APPENDIX 4C – 30 SEPTEMBER 2023

QUARTERLY ACTIVITIES & CASHFLOW REPORT

Highlights:

- *Ethics approval received allowing the Company to undertake its proof-of-concept Phase 2 clinical trial of ARG-007 in acute ischaemic stroke patients. Trial sites are currently being established in up to ten hospitals across Australia. Patient recruitment and dosing is expected to commence in Q1 CY 2024.*

- *ARG-007 has shown to be an effective stand-alone therapy in a preclinical study of term hypoxic ischaemic encephalopathy. Given the consistency in brain injury reduction seen with ARG-007 treatment in small animal studies, larger animal studies funded by the Stan Perron Charitable Foundation will now be completed to confirm these positive results.*

- *A $419,000 grant was awarded under the Western Australian government's Innovation Seed Fund Program to develop a non-intravenous administration route for ARG-007, aiming to better serve chronic conditions such as Alzheimer's Disease. Alzheimer's Disease preclinical efficacy study being repeated due to issues with control animals.*

- *Advance and Overseas Finding approved by AusIndustry during the quarter 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 2023, 2024 & 2025 financial years.*

- *Cash reserves of $7.4 million as at 30 September 2023. R&D tax incentive claim for the financial year ending 30 June 2023 has been lodged, a rebate of $2.089 million expected in the current quarter, subject to review and payment by the ATO.*

Perth, Australia; 26 OCTOBER 2023 - 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 update and attached Appendix 4C Quarterly Cashflow Report for the 3-month period ended 30 September 2023.

Argenica's core focus is the preparatory activities for its imminent Phase 2 clinical trial of ARG-007 in ischaemic stroke patients. This proof-of-concept clinical trial to assess safety and preliminary efficacy in a human patient population is a pivotal moment for the Company.

In parallel, the Company is undertaking focussed preclinical studies supported by non-dilutive funding to generate the efficacy data required to progress ARG-007 into clinical trials for other neurological conditions where ARG-007 may have a therapeutic benefit, including hypoxic ischaemic encephalopathy (HIE) traumatic brain injury (TBI) and Alzheimer's Disease. Over $4 million in non-dilutive grant and philanthropic funding has been secured 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.

ETHICS APPROVAL RECEVIED FOR PHASE 2 CLINICAL TRIAL IN STROKE PATIENTS, ON TRACK FOR PATIENT RECRUITMENT AND DOSING TO COMMENCE IN Q1 CY 2024

During the quarter, Argenica was pleased to obtain ethics approval from the St Vincent's Hospital Melbourne's Human Research Ethics Committee (HREC), allowing the Company to undertake a Phase 2 proof-of-concept clinical trial of ARG-007 in acute ischaemic stroke (AIS) patients. This approval allows Argenica to commence establishing trial sites in up to ten hospitals across Australia. Site governance activities are now underway in conjunction with our Clinical Research Organisation (CRO) partners ProPharma and Alithia Life Sciences. Preparations remain on track to enable patient recruitment and dosing to commence in Q1 CY 2024.

Up to 92 eligible patients will be dosed in the trial who will be randomly assigned to receive either ARG-007 or a saline placebo (ratio 1:1 respectively) administered as a single intravenous (IV) dose soon after presentation to the emergency department. Both the site staff treating patients and the patients themselves will be blinded to the treatments.

The Primary Objective of the trial is to evaluate the safety of a single dose of ARG 007 in participants with AIS. The Secondary Objective is to characterize the effect of ARG 007 on reducing infarct volume (volume of brain cell death) in participants with AIS. The Company's ASX announcement released on 12 September 2023 provides detail on the clinical trial design.

The Company is confident that it has designed a robust trial that is well structured and considered. Positive feedback and guidance was obtained during the quarter from the from the US Food and Drug Administration (FDA) under a pre-investigational new drug type B meeting request (pre-IND meeting). This guidance includes a review of Argenica's Chemistry, Manufacturing and Controls (CMC) program, preclinical efficacy data, safety and toxicology data, and clinical trial program. The FDA's feedback confirmed the Phase 2 trial protocol assessing ARG-007 in acute ischaemic stroke patients was acceptable to assess preliminary efficacy (proof-of-concept) of ARG-007.

