

# APPENDIX 4C – 30 JUNE 2025 QUARTERLY ACTIVITIES & CASHFLOW REPORT

#### **Highlights:**

- Key milestone achieved in Argenica's Phase 2 clinical trial of ARG-007 in acute ischaemic stroke (AIS) patients with the final patient dosed in April 2025. Topline data from the trial is anticipated to be released in Q3 calendar year 2025.
- Positive preclinical data in a large cohort ferret study assessing ARG-007 efficacy out to a 14-day duration post moderate traumatic brain injury (modTBI). A robust preclinical package now developed which consistently exhibits significant and sustained benefit conferred by ARG-007 in the treatment of modTBI.
- Awarded non-dilutive funding up to a total of \$1.5 million under the Australian Government's Medical Research Future Fund (MRFF) Targeted Translation Research Accelerator program for Diabetes and Cardiovascular Disease, delivered by MTPConnect.
- Argencia's Investigational New Drug (IND) Application was lodged with the Food and Drug Administration (FDA). Following the notification of the FDA placing the IND on clinical hold, no further details on the FDA's additional requirements have been provided to Argenica at this time due to resourcing constraints at the FDA. This correspondence does not impact the current Phase 2 clinical trial being conducted in Australia.
- Cash reserves of \$10.5 million as at 30 June 2025 to fund the completion and release of results of the Phase 2 AIS clinical study. Preparation of R&D Tax Incentive return for the year ended 30 June 2025 has commenced and anticipated to be received in Q4 calendar year 2025.

**Perth, Australia; 23 JULY 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 12-month period ended 30 June 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 achieve a key milestone in its Phase 2 clinical trial of ARG-007 in AIS patients with the final patient dosed in April 2025.

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 is blinded until the final patient dosed has their follow up functional assessment performed at 90 days post stroke and all data is collated in the clinical trial electronic data capture system. 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 and data capture, 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 database will be locked in mid-August, with this analysis to commence shortly after. The topline data, reporting on the primary and secondary endpoints, will be released in Q3 calendar year 2025. Argenica has no access to any study data until this topline data is released.

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.

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

Correspondence was received mid-June 2025 from the United States (US) Food and Drug Administration (FDA), advising that it has placed a clinical hold on the Company's acute ischaemic stroke (AIS) Investigational New Drug (IND) Application. Notwithstanding that within the submitted IND the Company had addressed all requests by the FDA for non-clinical information outlined in its pre-IND type B meeting, the FDA indicated that the non-clinical data package provided in the IND is not adequate to support initiation of a proposed AIS trial in the US at this time. It is important to note that this correspondence from the FDA does not impact the current Phase 2 clinical trial being conducted in Australia.

Under the US Code of Federal Regulations (CFR), 312.42, the FDA must "As soon as possible, and no more than 30 days after imposition of the clinical hold, the Division Director will provide the sponsor a written explanation of the basis for the hold". The FDA had indicated in their original clinical hold email that they would meet this 30-day deadline. However, the FDA have now stated that due to resourcing constraints at the Agency they are unable to meet this deadline. No further information has been provided on an anticipated date to receive the Full Clinical Hold Letter. Argenica is currently working with its regulatory consultants to formulate next steps to expedite the receipt of the letter.

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.

Argenica had anticipated there may be some challenges in receiving an open IND within the 30-day time period due to current resourcing challenges at the FDA, hence the decision to submit the AIS IND application much earlier than required to actually start anticipated future clinical trials in the US. The Company is committed to providing any additional specific data that the FDA may require.

#### **GRANTED NEW US PATENT FOR SURGICALLY INDUCED STROKE**

In May 2025, Argenica was granted a new US patent (patent number 12,303,550) entitled "Neuroprotective Peptides" by the United States Patent Office (USPTO). This patent was filed with the USPTO as a divisional application and extends the scope of the Company's earlier parent patent filing by covering the specific use of Argenica's neuroprotective peptides in a method of treating a surgery patient at risk of suffering cerebral ischaemia or stroke. This protection is especially relevant in high-risk cardiac and vascular operations—such as proximal thoracic-aortic repairs and valve replacements—where peri-operative stroke rates can be up to 10 % above baseline.

The new patent builds on the protection provided by Argenica's previously granted parent patent for novel neuroprotective peptides covering a broad range of neurological conditions

including, but not limited to, ischaemic stroke, traumatic brain injury, hypoxic ischaemic encephalopathy. The expiry date of the parent and divisional patents is 30 October 2034.

## ARGENICA TO PROGRESS CLINICAL DEVELOPMENT OF ARG-007 IN TRAUMATIC BRAIN INJURY (TBI) FOLLOWING FURTHER POSITIVE PRECLINICAL DATA

During the quarter, Argenica was pleased to announce positive preclinical data in a large cohort ferret study assessing ARG-007 efficacy out to a 14-day duration post moderate traumatic brain injury (modTBI). Refer to ASX announcement titled "Argenica to Progress Clinical Development of ARG-007 in Traumatic Brain Injury following Positive Preclinical Data" on 18 June 2025 for further detail on the study results.

Results from this preclinical study, together with previously completed studies, provides Argenica with a robust preclinical package which consistently exhibits significant and sustained benefit conferred by ARG-007 in the treatment of modTBI.

