



# INVESTOR PRESENTATION ASX: AGN

BIOSHARES 2025

MANAGING DIRECTOR PRESENTATION



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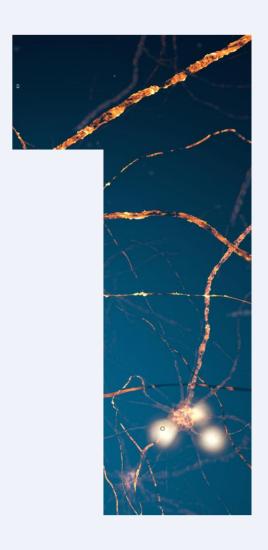
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# NEUROPROTECTION THE THERAPEUTIC OPPORTUNITY



# BREAKTHROUGH NEUROPROTECTIVE THERAPY



#### **MISSION**

Commercialise neuroprotective treatments that minimises brain damage and fosters recovery following stroke & other neurological conditions



#### **VISION**

Redefine the standard of care for stroke and other neurological conditions by reducing brain injury



**IMPACT** 

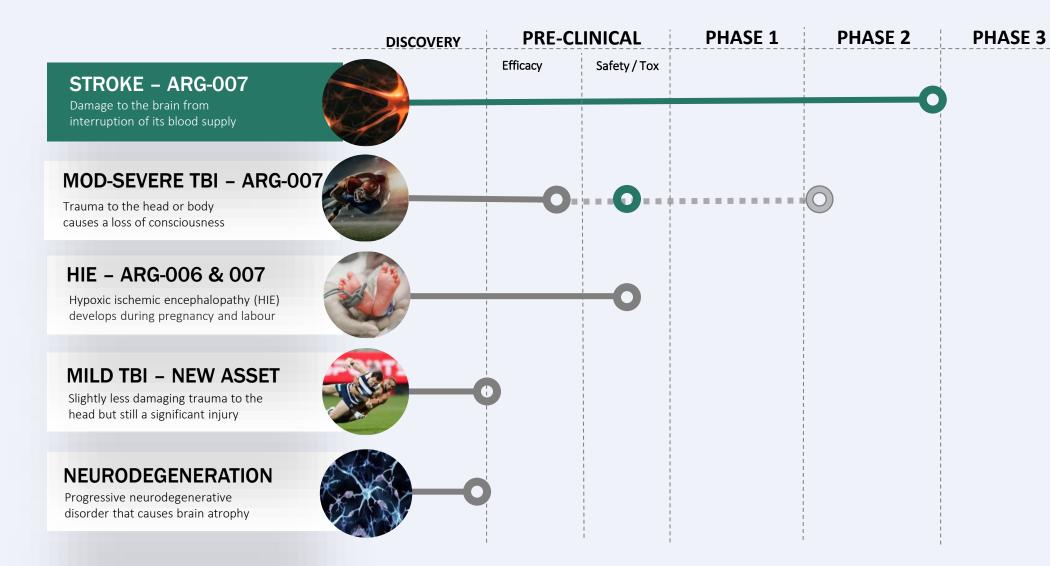
Create positive, life-altering impact for millions suffering from neurological conditions, offering new hope