The drug manufacturing process is being undertaken by Melbourne based peptide manufacturer AusPep Clinical Peptides who are producing the Good Manufacturing Practices (GMP) drug substance. The drug substance will be delivered to European based specialised contract drug manufacturer Corden Pharma, who has the expertise to produce ARG-007 in a sterilised form ready for patient administration. The drug manufacture activities remain on track to enable vials to arrive at trial sites in Australia ready for dosing of patients in Q1 CY2024.

Argenica has also recently engaged Brainomix (a University of Oxford spin-out and now an established SME), who pioneered the development of Brainomix 360, a platform incorporating artificial intelligence (AI) modules that automates validated and proprietary imaging biomarkers to support accurate imaging diagnosis and assessment of endpoints in clinical trials. Brainomix owns the world's most comprehensive stroke imaging solution, which has received FDA clearance along with regulatory clearances in Europe, Middle East, and South America. Argenica will be collaborating with Brainomix on a program of work to overlay the AI biomarkers driven by the Brainomix 360 platform across all images generated in the Company's Phase 2 clinical trial to provide further data on infarct volumes and treatment effect.

***HYPOXIC ISCHAEMIC ENCEPHALOPATHY (HIE)* – ARG-007 AN EFFECTIVE STAND-ALONE THERAPY IN A PRECLINICAL STUDY OF TERM 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.

To meet the requirements to undertake clinical trials in HIE in the US, Argenica has initiated 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.

Subsequent to quarter end, Argenica was pleased to announce the results of a preclinical study to assess the reduction in total brain injury following HIE following standard of care therapeutic hypothermia and ARG-007, and the combination of the two, to determine if there was any benefit to combining ARG-007 with standard of care hypothermia. The findings indicate ARG-007 could be suitable as a combined neuroprotection therapy for HIE with hypothermia or as a stand-alone therapy when hypothermia cannot be used. Please refer to the ASX announcement released on 18 October 2023 for further details on the study.

Given the consistency in brain injury reduction seen with ARG-007 treatment in small animal studies, these latest results now draw these studies to completion and the larger animal studies funded by the SPCF will be completed to confirm these positive results.

ALZHEIMER'S DISEASE – GRANT FUNDING AWARDED TO DEVELOP A NON-INTRAVENOUS ADMINISTRATION ROUTE FOR ARG-007, AIMING TO BETTER SERVE CHRONIC CONDITIONS SUCH AS ALZHEIMER'S DISEASE, AND PRE-CLINICAL EFFICACY STUDY TO BE REPEATED.

During the quarter, Argenica was awarded $419,000 in non-dilutive grant funding under the Western Australian government's Innovation Seed Fund Program to develop a non-intravenous administration route for ARG-007, aiming to better serve chronic conditions such as Alzheimer's Disease.

Multiple drug delivery methods would better enable Argenica to develop additional drug products relevant to patient needs. Traditionally methods such as tablets or nasal sprays are preferable for chronic conditions requiring ongoing treatment, whereas acute conditions, like strokes, which require rapid and one-off treatment, are more suited to intravenous delivery. Once grant documentation is finalised, Argenica's next steps involve developing a new route of administration formulation of ARG-007 and optimising its dose in a preclinical Alzheimer's Disease model to determine efficacy.

In March 2023, the Company engaged QPS, an Austrian based Contract Research Organisation to undertake an *in vivo* preclinical study to assess the efficacy of ARG-007 in the 5xFAD mouse model of Alzheimer's Disease, a mouse model with a total of five Alzheimer's Disease linked mutations. The study involves aged mice receiving multiple doses of ARG-007 over an extended period of time, with results to assess the effect on Abeta levels and plaques, Tau protein levels, neuroinflammation, and neurodegeneration.

