ARGENICA THERAPEUTICS

# INVESTOR PRESENTATION ASX: AGN

OCTOBER 2023

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# INTRODUCTION TO ARGENICA

## NOVEL NEUROPROTECTIVE TREATMENTS

**ARG-007**
Argenica's novel neuroprotective drug

- Reduces brain damage after stroke and other brain injuries[1]
- Over a decade of development
- Potential to change stroke treatment

## A NEW FRONTIER IN MEDICINE

- There are **no** marketed drugs that protect the brain after stroke
- ARG-007 aims to fill this urgent and **unmet clinical need**
- There is **increasing interest** in neuroprotection from big pharma
- **Untapped** commercial opportunity with limited competition

## TARGETING MULTIPLE INDICATIONS

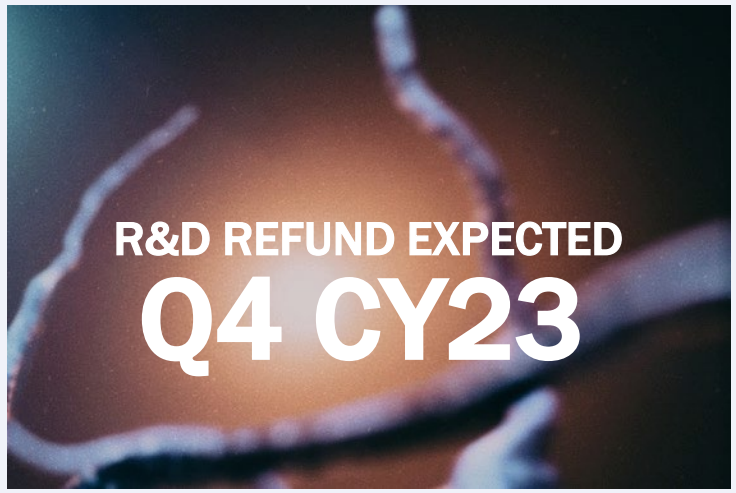
| | |
|---|---|
| **STROKE** | PHASE 2 |
| **SIS**[2] | PHASE 2 |
| **HIE** | PRE-CLINICAL |
| **TBI** | PRE-CLINICAL |
| **ALZHEIMER'S** | PRE-CLINICAL |
| **CARDIAC ARREST** | DISCOVERY |

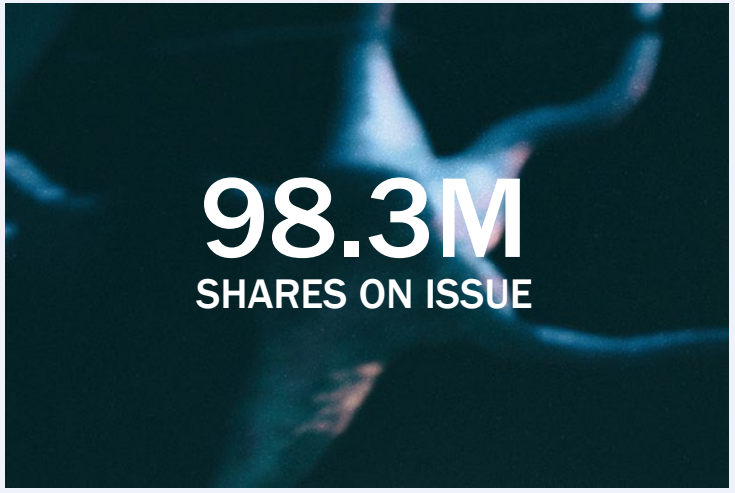
*1. Preclinical animal studies. Argenica's lead drug candidate ARG-007 is under development and subject to clinical validation*

*2. Data collected from the recent Phase 1 clinical trial could potentially be used to progress directly into surgically induced stroke (SIS) Phase 2 trials*

# KEY COMPANY METRICS








*1. Cash balance as @ 30 June 2023*
*2. Various ASX Announcements dated 20 January 2023, 22 March 2023, 30 March 2023, 12 September 2023*
*3. Calculated with closing price on @ 20th October being $0.35*

# THE DEVASTATING IMPACT OF STROKE

## INCIDENCE

**ONE IN FOUR**

people will suffer a stroke in their lifetime[1]

