

# APPENDIX 4C – 31 MARCH 2025

## QUARTERLY ACTIVITIES & CASHFLOW REPORT

### Highlights:

- *The final Data Safety Monitoring Board (DSMB) of Argenica’s Phase 2 clinical trial of ARG-007 in acute ischaemic stroke (AIS) patients was held during the quarter and reviewed the safety data of the first 76 patients dosed and recommended the study continue with no modifications required to the Study Protocol.*
- *Substantial progress was made in patient dosing in the Phase 2 clinical trial during the quarter, with the final patient dosed just after quarter end. Topline data from the trial is anticipated to be released in Q3 calendar year 2025.*
- *Results from a larger preclinical study assessing the efficacy of ARG-007 in a rat model of moderate traumatic brain injury (TBI) was released, indicating that ARG-007 can prevent the axonal injury and neuroinflammation which significantly contributes to the acute and chronic consequences of TBI.*
- *Cash reserves of **\$12.9 million** as at 31 March 2025 to fund the completion and release of results of the Phase 2 AIS clinical study.*

**Perth, Australia; 30 APRIL 2025** – 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 9-month period ended 31 March 2025.

Argenica’s core focus is on its Phase 2 clinical trial of ARG-007 in acute ischaemic stroke (AIS) 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 AIS patients presenting to emergency departments across Australia. Topline data from the trial is expected in Q3 calendar year 2025.

In parallel, the Company has projects 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 its Phase 2 clinical trial of ARG-007 in AIS patients.

### **Patient Dosing**

Just after quarter end, the final patient in the Phase 2 clinical trial of ARG-007 in AIS patients was dosed.

The Phase 2 clinical trial dosed a total of 92 patients with confirmed large vessel occlusion strokes, and who underwent an endovascular thrombectomy procedure to remove the clot. Of the total of 92 patients dosed, 50% received an intravenous infusion of a saline placebo and 50% received an intravenous infusion of ARG-007. The trial will remain blinded until the final patient dosed has their follow up functional assessment performed at 90 days post stroke. This means no one involved in the dosing of patients or performing follow up assessments, including principal investigators, hospital staff and Argenica staff, know which patients have been administered the saline placebo and which patients have been administered ARG-007. Following the final 90-day functional assessment, the trial database will be locked, and the data will be unblinded and analysed to confirm whether the trial has met its endpoints.

It is anticipated the topline data, reporting on the primary and secondary endpoints, will be released in Q3 calendar year 2025.

The endpoints in the trial are:

**Primary** – To evaluate the safety of a single dose of ARG-007 in participants with AIS, including mortality rate, incidence of serious adverse events, and incidence of symptomatic intracranial haemorrhage.

**Secondary** – To characterize the effect of ARG-007 on reducing infarct volume in participants with AIS, specifically the difference in infarct volume (brain injury volume) between ARG-007 and placebo groups as measured by magnetic resonance imaging (MRI) or non-contrast computed tomography (CT) at 48 hours post drug/placebo administration.

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

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

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 provides 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.

The primary purpose of the data review meeting is to allow the DSMB to review and discuss the safety data outputs in order to make recommendations on whether any variations to the study protocol may be required and to confirm that the study can continue. The outcomes of these meetings are made available to the market.

During the quarter, the final DSMB of the Phase 2 clinical trial was held and reviewed the safety data of the first 76 patients dosed, a review of 83% of patients in the study, and recommended the study continued with no modifications required to the Study Protocol.

## **INVESTIGATIONAL NEW DRUG APPLICATION TO THE US FOOD & DRUG ADMINISTRATION**

During the quarter, Argenica continued to progress the preparation of its Investigational New Drug (IND) Application for ARG-007 in acute ischaemic stroke. By opening an IND application with the FDA, sponsors of clinical trials receive authorisation to administer an investigational drug or biological product to humans. Any future later phase clinical trials of ARG-007 to be undertaken at sites in the US requires this authorisation from the FDA. The submission and approval of Argenica's IND has no bearing on the ability of the Company to complete its current Phase 2 AIS clinical trial.

Preparing an IND application is a lengthy process and requires extensive data to be included on a drug's preclinical and nonclinical efficacy, safety and tolerability, as well as the drug's chemistry, manufacturing and development controls. Argenica has been working with its US based regulatory consultant to prepare the IND application for submission to the FDA, with the majority of the submission already complete.