#### **ABOUT ARG-007**

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



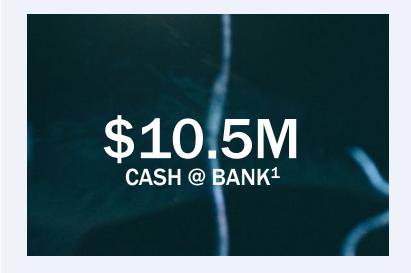
# **OUR LEAD INDICATIONS**







# **KEY COMPANY METRICS**











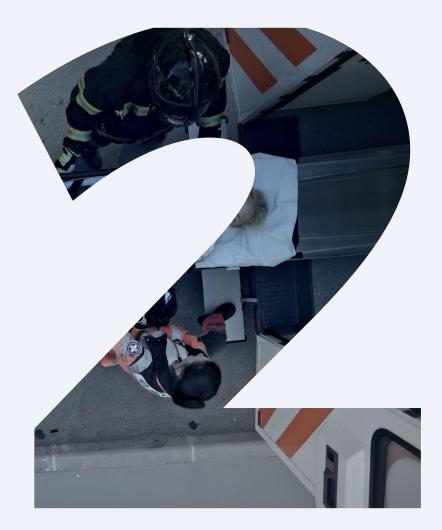


<sup>1.</sup> Cash balance as @ 30 June 2025

<sup>2.</sup> Calculated with closing price on @29<sup>th</sup> July 2025 being \$0.68

<sup>3.</sup> Various ASX Announcements dated 20 January 2023, 22 March 2023, 30 March 2023, 12 September 2023





# ISCHAEMIC STROKE TRIAL UPDATE



# SO WHY ARE WE TARGETING STROKE FIRST?

#### **INCIDENCE**



#### **45 SECONDS**

How often someone suffers an ischaemic stroke in the US<sup>1</sup>

#### **SOCIETAL IMPLICATIONS**



### **ONLY 10%**

will recover almost completely, due to the extent of brain cell damage<sup>2</sup>

#### THE IMPORTANCE OF TIME



#### 1.9 MILLION

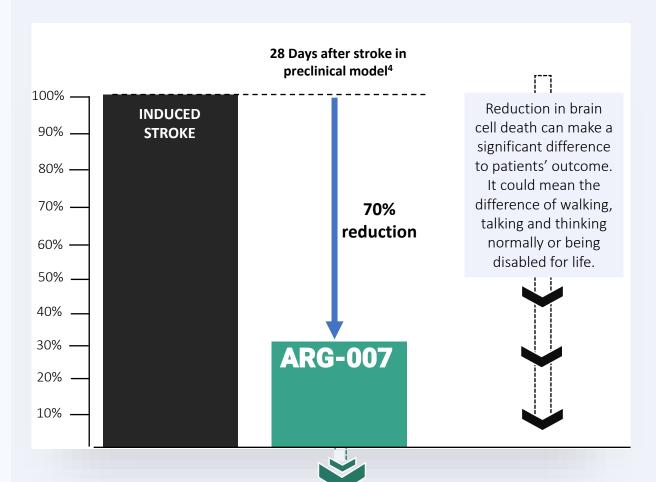
brain cells are attacked each minute during a stroke<sup>3</sup>

#### FIRST IN CLASS DRUG ADDRESSING LARGE UNMET NEED

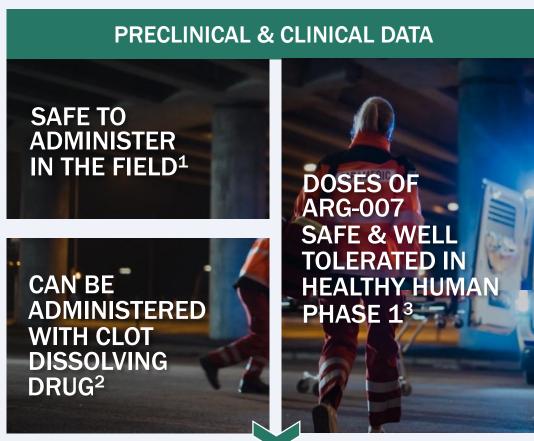
- 1. US Centers for Disease Control and Prevention (CDC)
- 2. Stoke Foundation
- 3. Saver, JL (2006). "Time is Brain". Stroke, 37 (1), pp 236-266



# **ENCOURAGING STROKE RESULTS TO DATE**



This protective effect remained significant (70%), showing a significant reduction in brain tissue death for at least 28 days post stroke following a single i.v. injection of ARG-007