## SOCIETAL IMPLICATIONS

**ONLY 10%**

will recover almost completely, due to the extent of brain cell damage[1]

## THE IMPORTANCE OF TIME

**1.9 MILLION**

brain cells are attacked each minute during a stroke[2]

**Current markets cater to treatment & diagnosis of stroke, <u>not</u> protecting brain cells**

*[1] Stroke Foundation*

*[2] Saver, JL. (2006). "Time is Brain". Stroke., 37 (1), pp. 263-266*

# ARG-007 COULD PROVIDE A SOLUTION

## ARG-007

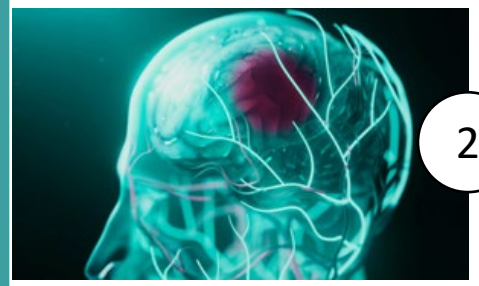
- Cationic poly-arginine peptide
- Multiple mechanisms of action
- Granted patents & strong IP
- Significant pre-clinical efficacy
- 25+ peer reviewed papers
- Proven safe for healthy humans

## HOW IT WORKS

ISCHEMIC STROKE EXAMPLE

1

INITIAL INFARCTION (STROKE) SETS OFF A CASCADE OF CELL DEATH



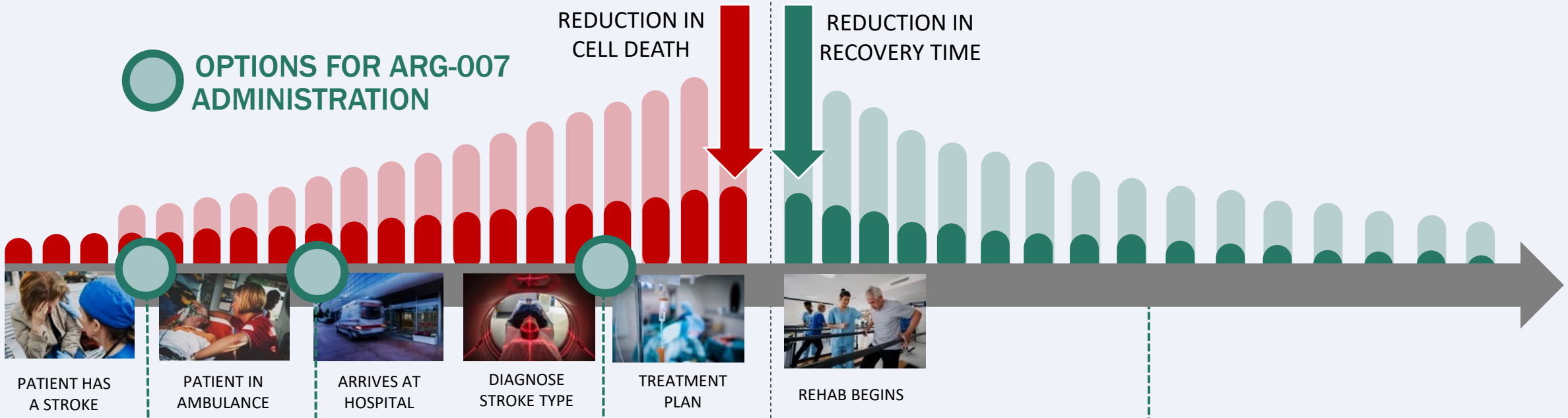
2

CELL DEATH **WILL CONTINUE SPREADING FROM LOCATION**

3

**ARG-007 STOPS THE CASCADE OF CELL DEATH** & PROVIDES A PROTECTION BARRIER AROUND THE INITIAL INFARCTION

# IMPLICATIONS FOR STROKE PATIENTS




- Point of care intervention in ambulance or hospital
- Slows the progression of brain cell death
- Extends treatment window

- Alternatively, can be administered prior to stroke treatment
- Clot removal can cause second wave of cell death as blood flow is restored

