

## APPENDIX 4C – 30 SEPTEMBER 2024

# QUARTERLY ACTIVITIES & CASHFLOW REPORT

### Highlights:

- *Positive progress made in Argenica's Phase 2 clinical trial during the quarter with all 10 hospital sites now activated to recruit and dose patients. The second Data Safety Monitoring Board (DSMB) meeting held during the quarter recommended that the study continue with no modifications required to the Study Protocol.*
- *The trial has made significant progress in patient dosing during the quarter and the half-way recruitment milestone to trigger the third DSMB meeting (46 out of 92 patients) was reached in September.*
- *Argenica generated positive results in a number of key safety studies required by the US Food & Drug Administration (FDA) for inclusion in the Company's Investigational New Drug (IND) Application, which is being prepared. The data further demonstrates that ARG-007 has a unique mechanism of action and pharmacological benefits compared to competitor drugs.*
- *Cash reserves of \$13.9 million as at 30 September 2024. The Company has lodged its R&D Tax Incentive return for the year ended 30 June 2024 and anticipates a R&D tax rebate of \$2.75m in the Dec24Q.*

**Perth, Australia; 31 OCTOBER 2024** – Argenica Therapeutics Limited (ASX: AGN) ("Argenica" or the "Company"), a biotechnology company developing novel therapeutics to reduce brain tissue death after stroke and other types of brain injury, is pleased to lodge the following quarterly update and attached Appendix 4C Quarterly Cashflow Report for the 12-month period ended 30 September 2024.

Argenica's core focus is on its Phase 2 clinical trial of ARG-007 in acute ischaemic stroke patients being conducted across Australian hospitals. This proof-of-concept clinical trial will provide data on the safety and measures of preliminary efficacy of ARG-007 in acute ischaemic stroke patients presenting to emergency departments across Australia.

In parallel, the Company is investigating the potential utility of ARG-007 in other neurological conditions. Underpinning this research, over \$4 million in non-dilutive grant and philanthropic funding has been secured throughout the life of the projects from the Federal and Western Australian governments, the Stan Perron Charitable Foundation, the McCusker Foundation, and donors to the Perron Institute.

Key activities undertaken during the quarter are outlined below.

## **PHASE 2 STROKE CLINICAL TRIAL UPDATE**

During the quarter, Argenica was pleased to make significant progress in patient recruitment in its Phase 2 clinical trial of ARG-007 in acute ischaemic stroke patients and complete activation of all 10 hospital trial sites across Australia.

### **Patient Dosing**

Patient recruitment progressed well during the quarter with all 10 hospital sites now activated and able to recruit and dose patients. As sites have become familiar with the trial protocol there has been an increase in the recruitment rate and dosing of patients in the trial. The half-way recruitment milestone to trigger the third Data Safety Monitoring Board (DSMB) meeting (46 out of 92 patients) was reached in September.

### **Data Safety Monitoring Board (DSMB)**

As part of the Phase 2 trial, Argenica has established an independent DSMB comprising a number of independent neurologists and a biostatistician, who will be responsible for reviewing the safety data as the trial progresses. The DSMB will also be supported by an unblinded project manager and statistician.

The purpose of the DSMB is to monitor the rates of adverse events (AEs), endpoints, and study progress in the Phase 2 trial. In addition, the DSMB will provide recommendations regarding the continuation, modification, or termination of the study to Argenica and will practice due diligence to ensure, given all available information, that subsequent subjects are not placed at any undue risk. Trial enrolment is not halted during each planned DSMB review of the safety data.

In September, the second meeting of the DSMB was held which reviewed the safety data of the first 23 patients dosed in the trial and recommended that the study continue with no modifications required to the Study Protocol. No serious adverse events or adverse events related to the dosing of patients were reported to the independent DSMB.

The third DSMB reviewing data from the 50% of patients dosed (46 out of 92 patients) has now been held and outcomes of that DSMB, together with an update on recruitment, will be reported to the market in the near term.

## **POSITIVE RESULTS IN KEY IND ENABLING STUDIES CONFIRMS COMPETITIVE POSITION OF ARG-007**

During the quarter, Argenica generated positive results in a number of key safety studies required by the US Food & Drug Administration (FDA) for inclusion in the Company's Investigational New Drug (IND) Application, which is currently being prepared.

genetic damage in bone marrow or peripheral blood cells of animals, in this case rats. This in vivo micronucleus study in rats confirmed ARG-007 does not impact genetic material, and a high maximum tolerated dose of 17.5 mg/kg was achieved, well above the therapeutic dose u

The first IND enabling study, known as an in vivo micronucleus assay, is designed to evaluate the potential of a substance (e.g., a drug, chemical, or other compound) to cause sed in the current Phase 2 acute ischaemic stroke (AIS) clinical trial.

At the request of the FDA, Argenica undertook a further study assessing the impact of ARG-007 on standard of care drug tissue plasminogen activator (tPA). The study, utilising human blood clot, confirmed ARG-007 did not impact the clot dissolving activity of tPA, indicating ARG-007 can be used with the standard of care tPA therapy.

The third study examined the recycling/recovery of neuronal glutamate receptors after treatment of neuronal cultures with ARG-007 by assessing the sensitivity of neurons to glutamate excitotoxicity over an extended time duration. This glutamate receptor recycling study confirmed ARG-007 does not permanently downregulate receptors responsible for calcium influx, suggesting the drug mechanism of action will not cause neurotoxicity.