TBI affects 69 million people globally annually, with no approved therapies available that can protect against the devastating brain injury sustained. The global TBI treatment market represents a significant commercial opportunity for Argenica, with ARG-007 poised to address a critical gap.

Argenica is now establishing a globally renowned Clinical Advisory Committee to be chaired by leading Australian neurologist Clinical Professor Terry O'Brien and supported by world leading TBI neurology clinicians from across Australia and the US, to provide advice and input into a clinical development plan for ARG-007 in TBI.

#### AWARDED FUNDING UNDER THE AUSTRALIAN GOVERNMENT'S TTRA PROGRAM

During the quarter, Argenica was also pleased to be awarded non-dilutive funding up to a total of \$1.5 million under the Australian Government's Medical Research Future Fund (MRFF) Targeted Translation Research Accelerator program for Diabetes and Cardiovascular Disease, delivered by MTPConnect.

The funding covers activities to support Argenica's proposed later stage clinical trial of ARG-007 in acute ischaemic stroke patients. The funding will be paid in two tranches, with the first tranche totalling \$1 million, and a further \$0.5 million provided on successful completion of activities under the first tranche and if the project demonstrates high commercial potential. The first grant instalment of \$0.243 million was received subsequent to quarter end.

#### CASHFLOW COMMENTARY, CASH RESERVES OF \$10.5 MILLION AS AT 30 JUNE 2025

With cash reserves of \$10.5 million as at 30 June 2025, the Company is funded to the completion and release of results of the Phase 2 AIS clinical study.

Argenica benefited from non-dilutive grant funding of \$0.225 million during the quarter being the final instalment of the WA Innovation Seed Fund Grant. This program is providing funding to explore the development of a nasal formulation for ARG-007, a non-invasive route of administration that may be more suitable for less acute indications.

The Company had net operating cash outflows of \$2.362 million for the quarter ended 30 June 2025. Operating cashflows in the quarter included expenditure on research and development activities of \$2.103 million (Mar25Q: \$1.695 million), staff costs (including research and development employees) of \$0.395 million (Mar25Q: \$0.394 million) and corporate administration of \$0.200 million (Mar25Q: \$0.263 million). Research and development expenditure included payments to third party contractors undertaking preclinical and non-clinical studies, Phase 2 clinical trial activities including CRO costs and hospital site fees, investment in manufacturing start-up costs for a future Phase 2b/3 trial and regulatory consultants.

Argenica has commenced preparation of its R&D Tax Incentive return for the year ended 30 June 2025, which is anticipated to be received in Q4 calendar year 2025. An Advance and Overseas Finding has previously been approved by AusIndustry enabling both domestic and overseas expenditure on the Company's Phase 2 clinical trial, including supporting manufacturing and regulatory activities, to be included as eligible R&D expenditure.

As required by ASX Listing Rule 4.7C3, the Company notes that \$0.165 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

#### **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

78 637 578 753

ARGENICA THERAPEUTICS LIMITED	
ABN	Quarter ended ("current quarter")

30 JUN 2025

Con	solidated statement of cash flows	ment of cash flows Current quarter Yea \$A'000 (12)	
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(2,103)	(6,868)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(395)	(1,557)
	(f) administration and corporate costs	(200)	(975)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	125	551
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives		
	- CRCP grant	-	110
	- WA Seed Innovation Grant	225	225
	- Other grants	-	32
	- R&D tax rebate	-	2,757
1.8	Other (provide details if material)		
	<ul> <li>Net GST (paid) / received</li> </ul>	(14)	28
1.9	Net cash from / (used in) operating activities	(2,362)	(5,697)

2.	Cash flows from investing activities	
2.1	Payments to acquire or for:	
	(a) entities	-
	(b) businesses	-

ASX Listing Rules Appendix 4C (17/07/20)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12months) \$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)	-	-
2.6	Net cash from / (used in) investing activities	0	0

3.	Cash flows from financing activities		
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)	-	-
3.10	Net cash from / (used in) financing activities	-	341

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	12,906	15,900
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,362)	(5,697)
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	-	-
4.6	Cash and cash equivalents at end of period	10,544	10,544

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	2,505	1,380
5.2	Call deposits	8,050	11,550
5.3	Bank overdrafts	(11)	(24)
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	10,544	12,906

Payments to related parties of the entity and their associates	Current quarter \$A'000
Aggregate amount of payments to related parties and their associates included in item 1	165
Aggregate amount of payments to related parties and their associates included in item 2	-
	Aggregate amount of payments to related parties and their associates included in item 1  Aggregate amount of payments to related parties and their

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.

7.	Financing facilities  Note: the term "facility' includes all forms of financing arrangements available to the entity.  Add notes as necessary for an understanding of the sources of finance available to the entity.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	-	-
7.5	Unused financing facilities available at qu	uarter end	
7.6	Include in the box below a description of each rate, maturity date and whether it is secured facilities have been entered into or are proposinclude a note providing details of those facilities.	or unsecured. If any add osed to be entered into af	itional financing

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,362)
8.2	Cash and cash equivalents at quarter end (item 4.6)	10,544
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	10,544
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	4.5
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item	8.5 as "N/A". Otherwise. a

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: 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

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

#### **Compliance statement**

- 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:	23 JULY 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.
- 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".
- 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.