**Even a small reduction in cell death could have a huge impact…**

- Improves recovery time and quality of life
- Reduces hospitalisation time
- Potential to decrease post-care costs

*Potential benefits only. ARG-007 is under development and subject to clinical validation.*

# THE IDEAL STROKE THERAPEUTIC

## PREVIOUS BARRIERS FOR NEUROPROTECTIVE DRUGS

- Do not fit into current **standard of care**
- Past drugs focused on targeting **singular** mechanisms of action and used ineffective models
- Single target treatments **have not** been effective in clinical trials
- Industry is seeking drugs that target **multiple pathways** for stroke[1]

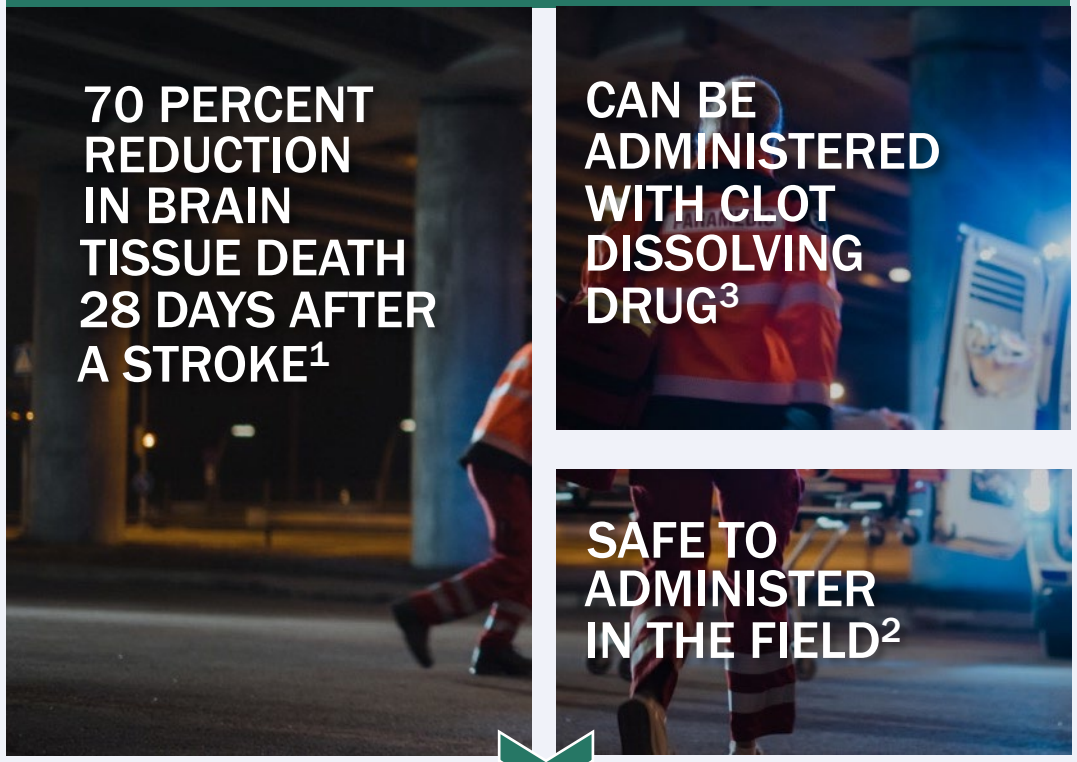
## WHAT SETS ARG-007 APART

- ARG-007 has **multi-functional** mechanisms of action
- Has shown **significant efficacy** in different animal models of ischaemic stroke
- **Cell penetrating peptide** can deliver therapeutic agent to the injured brain
- **Is not degraded** by current standard of care clot dissolving drugs[2]
- **Does not exacerbate bleeding**[3]

1. *Recommendations from the Stroke Treatment Academic Industry Roundtable (STAIR) urged a focus on plurifunctional agents that target multiple pathways for effective stroke therapy.*
2. *ASX Announcement 'Study shows arg-007 does not degrade when co-administered with ischemic stroke therapeutics' 12 July 2021*
3. Liddle, L. et al (2019). *PloS one*, *14*(11), e0224870.

