# APPENDIX 4C – 30 JUNE 2024

# QUARTERLY ACTIVITIES & CASHFLOW REPORT

**Highlights:**

- *Positive progress made in Argenica's Phase 2 clinical trial. Eight of the ten participating hospitals have now been activated, with the remaining two hospitals to be activated by the end of July 2024. Since the first patient was dosed at the end of March 2024, a total of* ***23 patients*** *(out of 92) have been recruited into the trial and dosed at five of the eight activated sites. This now triggers the second DSMB meeting to review safety data.*

- *Pre-clinical study showed ARG-007 significantly reduced damage to brain cells in a ferret animal model of mild to moderate traumatic brain injury (modTBI), a model that closely resembles the gross anatomy of the human brain.*

- *Cash reserves of $15.9 million as at 30 June 2024.*

- *Successfully raised $12.0 million (before costs) via a placement to institutional and sophisticated investors. The Company is now fully funded to complete its Phase 2 trial of ARG-007 in ischaemic stroke patients, as well as progress studies in its other neurological indications.*

**Perth, Australia; 31 JULY 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 12-month period ended 30 June 2024.

Argenica's core focus is on its Phase 2 clinical trial of ARG-007 in acute ischaemic stroke 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 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. 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 positive progress in activating trial sites and patient recruitment in its Phase 2 clinical trial of ARG-007 in acute ischaemic stroke patients.

### Clinical Trial Sites

Eight of the ten hospitals participating in the Phase 2 trial have now been activated, with the remaining two hospitals, being Monash Health and Gold Coast Hospital, expected to be activated imminently, both sites have now completed site initiation visits and final paperwork is being prepared for activation. Of the eight activated sites, two only completed activation at the end of June, being Fiona Stanley Hospital and Royal Brisbane & Women's, and Sir Charles Gairdner in mid July.

Having all hospitals activated from the beginning of August 2024 will mean more access to eligible patients presenting to hospital emergency departments with diagnosed acute ischaemic strokes, and which meet the trial's inclusion criteria.

### Patient Dosing

Patient recruitment is progressing as anticipated, with five of the eight activated sites having recruited and dosed patients. Since the first patient was dosed at the end of March 2024, a total of 23 patients have now been recruited and dosed in the trial.

To date, feedback from the trial sites has been very positive, with no issues reported with regards to patient consent or the ability to recruit and dose patients. Based on anticipated recruitment rates at each site, recruitment of patients into the trial is on track to complete dosing of all 92 patients before the recruitment target of the end of calendar year 2025.

### Data Safety Monitoring Board (DSMB)

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

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 will provide 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 first data review meeting occurred in April after the first 5 subjects were dosed in the trial with no drug related adverse events reported (ASX announcement dated 29 April, 2024). Subsequent patient safety reviews by the DSMB are scheduled at least every six months, subject to recruitment rates, with meetings to be held post dosing of 23 patients, 46 patients, 69 patients, and at the completion of dosing of all 92 patients. Trial enrolment will not be halted during each planned DSMB review of the safety data. With 25% of patient recruitment now completed, the DSMB will meet at the end of Q3 CY2024 to determine whether there are any safety issues and determine whether the trial can continue under the current study protocol.

**NEUROLOGY PIPELINE RESEARCH AND DEVELOPMENT FOR ARG-007**

**Traumatic Brain Injury (TBI) - ARG-007 Significantly Reduces Effects of TBI In Preclinical Ferret Study**

During the quarter, results were released on a pre-clinical efficacy study which showed ARG-007 significantly reduced damage to brain cells in a ferret animal model of mild to moderate traumatic brain injury (modTBI), a model that closely resembles the gross anatomy of the human brain.

The observed therapeutic effects of ARG-007 in the modTBI model included:

- a significant reduction in the accumulation of key proteins, amyloid precursor protein and neurofilament M-14.9, which are known markers of brain cell injury following modTBI. The protein levels following ARG-007 treatment in brain regions associated with memory and mental functioning were reduced back to the equivalent to non-injured animals.
- a significant reduction in the level of inflammation markers GFAP and Iba1 back to levels seen in non-injured animals, in the brain region associated with memory. This is important because inflammation in the brain following TBI is a cause of secondary brain injury which usually lasts far beyond the initial injury.

