

## APPENDIX 4C – 30 JUNE 2023

# QUARTERLY ACTIVITIES & CASHFLOW REPORT

### Highlights:

- *Final Phase 1 Clinical Trial Report received confirming Argenica successfully passes critical milestone.*
- *Planning for the Phase 2 clinical trial in acute ischaemic stroke patients is well advanced with key suppliers selected, contracts advanced, preliminary manufacturing activities underway, long lead time items ordered, and the protocol and investigational brochure finalised. Ethics application submitted in July 2023 which seeks approval to commence this trial in Australian hospitals.*
- *Progressed preclinical studies in other key neurological indications outside of stroke in which ARG-007 may have a therapeutic benefit, with positive results in HIE and TBI during the quarter.*
- *Successfully completed a \$4.0 million placement. The capital raise was well supported by large existing shareholders, family offices, new institutional investors, and sophisticated high-net-worth investors. The funding will enable the Company to commence its Phase 2 trial of ARG-007 in acute ischaemic stroke patients.*
- *Cash reserves of \$9.3 million as at 30 June 2023 including placement funds. Argenica benefited from non-dilutive cash funding totalling \$0.4 million during the quarter from a CRC-P grant program. This funding will be used to progress preclinical studies into the efficacy of ARG-007 in TBI.*

**Perth, Australia; 24 JULY 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 12-month period ended 30 June 2023.

In parallel with planning for a Phase 2 clinical trial of ARG-007 in ischaemic stroke patients, Argenica is actively undertaking preclinical studies to generate 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. Given ARG-007 has already proven safe in the Phase 1 clinical trial, and following generation of sufficient preclinical data, the Company will be able to move straight into Phase 2 trials in other indications where a single dose of ARG-007 is given, such as severe TBI and HIE, as well as surgically induced stroke.

Over \$4 million in non-dilutive grant and philanthropic funding has been secured to support further preclinical activities in these other neurological indications. Argenica is very appreciative of the funding support received from the federal government, the Stan Perron Charitable Foundation, the McCusker Foundation, and donors to the Perron Institute to progress therapeutic areas of TBI, HIE and Alzheimer's Disease.

Key activities undertaken during the quarter are outlined below.

#### **FINAL PHASE 1 CLINICAL TRIAL REPORT RECEIVED CONFIRMING ARGENICA SUCCESSFULLY PASSES CRITICAL MILESTONE**

The final Phase 1 Clinical Trial Report was received during the quarter provided by clinical research organisation Linear Clinical confirming ARG-007 is safe, well tolerated and has a favourable pharmacokinetics profile. Please refer to ASX announcement on 15 May 2023 for further detail on trial results. The final clinical trial report is a critical component of Argenica's ethics submission for initiating a Phase 2 trial in ischaemic stroke patients.

#### **PLANNING FOR PHASE 2 CLINICAL TRIAL IN STROKE PATIENTS WELL ADVANCED WITH ETHICS APPLICATION SUBMITTED**

During the quarter, Argenica was pleased to secure additional funding via a \$4.0 million placement which will enable the Company to commence its Phase 2 trial of ARG-007 in ischaemic stroke patients.

Planning activities for the Phase 2 trial were significantly advanced with global Clinical Research Organisation ProPharma engaged, who have extensive experience in supporting acute trials in emergency settings. Site start-up activities at each of the proposed clinical trial sites commenced, with global stroke leader Prof Graeme Hankey (the trial's National Coordinating Principal Investigator) and key trial personnel engaging the Neurology and Stroke Departments at each of the proposed trial sites to provide background on the trial and determine the most appropriate Principal Investigator Neurologist at each hospital.

The drug manufacturing process was also initiated with Melbourne based peptide manufacturer AusPep Clinical Peptides who will produce the Good Manufacturing Practices (GMP) drug substance for delivery to European based specialised contract drug manufacturer

Corden Pharma, who has the expertise to produce ARG-007 in a sterilised form in vials ready for immediate patient administration. It is expected that the vials will arrive at trial sites in Australia by mid-December 2023 ready for administration to patients as recruitment and dosing of patients commences in Q1 CY2024.

This week, Argenica submitted an ethics application seeking approval to commence a Phase 2 trial of ARG-007 in AIS patients to St Vincent's Hospital Melbourne's (SVHM) Human Research Ethics Committee (HREC). The ethics approval will allow Argenica to undertake its Phase 2 trial in up to 10 hospitals (trial sites) across Australia. The ethics submission for Argenica's Phase 2 trial is through the National Mutual Acceptance program. This means Argenica is only required to submit its ethics application to one HREC at one hospital to gain approval to conduct its trial across multiple Australian hospitals, thereby speeding up the time to commence the trial. SVHM has confirmed that a decision on the outcome will be received by Argenica in mid-September 2023.