# ENCOURAGING RESULTS TO DATE

## PRE-CLINICAL (ANIMAL STUDIES)




Efficacy is a <u>secondary</u> endpoint in our Phase 2 study

## SUCCESSFUL PHASE 1 (HUMAN STUDY)

- Doses of ARG-007 proved **safe and well-tolerated** in healthy human Phase 1
- **No serious adverse events were detected**
- ARG-007 did not cause an immune reaction
- Data shows ARG-007 is rapidly taken up by the body, with the highest concentration of AGR-007 observed at the end of infusion (10 minutes)
- More treatment-related adverse events were recorded from the group who received placebo

**Safety is our Phase 2 primary end point**

*These findings are preliminary in nature. A larger dataset will be required for clinical validation.*

*[1]* Meloni, B. P. et al (2020) *Neurotherapeutics : the journal of the American Society for Experimental NeuroTherapeutics*, *17*(2), 627–634
*[2]* Liddle, L. et al (2019). *PloS one*, *14*(11), e0224870.
*(3) ASX Announcement 'Study shows arg-007 does not degrade when co-administered with ischemic stroke therapeutics' 12 July 2021*

# PHASE 2 CLINICAL TRIAL IN STROKE

## OVERVIEW

- Up to 10 Australian hospitals
- Double-blinded, randomised, placebo-controlled study
- ARG-007 will be given to patients that have suffered a diagnosed **acute ischemic stroke eligible for thrombectomy**
- Objectives;
  1. Safety
  2. Tolerability
  3. Pharmacokinetics
  4. Preliminary Efficacy

## NEAR TERM TIMELINE

| | Q3 CY23 | Q4 CY23 | Q1 CY24 | Q2 CY24 |
|---|---|---|---|---|
| Pre-IND FDA meeting | ✓ | | | |
| Ethics approval | ✓ | | | |
| Hospital site start-up | | ★ | | |
| Manufacturing finalised | | ★ | | |
| ARG-007 arrives | | ★ | | |
| First patient dosed | | | ★ | |
| First independent review of patient safety data | | | | ★ |

*Timeline subject to change*

# PHASE 2 PROTOCOL

**ASSESSMENT**

**Scanning and diagnosis of stroke type in hospital**

**INCLUSION CRITERIA**

**Large vessel occlusion (LVO) stroke**

Diagnosed LVO stroke
+
Eligible for endovascular thrombectomy (mechanical removal of clot in the brain)

**RANDOMISED INTO TRIAL**

**ARG-007**

**Placebo**

Administrated via intravenous infusion over a 10 minute period prior to endovascular thrombectomy

**CLOT REMOVAL**

**Mechanical removal of clot in the brain**

Mechanical clot removal can result in **reperfusion injury**

**RECOVERY**

**Monitoring of the patient**

**Safety**

Participants will be followed up on Day 2, Day 3, Day 6 (or Discharge), Day 30, and Day 90 (End of Study)

**Efficacy**

Includes brain infarct volume between treatment groups as measured by imaging (MRI or non-contrast computer tomography)

**LVO STROKES ARE CONSIDERED THE MOST DEVASTATING TYPE OF STROKE:[1]**

- Account for close to 40% of all acute ischaemic strokes
- 60% of post-stroke dependency
- 90% of mortalities after stroke

1 - Malhotra K, Gornbein J, Saver JL. Ischemic Strokes Due to Large-Vessel Occlusions Contribute Disproportionately to Stroke-Related Dependence and Death: A Review. Front Neurol. 2017 Nov 30;8:651.