This study expands on previous published and announced data in rodent models of mod-TBI. It provides Argenica with further robust evidence regarding the potential of ARG-007 as a treatment following TBI. Argenica will continue to advance the preclinical efficacy studies in TBI including validating this study in a larger ferret study.

Please refer to ASX Announcement “ARG-007 Significantly Reduces Effects of TBI In Preclinical Ferret Study” released on 15 May 2024 for further details on the study

**CASHFLOW COMMENTARY, CASH RESERVES OF $15.9 MILLION AS AT 30 JUNE 2024, FOLLOWIING A SUCCESSFULLY COMPLETED $12.0M PLACEMENT**

The Company had net cash operating outflows for the quarter of $1.933 million and cash reserves of $15.900 million as at 30 June 2024.

During the quarter, the Company benefited from $0.077 million of 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".

Operating cash outflows in the quarter included expenditure on research and development activities of $1.348 million (Mar24Q: $1.533 million), staff costs (including research and development employees) of $0.308 million (Mar24Q: $0.318 million) and corporate administration of $0.327 million (Mar24Q $0.179 million). Research and development expenditure included payments to third party contractors undertaking pre-clinical studies and Phase 2 clinical trial activities including drug manufacture.

During the quarter, the Company raised $12.0 million (before costs) via a placement of 23,076,924 new fully paid ordinary shares at an issue price of $0.52. The placement was strongly supported by large existing shareholders, new institutional investors, family offices, and sophisticated high-net-worth investors. Following the placement, the Company is fully funded to complete its Phase 2 trial of ARG-007 in ischaemic stroke patients, as well as progress studies in its other neurological indications.

The Company has commenced preparation of its R&D Tax Incentive rebate return for the year ended 30 June 2024. 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 $0.161 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 has now initiated a Phase 2 clinical trial in ischaemic stroke patients, 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** | **Quarter ended ("current quarter")** |
| 78 637 578 753 | 30 June 2024 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date (12months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | - | 32 |
| 1.2 | Payments for | | |
| | (a) research and development | (1,348) | (5,649) |
| | (b) product manufacturing and operating costs | - | - |
| | (c) advertising and marketing | - | - |
| | (d) leased assets | - | - |
| | (e) staff costs | (308) | (1,156) |
| | (f) administration and corporate costs | (327) | (897) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 18 | 94 |
| 1.5 | Interest and other costs of finance paid | - | - |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | | |
| | - CRCP grant | 77 | 308 |
| | - WA Seed Innovation Grant | - | 209 |
| | - Other grants | - | 4 |
| | - R&D tax rebate | - | 2,089 |
| 1.8 | Other (provide details if material) | | |
| | - Net GST (paid) / received | (45) | (90) |
| **1.9** | **Net cash from / (used in) operating activities** | **(1,933)** | **(5,056)** |

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

| Consolidated 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) | 12,000 | 12,000 |
| 3.2 | Proceeds from issue of convertible debt securities | - | - |
| 3.3 | Proceeds from exercise of options | - | 417 |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | (783) | (800) |
| 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** | **11,217** | **11,617** |

| 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 | 6,616 | 9,339 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (1,933) | (5,056) |
| 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) | 11,217 | 11,617 |
| 4.5 | Effect of movement in exchange rates on cash held | - | - |
| **4.6** | **Cash and cash equivalents at end of period** | **15,900** | **15,900** |

| 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 | 3,861 | 6,578 |
| 5.2 | Call deposits | 12,051 | 51 |
| 5.3 | Bank overdrafts | (12) | (13) |
| 5.4 | Other (provide details) | - | - |
| **5.5** | **Cash and cash equivalents at end of quarter (should equal item 4.6 above)** | **15,900** | **6,616** |

| 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 | 161 |
| 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**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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) | (1,933) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 15,900 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 15,900 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 8.2 |

*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: ....31 July 2024.....

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.