The Phase 2 trial will be a Multicenter, Double-Blinded, Randomized, Placebo-Controlled, Parallel-Group, Single-Dose Study to Determine the Safety, Preliminary Efficacy, and Pharmacokinetics of ARG-007 in Acute Ischemic Stroke Patients (SEANCON). The trial will be conducted in up to 10 hospitals across Australia that have dedicated stroke care units capable of performing endovascular thrombectomy. Following treatment, patients will be assessed for key safety outcomes as well as infarct volume and functional outcomes via a number of standard assessments. The detailed Phase 2 protocol and an overview of the Phase 2 timeline will be provided following HREC approval.

Argenica has also been granted a pre-Investigational New Drug Application (pre-IND) Type B meeting with the FDA which will be provided as a written response. The FDA will review Argenica's proposed development program for ARG-007 in acute ischaemic stroke and provide feedback on its view on the appropriateness of the program of work under its IND regulations. Argenica will submit its briefing book to the FDA shortly, with an expected written response due by late August 2023.

#### **TRAUMATIC BRAIN INJURY (TBI) - ARG-007 PROTECTS BRAIN CELLS IN MODERATE TRAUMATIC BRAIN INJURY MODEL, CRC-P GRANT PROJECT UNDERWAY**

During the quarter, Argenica released results of a preclinical study in which ARG-007 was shown to significantly reduce damage to brain cells caused by moderate traumatic brain injury (modTBI) as assessed in a preclinical rat model, compared to placebo treated controls.

Damage to brain cells was assessed by measuring the accumulation of key proteins which contribute to brain cell injury and death following moderate TBI. Importantly, the protein levels following ARG-007 treatment were equivalent to non-injured animals. The level of an inflammation marker (Iba1) in the brain was also significantly reduced back to non-injured levels. Inflammation in the brain following TBI is an important cause of secondary brain injury

which lasts far beyond the initial injury. Refer to the ASX announcement on 22 June 2023 for further detail on the study.

The results from Argenica's first preclinical study in a moderate TBI animal model were pleasing and we will now look to progress further studies, supported by funds provided by a CRC-P grant, to provide greater evidence of ARG-007's efficacy in TBI before establishing a clinical program of work.

As previously advised, Argenica has been awarded \$1.2M in 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". See announcement dated 20 January 2023.

This funding will contribute towards a preclinical program of work 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. The CRC-P program provides matched funding grants to recipients. The project's total cost is approximately \$2.7 million, therefore Argenica and its project collaborators will make salary, cash and in-kind contributions towards the remaining \$1.5 million of project costs. All intellectual property and commercialisation rights related to the project outcomes will remain solely with Argenica.

During the quarter, key contracts were finalised with The University of Adelaide and Curtin University to enable commencement of the next TBI pre-clinical study in Q3 CY 2023 and with Auspep who have commenced manufacturing the drug for the study.

#### **HYPOXIC ISCHAEMIC ENCEPHALOPATHY (HIE) - ARG-007 PROVIDES PROLONGED REDUCTION OF BRAIN INJURY IN LATEST PRECLINICAL STUDY & SIGNIFICANT NON-DILUTIVE FUNDING SECURED FOR PRECLINICAL EFFICACY STUDIES**

As noted in the last quarterly report, in April 2023, Argenica was pleased to announce the latest positive preclinical data in HIE showing the effect of a single dose of ARG-007 lasting out to four weeks in a preclinical term animal model of 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 requirements to undertake clinical trials in HIE in the US, Argenica has initiated a preclinical juvenile toxicology study and preclinical efficacy studies in a large animal term model of HIE. If these studies elicit positive results, then the Company's aim is to commence a Phase 1/2 trial in HIE in the US.

The preclinical efficacy studies are generously funded by a grant from the Stan Perron Charitable Foundation (see announcement dated 30 March 2023). Results of these studies

will be announced as they come to hand. Further pilot studies have now been initiated in the piglet and lamb models of HIE as covered by the grant, with data expected in CY2024. Additional studies assessing the combination of ARG-007 with standard of care hypothermia in a term rat animal model have also commenced with results expected in Q3 CY2023.

