

APPENDIX 4C – 31 DECEMBER 2023 QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- Argenica remains on track for patient recruitment and dosing to commence in Q1 CY 2024. Substantial progress made on manufacturing, with completion of manufacturing of the clinical trial batch of ARG-007, and site set up activities for the Phase 2 clinical trial in acute ischaemic stroke patients during the December quarter.
- Orphan Drug Designation status granted by U.S. Food and Drug Administration to ARG-007 for the treatment of Hypoxic Ischaemic Encephalopathy (HIE).
- The Company made two significant appointments: Dianne Angus was appointed as Non-Executive Chair and Celina Chew was appointed Vice President of Business Development.
- Promising research activities and results for ARG-007 in HIE and Alzheimer's disease.
- Cash reserves of \$8.4 million as at 31 December 2023 following receipt during the quarter of a \$2.089 million R&D tax incentive claim for the financial year ending 30 June 2023.

Perth, Australia; 31 JANUARY 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 6-month period ended 31 December 2023.

Argenica's core focus is its Phase 2 clinical trial of ARG-007 in acute ischaemic stroke patients. 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, including hypoxic ischaemic encephalopathy (HIE) traumatic brain injury (TBI) and Alzheimer's Disease. 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 CLINICAL TRIAL IN STROKE PATIENTS – ON TRACK FOR PATIENT RECRUITMENT AND DOSING TO COMMENCE IN Q1 CY 2024

Argenica remains on track for patient recruitment and dosing to commence in Q1 CY 2024. During the quarter, substantial progress was made on manufacturing and site set up activities for the Phase 2 clinical trial in acute ischaemic stroke patients.

Manufacturing

During the quarter, Melbourne based peptide manufacturer, Auspep Clinical Peptides, completed the manufacturing of the ARG-007 drug substance (in powder form) which was sent to Argenica's European based contract manufacturer, CordenPharma, to be fill and finished as sterilised vials of the ARG-007 drug product solution under Good Manufacturing Practices (GMP) ready for dosing of patients in the Phase 2 clinical trial.

CordenPharma successfully completed the scale up of its manufacturing processes required to manufacture ARG-007 under GMP conditions during the quarter. The GMP clinical trial batch manufacturing of ARG-007 was completed in late December, and release testing (testing concentration, consistency, etc.) of the vials will be completed in January. Shipment of the vials of ARG-007 and placebo to Central Pharmacy Logistics (CPL) in Australia is expected shortly. CPL will then log all vials and distribute them to each hospital site, ready for patient dosing this quarter.

Establishing Clinical Trial Sites

Since receiving ethics approval in September 2023, Argenica's clinical trial team has also been working with a number of hospitals across Australia to establish them as clinical trial sites for the Phase 2 clinical trial. The trial will be conducted in up to 10 hospitals across Australia that have dedicated stroke care units capable of performing endovascular thrombectomy.

Each hospital undergoes a site-specific assessment (SSA) process which forms good research governance and is an essential component for the responsible conduct of research. Once SSAs have been approved in each hospital by their respective Research Governance Offices, they may commence dosing patients under the approved Phase 2 clinical trial protocol.

Currently 3 sites have received approval Royal Melbourne, Princess Alexandra and John Hunter hospitals and a further 2 sites, Royal Adelaide and Liverpool Hospitals, have submitted

their SSA research governance documentation. The additional five hospitals are expected to submit their SSA research governance documentation shortly.

Further detail on the Phase 2 clinical trial design can be found in the following ASX announcements (i) Argenica Receives Ethics Approval for its Pivotal Phase 2 Trial in Stroke Patients released on 12 September 2023 and (ii) Phase 2 Stroke Clinical Trial Update released on 14 December 2023.

NEUROLOGY PIPELINE RESEARCH AND DEVELOPMENT FOR ARG-007

Hypoxic Ischaemic Encephalopathy (HIE)

HIE is a type of brain injury sustained by newborns where the brain doesn't receive enough oxygen or blood flow for a period. Whilst HIE is a rare paediatric condition, it has devastating outcomes for these babies, and a treatment is desperately needed.

During the quarter, Argenica was pleased to be granted Orphan Drug Designation (ODD) status by the U.S. Food and Drug Administration (FDA) to ARG-007 for the treatment of HIE. The FDA has authority to grant ODD to a drug or biological product to prevent, diagnose or treat a rare disease or condition. ODD qualifies companies for incentives including (i) tax credits for qualified clinical trials, (ii) exemption from user fees and (iii) potential seven years of market exclusivity after approval.

The Company commenced a preclinical juvenile toxicology study being undertaken by Labcorp Drug Development who have extensive experience in global paediatric clinical trials.

In addition, the required preclinical efficacy studies in a large animal term model of HIE are being generously funded by a grant from the Stan Perron Charitable Foundation (SPCF) to the Perron Institute for Neurological and Translational Sciences.

Alzheimer's Disease

During the quarter, Argenica released preclinical data from two separate studies which show ARG-007 significantly inhibits the cellular uptake and aggregation of tau protein in two different in vitro Alzheimer's disease models. The aggregation of tau protein into tangles inside brain cells, and the spread of abnormal tau within the brain through cellular uptake, is thought to be a significant cause of Alzheimer's disease, with the spread and cellular uptake of abnormal tau a key hallmark of Alzheimer's disease progression.