# POST PHASE 2 STRATEGY

## ESTIMATED TIMELINE FOR COMPLETION OF PHASE 2

- Final trial data could potentially be anytime from **H2 CY25 to H1 CY26**
- Timing is highly dependent on recruitment progress
- Argenica aims to provide updates during the trial as recruitment progresses
- All trial sites are located at hospitals with experience in conducting stroke clinical trials

**LICENSING OR PARTNERING:**
If the Phase 2 trial shows promising results, Argenica may license ARG-007 for stroke to a larger pharmaceutical group that has the resources to carry out larger Phase 3 trials and commercialisation

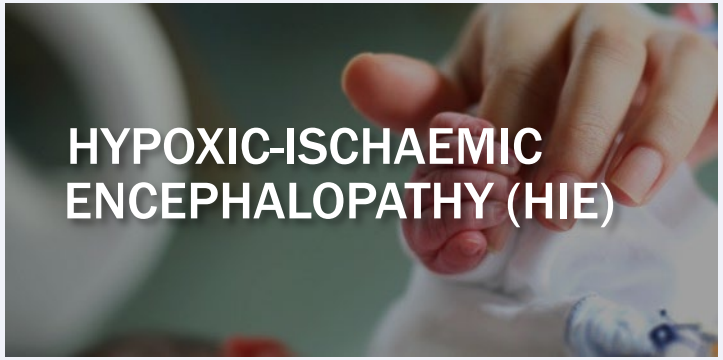
**MERGER & ACQUISITION:**
Successful Phase 2 results could make Argenica an attractive target for acquisition by larger pharmaceutical companies looking to bolster their pipeline across all Argenica's indications

**CO-DEVELOPMENT:**
Co-development in a stroke Phase 3 clinical trial involves collaboration between drug companies to jointly develop and potentially market a drug, pooling resources, expertise, and risks

# PIPELINE OF ADDITIONAL INDICATIONS


- Estimated USD$18.6bn market size by 2031[1]
- ARG-007 has shown efficacy in pre-clinical studies[2]
- Awarded A$1.2m grant to advance pre-clinical studies[3]


- Alzheimer's therapeutics market USD$13bn by 2031[4]
- Preclinical data shows ARG-007 inhibits amyloid beta aggregation, a key cause of Alzheimer's[5]
- Awarded A$350,000 grant to advance pre-clinical studies[6]




- HIE occurs in 1.5 to 2.5 births per 1000[7]
- Orphan drug designation / rare paediatric disease
- Awarded A$2.5m grant to advance pre-clinical studies[9]

*1. Traumatic brain injuries assessment market research, 2031 – Allied Market Research*

*2. ASX Announcement titled 'ARG-007 protects brain cells in moderate traumatic brain injury model' 22 June 2023*

*3. ASX Announcement titled 'Argenica awarded $1.2m grant for Traumatic brain injury project under the CRC-P program' dated 20 Jan 2023*

*4. Alzheimer's Therapeutics Market Global Opportunity Analysis 2021-2031 – Allied Market Research*

*5. Announcement titled 'Preclinical data shows arg-007 inhibits one of The main causes of alzheimer's disease' Dated 9 Feb 2023*

*6. ASX Announcement titled 'Non-dilutive funding received to progress Alzheimer's disease studies' dated 22 Feb 2023*

*7. Hypoxic Ischemic Encephalopathy: Pathophysiology and Experimental Treatments Kimberly A. Allen, MSN, RN and Debra H. Brandon, PhD, RN, CCNS, FAAN*

*8. Pre-clinical studies have shown ARG-007 provides neuroprotection in a term animal model of Perinatal Hypoxic Ischemic Encephalopathy (HIE) – ASX Announcement 29th September 2022.*

*9. ASX Announcement titled 'Significant non-dilutive funding to Complete preclinical hypoxic ischaemic Encephalopathy studies' dated 30 March 2023*

# DEVELOPING DIFFERENT ADMINISTRATION ROUTES

- Awarded $419,000 in non-dilutive grant funding under the Western Australian government's Innovation Seed Fund Program
- The funding will be used to develop a non-intravenous administration route for ARG-007, aiming to better serve chronic conditions
- Multiple drug delivery methods would better enable Argenica to develop additional drug products relevant to patient needs

## TABLETS, NASAL SPRAYS OR EPIPEN STYLE

Preferable for chronic conditions requiring ongoing neuroprotective treatment:

ALZHEIMER'S

MILD TBI

## INTRAVENOUS DELIVERY

Preferable for acute conditions which require rapid delivery to the blood stream:

STROKE

HIE

# INVESTMENT HIGHLIGHTS






ARGENICA THERAPEUTICS

For further information please contact:

**Dr Liz Dallimore**
CEO & Managing Director
E: info@argenica.com.au