### **CASHFLOW COMMENTARY, CASH RESERVES OF \$9.3 MILLION AS AT 30 JUNE 2023**

The Company had net cash operating outflows for the quarter of \$1.886 million and cash reserves of \$9.339 million as at 30 June 2023.

During the quarter, the Company benefited from non-dilutive grant funding from a federal government CRC-P grant program (\$0.400 million) which will be used to progress preclinical studies into the efficacy of ARG-007 in TBI. Argenica has received \$0.681 million of the \$1.200 million CRC-P grant to date 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 \$1.681 million (Mar23Q: \$0.888 million), staff costs (including research and development employees) of \$0.256 million (Mar23Q: \$0.256 million) and corporate administration of \$0.307 million (Mar23Q \$0.176 million). Research and development expenditure included payments to third party contractors undertaking pre-clinical studies for the Phase 1 clinical trial and additional applications of ARG-007, Phase 1 trial contractors, regulatory consultants and up-front payments to enable commencement of drug product manufacture for the Phase 2 trial which is a key long lead item.

The Company had net financing cash inflows for the quarter of \$3.725 million from the issue of 11,428,572 new fully paid ordinary shares at an issue price of \$0.35 to raise \$4.000 million (before costs).

As required by ASX Listing Rule 4.7C3, the Company notes that \$0.155 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).

### **IPO PROSPECTUS USE OF FUNDS COMPARED TO ACTUAL EXPENDITURE**

In accordance with ASX listing rule 4.7C.2, the Company provides below a use of funds comparison table showing actual spend for the period 23 April 2021 to 30 June 2023 compared to the intended use of funds table provided in the Company's IPO prospectus lodged with ASIC on 23 April 2021.

The use of funds table in the Prospectus outlined the Company's intended use of funds in the two-year period following Admission of the Company to the Official List of the ASX. It should

be noted that these are estimates and will be subject to modification on an ongoing basis depending on the results obtained from the Company's activities.

It should also be noted Argenica has and intends to apply for and has received cash rebates on eligible research and development (R&D) expenses under the Australian Commonwealth Government's R&D tax incentive program to assist funding its R&D activities. The current scheme provides a refundable tax offset for expenditure on certain eligible R&D activities. As this funding is uncertain it was not included in the use of funds in the Prospectus.

Source of funds	Prospectus \$'000	Actual \$'000
Approximate cash as at the date of Prospectus / Opening cash balance	\$1,034	\$1,034
Proceeds from the IPO Public Offer	\$7,000	\$7,000
Placement	-	\$9,500
Grant funding	-	\$1,031
R&D tax incentive rebate	-	\$1,637
Interest received	-	\$64
<b>Total funds available</b>	<b>\$8,034</b>	<b>\$20,266</b>
Use of funds		
Pre-clinical development activities	\$2,175	\$3,771
Clinical trial and safety assessment (phase 1)	\$1,525	\$1,776
Product development and planning activities for clinical trial (phase 2a)	\$300	\$894
Regulatory approval strategy and preparation	\$550	\$452
IP protection costs	\$150	\$134
Corporate administration & working capital	\$2,579	\$2,494
Placement share costs	-	\$637
Costs of the IPO Offer	\$755	\$769
<b>Total Expenditure</b>	<b>\$8,034</b>	<b>\$10,927</b>
<b>CLOSING CASH BALANCE</b>	<b>-</b>	<b>\$9,339</b>

*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 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**

78 637 578 753

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

30 JUNE 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	350
1.2 Payments for		
(a) research and development	(1,681)	(3,942)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(256)	(1,023)
(f) administration and corporate costs	(307)	(778)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	21	61
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives		
- CRCP grant	400	681
- R&D tax rebate	-	1,378
1.8 Other (provide details if material)		
- Net GST (paid) / received	(63)	(21)
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,886)</b>	<b>(3,294)</b>

<b>2. Cash flows from investing activities</b>		
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 (12months) \$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	<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)	4,000	4,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(275)	(281)
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	<b>Net cash from / (used in) financing activities</b>	<b>3,725</b>	<b>3,719</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	7,500	8,914
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,886)	(3,294)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12months) \$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)	3,725	3,719
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	<b>Cash and cash equivalents at end of period</b>	<b>9,339</b>	<b>9,339</b>

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	9,289	7,500
5.2	Call deposits	50	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>9,339</b>	<b>7,500</b>

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	155
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. 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>		
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)	(1,886)
8.2 Cash and cash equivalents at quarter end (item 4.6)	9,339
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	9,339
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	5.0
<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: ....24 July 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.