These two studies indicate ARG-007 has the capacity to significantly reduce the uptake of abnormal tau into brain cells. Utilising two separate preclinical models, the studies showed a 68% and 49% reduction in the two models respectively, thereby potentially limiting the spread of abnormal tau between brain cells. The studies also indicate that ARG-007 inhibits intracellular tau aggregation by up to 89% in the first study and 35% in the second study.

This data, together with previously reported data, demonstrates that ARG-007 has a significant impact on a number of key proteins implicated in neurodegenerative diseases, namely beta-amyloid, alpha-synuclein, and now tau, making ARG-007 an exciting multi-modal protein targeting therapeutic.

Please refer to ASX announcement "Preclinical Data Shows ARG-007 Inhibits a Second Main Cause of Alzheimer's Disease" released on 3 November 2023 for further detail on the studies. Argenica is continuing to progress in vivo animal studies to further confirm the efficacy of ARG-007 in Alzheimer's disease and will update the market as milestones are met.

PERSONNEL UPDATES

During the quarter, Argenica was pleased to welcome two additions to the Company.

Celina Chew was appointed Vice President of Business Development and will work closely with Managing Director Liz Dallimore in a part-time capacity to assist on business development activities, including partnering and M&A activities. Celina is a qualified lawyer by training having graduated from the University of Western Australia and University of Hong Kong. From 2014 to2019 Celina was the President for the Greater China area for global life sciences company Bayer and was named in Forbes' China 100 Most Powerful Businesswomen Lists of 2017 and 2018.

Ms Dianne Angus was appointed as Non-Executive Chair, effective 1 December 2023. Dianne brings extensive executive managerial and company director experience in the life sciences sector across both public and private companies in biotechnology, biopharmaceutical, agritech and healthcare. She has long been involved in shaping new asset innovation and path to market development and commercialisation in these industries, notably including the clinical validation of drug therapeutics to create asset valuation uplift. Dianne has expertise in forging partnerships, technology valuation and product licensing to accelerate commercialisation into global markets. She has held executive and director roles in a number of ASX and NASDAQ-listed companies and as is currently Non-Executive director of Neuren Pharmaceuticals Ltd (ASX: NEU), Cyclopharm Ltd (ASX: CYC) and Imagion Biosystems Ltd (ASX: IBX). Dianne is a council member of Deakin University and serves on its Finance and Business Affairs committee.

Dianne holds a Master of Biotechnology, Bachelor of Science (Hons) and a Graduate Diploma of Intellectual Property (IP) Law. She is a registered patent attorney and a member of Australian Institute of Company Directors (AICD).

CASHFLOW COMMENTARY, CASH RESERVES OF \$8.4 MILLION AS AT 31 DECEMBER 2023

The Company had net cash operating <u>inflows</u> for the quarter of \$1.014 million including receipt of a \$2.089 million R&D tax rebate for the financial year ending 30 June 2023 and cash reserves of \$8.421 million as at 31 December 2023.

During the quarter, the Company also benefited from \$0.286 million of non-dilutive grant funding under the Western Australian government's Innovation Seed Fund Program. As previously announced, the project "Improving Therapeutic Delivery to Halt or Slow Alzheimer's Disease Progression" has been awarded a total of \$0.419 million in grant funding to contribute towards Argenica's ongoing preclinical program of work to develop a new administration route for ARG-007 that is non-invasive, i.e. not delivered through intravenous administration.

Operating cash outflows in the quarter included expenditure on research and development activities of \$1.040 million (Sep23Q: \$1.728 million), staff costs (including research and development employees) of \$0.240 million (Sep23Q: \$0.258 million) and corporate administration of \$0.183 million (Sep23Q \$0.208 million). Research and development expenditure included payments to third party contractors undertaking pre-clinical studies and Phase 2 clinical trial preparation activities and drug manufacture.

An Advance and Overseas Finding has 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 \$0.145 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 recently 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 progressing towards a Phase 2 clinical trial in ischaemic stroke patients, as well as continuing to generate preclinical data in other neurological conditions, including in TBI, HIE and Alzheimer's Disease.



Appendix 4C

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

Name of entity

	7
ARGENICA THERAPELITICS LIMITED	
A COLINO A THE CALL ESTIGNET COLOR	
<u> </u>	

ABN

Quarter ended ("current quarter")

78 637 578 753 31 DECEMBER 2023

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,040)	(2,768)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(240)	(498)
	(f) administration and corporate costs	(183)	(391)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	25	52
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives - CRCP grant	-	77
	- WA Seed Innovation Grant	286	286
	- R&D tax rebate	2,089	2,089
1.8	Other (provide details if material)		
	- Net GST (paid) / received	77	9
1.9	Net cash from / (used in) operating activities	1,014	(1,144)

2.	Cash flows from investing activities	
2.1	Payments to acquire or for:	
	(a) entities	-
	(b) businesses	-
	(c) property, plant and equipment	-

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

Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (6months) \$A'000
	(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	-	240
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(14)
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	-	226

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	7,407	9,339
4.2	Net cash from / (used in) operating activities (item 1.9 above)	1,104	(1,144)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6months) \$A'000
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)	-	226
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	8,421	8,421

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	8,377	7,357
5.2	Call deposits	51	50
5.3	Bank overdrafts	(7)	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	8,421	7,407

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	145
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
	if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include nation for, such payments.	a description of, and an

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	arter end	
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.		itional financing

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	1,014
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,421
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	8,421
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/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.

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.

8.6

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 JANUARY 2024
Authorised by:	By the Board of the Company

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".
- 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.