risk-free interest rate (%)	0.48%	1.00%	1.00%	1.00%
Expected life of option (years)	4	4	4	4
Exercise price (cents)	7.5	5.2	7.5	4.4
Grant date share price (cents)	4.6	4.0	4.0	4.0
Fair value per option at grant date (cents)	3.73	3.32	3.19	3.37

#### Options issued during the period to Consultant 1

31 December 2021	Tranche 1	Tranche 2	Tranche 3
Number of options	1,000,000	1,000,000	1,000,000
Grant date	2 Aug 2021	2 Aug 2021	2 Aug 2021
Dividend yield (%)	0.00%	0.00%	0.00%
Expected volatility (%)	144.44%	144.44%	144.44%
Risk-free interest rate (%)	0.14%	0.14%	0.14%
Expected life of option (years)	4	4	4
Exercise price (cents)	7.4	7.9	8.4
Grant date share price (cents)	5.1	5.1	5.1
Fair value per option at grant date (cents)	4.19	4.17	4.14

#### Options issued during the period to Consultant 2

31 December 2021	Tranche 1	Tranche 2	Tranche 3
Number of options	1,286,667	1,286,667	1,286,666
Grant date	18 Jun 2021	18 Jun 2021	18 Jun 2021
Dividend yield (%)	0.00%	0.00%	0.00%
Expected volatility (%)	142.56%	142.56%	142.56%
Risk-free interest rate (%)	0.19%	0.19%	0.19%
Expected life of option (years)	4	4	4
Exercise price (cents)	5.7	6.1	6.5
Grant date share price (cents)	3.6	3.6	3.6
Fair value per option at grant date (cents)	2.91	2.89	2.87

## **10 Events occurring after the reporting period**

On 1 February 2022, the Company issued 120,230,220 new ordinary shares at \$0.038 per share to new and existing institutional and sophisticated investors, including well known cornerstone participation by specialist life sciences investor, Merchant, to fund ongoing development of the iNKT cell therapy technologies and working capital. The funds will also be used to support potential acquisitions of new technologies in the fields of oncology.

Furthermore, the Company launched a Share Purchase Plan ("SPP") to raise up to \$2 million for eligible existing shareholders on 24 January 2022 and the expected closing date of SPP is on 9 March 2022.

Subject to shareholder approval at the upcoming General Meeting, the Company granted 4,854,999 unlisted options with an exercise price of \$0.057 each option expiring 31 January 2025 to an external consulting firm, Baker Young for professional service rendered. In addition, the Directors intend to participate in up to 4,210,526 new ordinary shares at \$0.038 per share amounting to \$160,000 before costs.

## **11 Commitments and contingencies**

### **Contingent liabilities**

HC Berlin Pharma AG - The Company entered into a settlement agreement with the Receiver of HC Berlin Pharma AG on 28 June 2018 for a settlement amount of €1,620,000 (approximately \$2,570,000) payable in instalments up to 31 December 2021. Under the terms of the agreement, if the Company does not meet the payment for each instalment within 10 calendar days after the due date of the instalment date, then the total claim of €8,000,000 plus interest and costs less amounts paid to date becomes due and payable. During the period, the Company has successfully renegotiated with HC Berlin Pharma AG for an extension of time on the repayment of last instalment plus interest payable to 30 June 2022. To 31 December 2021, the Company has paid \$2,025,763 (2020: \$1,620,892) in accordance with the settlement agreement, and the outstanding amount is \$684,202 (inclusive of \$169,462 interest payable).

## **12 Fair value measurements of financial instruments**

The Company has a number of financial instruments which are not measured at fair value in the statement of financial position. The Directors consider that the carrying amounts of these financial assets and liabilities are a reasonable approximation of their fair values.



**Arovella Therapeutics Limited**  
**(Formerly known as Suda Pharmaceuticals Limited)**  
**Directors' declaration**  
**31 December 2021**

The Directors of Arovella Therapeutics Ltd ("Company") declare that:

- (a) the financial statements and notes set out on pages 2 to 20 are in accordance with the *Corporations Act 2001*, including:
  - (i) complying with Accounting Standards, the *Corporations Regulations 2001* and other mandatory professional reporting requirements, and
  - (ii) giving a true and fair view of the Company's financial position as at 31 December 2021 and of its performance for the half-year ended on that date, and
- (b) there are reasonable grounds to believe that the Arovella Therapeutics Limited will be able to pay its debts as and when they become due and payable.

This declaration is signed in accordance with a resolution of the Board of Directors made pursuant to s.303(5) of the *Corporations Act 2001*.



Mr. Paul Hopper  
Non-Executive Chairman

Sydney  
28 February 2022

**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 accompanying half-year financial report of Arovella Therapeutics Limited ("the company") which comprises the condensed consolidated statement of financial position as at 31 December 2021, the condensed consolidated statement of profit or loss and other comprehensive income, the condensed consolidated statement of changes in equity and the condensed consolidated statement of cash flows for the half-year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration, for the consolidated entity comprising the company and the entities it controlled at the half-year end or from time to time during the half-year.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the 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 consolidated entity's financial position as at 31 December 2021 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 entity'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

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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.

*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 consolidated entity's financial position as at 31 December 2021 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 2022**

*L Di Giallonardo*

**L Di Giallonardo**  
**Partner**