In parallel to completing the IND application, Argenica has prepared a Fast Track Application to be submitted at the same time as the IND application. Fast Track designation by the FDA provides the Sponsor with more frequent meetings with the FDA to discuss the drug's development plans and clinical trial design, as well as potential eligibility for Accelerated Approval and Priority Review if relevant criteria are met.

Submitting a Fast Track Application with an IND is considered to be very advantageous as it maximises the potential for expedited review and early communication with the FDA. Submitting the Fast Track request alongside the IND allows the agency to quickly assess if the drug qualifies for the expedited pathway and enables early interactions to be initiated with the Company.

A final review of all documentation to be submitted to the FDA is currently taking place and Argenica expects to submit the IND and Fast Track Application in the first week of May.

### **ARG-007 EFFICACY IN TBI - PRECLINICAL RESEARCH UPDATE**

During the quarter, Argenica announced results from a larger preclinical study assessing the efficacy of ARG-007 in a rat model of moderate traumatic brain injury (TBI). The results indicated that ARG-007 can prevent the axonal injury and neuroinflammation which significantly contributes to the acute and chronic consequences of TBI.

Damage to brain cells was assessed by measuring key markers of axonal injury and neuroinflammation following moderate TBI. Importantly, the biomarker levels of axonal injury and neuroinflammation following ARG-007 treatment were equivalent to non-injured animals, suggesting ARG-007 prevents damage following TBI.

Axonal injury and neuroinflammation play crucial roles in determining outcomes following TBI. They contribute significantly to many of the acute and chronic consequences of TBI, making them important targets for therapeutic intervention.

ARG-007 treated animals also showed several signs of improvement in a motor function test (the rotarod test) and a significant reduction in weight loss.

This data verifies the data generated from the previous pilot study in rats and pilot study in ferrets, to confirm the extensive neuroprotective effect of ARG-007 in moderate TBI in multiple preclinical studies.

Refer to ASX announcement “ARG-007 Shows Significant Neuroprotection in Main Traumatic Brain Injury Study” released on 4 February 2025 for further detail.

### **CASHFLOW COMMENTARY, CASH RESERVES OF \$12.9 MILLION AS AT 31 MARCH 2025**

With cash reserves of \$12.9 million as at 31 March 2025, the Company is funded to the completion and release of results of the Phase 2 AIS clinical study.

The Company had net operating cash outflows of \$2.154 million for the quarter ended 31 March 2025. Operating cashflows in the quarter included expenditure on research and development activities of \$1.695 million (Dec24Q: \$1.212 million), staff costs (including

research and development employees) of \$0.394 million (Dec24Q: \$0.366 million) and corporate administration of \$0.224 million (Dec24Q: \$0.263 million). Research and development expenditure included payments to third party contractors undertaking pre-clinical and non-clinical studies, Phase 2 clinical trial activities including drug manufacture, CRO costs and hospital site fees, and regulatory consultants.

As required by ASX Listing Rule 4.7C3, the Company notes that \$0.172 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 is now undertaking a Phase 2 clinical trial in acute ischaemic stroke patients, with dosing in this trial now complete, 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")**

31 MAR 2025

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(1,695)	(4,765)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(394)	(1,162)
(f) administration and corporate costs	(224)	(775)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	138	426
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives		
- CRCP grant	34	110
- WA Seed Innovation Grant	-	-
- Other grants	-	32
- R&D tax rebate	-	2,757
1.8 Other (provide details if material)		
- Net GST (paid) / received	(13)	42
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,154)</b>	<b>(3,335)</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 (9months) \$A'000
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-
<b>2.2</b> Proceeds from disposal of:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-
<b>2.3</b> Cash flows from loans to other entities	-	-
<b>2.4</b> Dividends received (see note 3)	-	-
<b>2.5</b> 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. 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
3.4 Transaction costs related to issues of equity securities or convertible debt securities	-	(22)
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>-</b>	<b>341</b>

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9months) \$A'000</b>
<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	15,060	15,900
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,154)	(3,335)
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)	-	341
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>12,906</b>	<b>12,906</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	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	1,380	3,026
5.2	Call deposits	11,550	12,050
5.3	Bank overdrafts	(24)	(16)
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>12,906</b>	<b>15,060</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	172
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>		

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

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</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>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	-	-
<b>7.5 Unused financing facilities available at quarter end</b>	[ ]	
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. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,154)
8.2 Cash and cash equivalents at quarter end (item 4.6)	12,906
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	12,906
<b>8.5 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: ....30 April 2025.....

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.