This data further demonstrates that ARG-007 has a unique mechanism of action and pharmacological benefits compared to competitor drugs.

Please refer to ASX Announcement "Positive Results in Key IND Enabling Studies Confirms Competitive Position of ARG-007" released on 25 September 2024 for further details on these studies.

## **BOARD AND MANAGEMENT UPDATES**

Argenica was also pleased to welcome additions to its Board and management team with the appointment of Dr Mark Etherton and Mr Rob Black as Non-Executive Directors and Dr Stuart Gribble commencing as Vice President of Product Development in early October.

The new Directors bring significant industry-based skills and experience in neurology drug development and financial markets acumen to support the transition and growth of Argenica into a pharmaceutical development company. Whilst Stuart is a highly experienced biotechnology executive with an extensive background in drug development across large pharmaceutical companies and ASX listed biotechnology companies.

The Company also recently advised of the upcoming retirement of Non-Executive Director Ms Liddy McCall who has indicated that she intends to not seek re-election at this year's AGM on 12 November 2024. The Board thanks Ms McCall for her dedication and contribution and wishes her well.

## **CASHFLOW COMMENTARY, CASH RESERVES OF \$13.9 MILLION AS AT 30 SEPTEMBER 2024**

During the quarter, the Company had net operating cash outflows of \$2.330 million, net cash inflows from financing activities of \$0.344 million and cash reserves of \$13.914 million as at 30 September 2024.

Operating cash outflows in the quarter included expenditure on research and development activities of \$1.858 million (Jun24Q: \$1.348 million), staff costs (including research and development employees) of \$0.402 million (Jun24Q: \$0.308 million) and corporate administration of \$0.288 million (Jun24Q \$0.327 million). Research and development expenditure included payments to third party contractors undertaking pre-clinical and non-clinical studies and Phase 2 clinical trial activities including drug manufacture.

During the quarter, the Company benefited from \$0.077 million of non-dilutive grant funding under the federal government's Cooperative Research Centre Projects (CRC-P) program for the project "A novel therapeutic for the treatment of traumatic brain injury" and interest income of \$0.150 million.

Net financing cashflows of \$0.344 million in the quarter related to the exercise of options issued to the Lead Manager of the IPO in 2021.

The Company has lodged its R&D Tax Incentive return for the year ended 30 June 2024 and anticipates a R&D tax rebate of \$2.75m, subject to review and payment by the ATO. Advance and Overseas Findings have been approved by AusIndustry enabling both domestic and overseas expenditure on the Company's planned preclinical efficacy, nonclinical studies, manufacturing, regulatory activities and Phase 2 clinical trial activities to be included as eligible R&D expenditure for the purposes of a R&D tax incentive rebate in the 2024 & 2025 financial years.

As required by ASX Listing Rule 4.7C3, the Company notes that \$0.146 million was paid to related parties during the quarter (as noted in section 6 of the attached Appendix 4C) and these payments included salary and superannuation paid to Executive Directors and Directors fees and superannuation paid to Non-Executive Directors.

*This announcement has been approved for release by the Board of Argenica.*

For more information please contact: [info@argenica.com.au](mailto:info@argenica.com.au)

## **ABOUT ARGENICA**

Argenica (ASX: AGN) is developing novel therapeutics to reduce brain tissue death after stroke and other types of brain injury and neurodegenerative diseases to improve patient outcomes. Our lead neuroprotective peptide candidate, ARG-007, has been successfully demonstrated to improve outcomes in pre-clinical stroke models, traumatic brain injury (TBI) and hypoxic ischaemic encephalopathy (HIE). The Company has completed a Phase 1 clinical trial in healthy human volunteers to assess the safety and tolerability of a single dose of ARG-007. Argenica has now initiated a Phase 2 clinical trial in ischaemic stroke patients, as well as continuing to generate preclinical data in other neurological conditions.

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

ARGENICA THERAPEUTICS LIMITED

**ABN**

78 637 578 753

**Quarter ended ("current quarter")**

30 SEP 2024

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(1,858)	(1,858)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(402)	(402)
(f) administration and corporate costs	(288)	(288)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	150	150
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives		
- CRCP grant	76	76
- WA Seed Innovation Grant	-	-
- Other grants	-	-
- R&D tax rebate	-	-
1.8 Other (provide details if material)		
- Net GST (paid) / received	(8)	(8)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,330)</b>	<b>(2,330)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3months) \$A'000
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>0</b>	<b>0</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	363	363
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(19)	(19)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>344</b>	<b>344</b>

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3months) \$A'000
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	15,900	15,900
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,330)	(2,330)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	344	344
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>13,914</b>	<b>13,914</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	1,874	3,861
5.2	Call deposits	12,050	12,051
5.3	Bank overdrafts	(10)	(12)
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>13,914</b>	<b>15,900</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	146
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		



<b>7.</b>	<b>Financing facilities</b> <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	<b>Total financing facilities</b>	-	-
7.5	<b>Unused financing facilities available at quarter end</b> <div style="border: 1px solid black; height: 20px; width: 100%;"></div>		
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

<b>8.</b>	<b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,330)
8.2	Cash and cash equivalents at quarter end (item 4.6)	13,914
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	13,914
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	6.0
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>		
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1	Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
	Answer: N/A	
8.6.2	Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
	Answer: N/A	
8.6.3	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
	Answer: N/A	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>		

## Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: ....31 October 2024.....

Authorised by: ....By the Board of the Company.....  
(Name of body or officer authorising release – see note 4)

## Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.