This study is generously funded by the McCusker Charitable Foundation, who have a long history of supporting medical research and the advancement of medical science in Western Australia, in particular in Alzheimer's Disease research and Mr Jim Litis who is a long-standing and generous supporter of the Perron Institute. A total of $350,000 in non-dilutive funding has been received.

Argenica has been advised by QPS that the study has been terminated due to unexplained deaths in both the normal **control** animals and the 5xFAD **control** animals, meaning there were insufficient numbers of control animals to validate the experimental data. There were no deaths in the ARG-007 treatment 5xFAD mice group. Due to these unexplained deaths and lack of control animals, the study will be repeated at no additional cost to Argenica. The repeated study has now commenced with no deaths reported to date. Results of the repeated study are now expected later in 2024. Whilst the delay is unfortunate, it is a risk with small animal studies and the delay does not impact the timelines of the Company's planned core activities. We confirm that the termination was not a result of the administration of ARG-007.

***TRAUMATIC BRAIN INJURY (TBI)* – CRC-P GRANT PROJECT PROGRESSING**

Argenica is progressing its TBI preclinical activities through a project supported by $1.2 million in non-dilutive grant funding from the federal government's Cooperative Research Centre

Projects (CRC-P) program. The preclinical program of work is being undertaken in collaboration with Curtin University, The University of Adelaide, peptide manufacturer AusPep and Connectivity Traumatic Brain Injury Australia, to assess the efficacy of ARG-007 in preclinical animal models of mild to moderate TBI. These studies commenced during the quarter with results anticipated to be provided during 2024.

CASHFLOW COMMENTARY, CASH RESERVES OF $7.4 MILLION AS AT 30 SEPTEMBER 2023

The Company had net cash operating outflows for the quarter of $2.158 million and cash reserves of $7.407 million as at 30 September 2023. Argenica notes it has lodged its R&D tax incentive claim for the financial year ending 30 June 2023 and anticipates receiving a rebate of $2.089 million in the current quarter, subject to review and payment by the ATO.

During the quarter, the Company benefited from non-dilutive grant funding from the federal government CRC-P grant program ($0.077 million) being used to progress preclinical studies into the efficacy of ARG-007 in TBI. Argenica has now received $0.758 million of the $1.200 million CRC-P grant with remaining funds to be received in quarterly instalments up to April 2025 subject to satisfactory progress on project milestones.

Operating cash outflows in the quarter included expenditure on research and development activities of $1.728 million (Jun23Q: $1.681 million), staff costs (including research and development employees) of $0.258 million (Jun23Q: $0.256 million) and corporate administration of $0.208 million (Jun23Q $0.307 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.

The Company had net financing cash inflows for the quarter of $0.226 million from the exercise of 800,000 options to raise $0.240 million (before costs).

In addition, an Advance and Overseas Finding was approved by AusIndustry during the quarter 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 2023, 2024 & 2025 financial years.

As required by ASX Listing Rule 4.7C3, the Company notes that $0.156 million was paid to related parties during the quarter (as noted in section 6 of the attached Appendix 4C) and these payments included (i) salary and superannuation paid to Executive Directors ($0.119 million) and (ii) Directors fees and superannuation paid to Non-Executive Directors ($0.036 million).

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	
ARGENICA THERAPEUTICS LIMITED	
ABN	**Quarter ended ("current quarter")**
78 637 578 753	30 SEPTEMBER 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,728)	(1,728)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(258)	(258)
	(f) administration and corporate costs	(208)	(208)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	27	27
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives		
	- CRCP grant	77	77
	- R&D tax rebate	-	-
1.8	Other (provide details if material)		
	- Net GST (paid) / received	(68)	(68)
1.9	**Net cash from / (used in) operating activities**	**(2,158)**	**(2,158)**

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

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3months) $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	240
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(14)	(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**	**226**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	9,339	9,339
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,158)	(2,158)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3months) $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	226
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**7,407**	**7,407**

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	7,357	9,289
5.2	Call deposits	50	50
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**7,407**	**9,339**

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	156
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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 quarter 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.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,158)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,407
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,407
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3.4

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

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: ....26 October 2023.....

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.