#### PHASE 2 IN ISCHAEMIC STROKE PATIENT

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

- 1. Liddle, L. et al (2019). PloS one, 14(11), e0224870.
- 2. ASX Announcement 'Study shows arg-007 does not degrade when co-administered with ischemic stroke therapeutics' 12 July 2021
- 3. ASX Announcement 'Final Phase 1 Clinical Trial Report Confirms Argenica Successfully Passes Critical Milestone' 15 May 2023
- 4. Meloni, B. P. et al (2020) Neurotherapeutics: the journal of the American Society for Experimental NeuroTherapeutics, 17(2), 627–634



# PHASE 2 TRIAL DESIGN IN ACUTE ISCHAEMIC STROKE

PATIENT HAS A STROKE



PATIENT IN AMBULANCE



ARRIVES AT HOSPITAL



DIAGNOSE STROKE TYPE



**THROMBECTOMY** 



REHAB BEGINS



- Initial screening of patients to meet inclusion criteria
- Consent for thrombectomy & ARG-007 trial

- Administration of0.3mg/kg ARG-007 orsaline placebo
- All patients receive thrombectomy

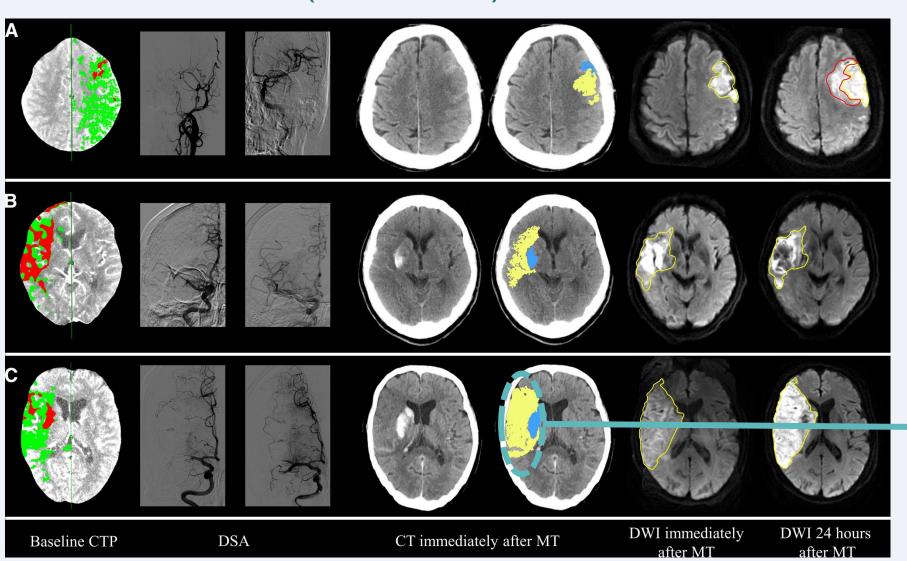
#### **Endpoints**

- PRIMARY: Mortality rate and frequency of Adverse and Serious Adverse Events; timepoints of Day 1, Day 2, Day 3, Day 6 or Discharge, Day 30 and Day 90
- SECONDARY: Infarct volume reduction between ARG-007 and placebo at 48 hours (Day 3 ± 1 day)



#### **EXAMPLE OF WHAT PHASE 2 TRIAL HOPES TO ACHIEVE:**

#### REDUCING INFARCT VOLUME (i.e. BRAIN DEATH) FOLLOWING STROKE & THROMBECTOMY



Infarct core:

permanent brain cell death (i.e. cannot be saved)

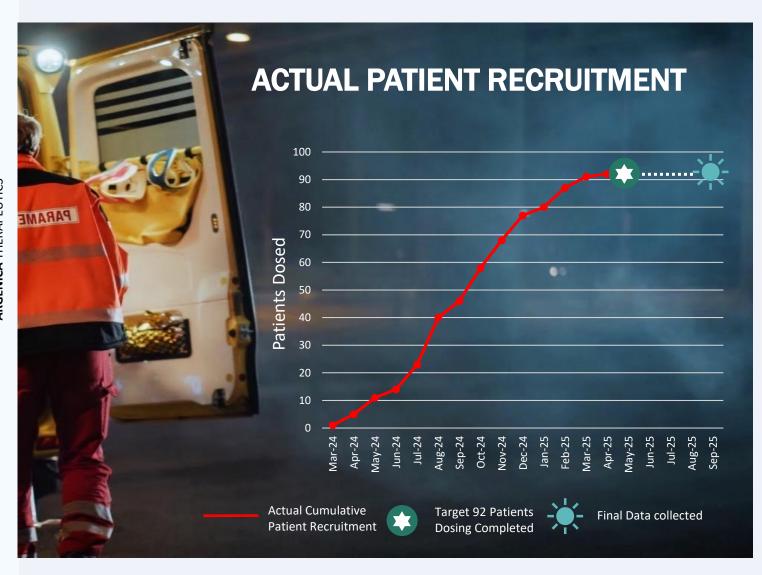
Vulnerable Penumbra:

Surrounding tissue that is vulnerable to dying (i.e. still alive, but likely to die without protection)

ARG-007 aims to reduce infarct volume
(i.e. brain death) by protecting the Vulnerable Penumbra from dying following stroke & thrombectomy



## PHASE 2 CLINICAL TRIAL IN STROKE



- 92 patients dosed at 8 Australian hospitals
- Exceptional recruitment rate due to ease of use of ARG-007 administration in acute emergency setting
- Easy consent for patients due to clinician confidence in extensive preclinical data package
- Objectives;
  - 1. Safety
  - 2. Tolerability
  - 3. Pharmacokinetics
  - 4. Preliminary Efficacy
- TOPLINE DATA DUE EARLY SEPTEMBER 2025.



#### WHAT DOES A REDUCTION IN INFARCT MEAN FOR PATIENTS?

Reducing infarct volume after an ischemic stroke is a crucial measure because data suggests it is the strongest predictor of better outcomes, including improved neurological function, independence, and lower mortality.<sup>1</sup>

#### mRS Scale (i.e. a measure of a patient's disability)



Ultimately, ARG-007 needs to move more people to the left on the mRS (into 0-2). If the Phase 2 trial shows a reduction in infarct volume, there will be a greater chance of seeing improved mRS in a larger pivotal trial (i.e. Phase III)

**Greater independence = greater savings to healthcare system** 



#### **HOW MUCH BRAIN DO YOU NEED TO SAVE?**

#### CLINICALLY MEANINGFUL FINAL INFARCT VOLUME REDUCTIONS



- A 1.6% decrease in infarct volume (decrease in brain cell death) is the minimum amount of decrease deemed to be clinically important<sup>1</sup>. This decrease, on average, results in 1.3 more patients out of 100 achieving functional independence (mRS 0-2).
- Studies have shown a decrease of 5%, 11.5% and 17% would result in 5, 10 and 15 more patients out of 100, respectively, achieving functional independence (mRS of 0-2). This means 5, 10 and 15 more patients per 100 who would move from being severely or moderately disabled to having no or only a slight disability<sup>1</sup>.
- There are currently no approved drugs to reduce brain death following stroke, therefore <u>any statistically</u> <u>significant reduction in infarct volume beyond 1.6%</u> would be seen as a positive outcome.

#### EVEN A SMALL REDUCTION IN INFARCT VOLUME INCREASES THE CHANCE A PATIENT WILL WALK, TALK & CARE FOR THEMSELVES

<sup>1.</sup> Liao NC, Bahr Hosseini M, Saver JL. Clinically important effect sizes for clinical trials using infarct growth reduction as the primary outcome: a systematic review. J Neurointerv Surg. 2023 Oct 31 – average final infarct volume across all studies is 38.4 ml

<sup>2.</sup> From Liao et al 2023 - Minimal clinically important difference-outcome specific is defined as the smallest change in a treatment outcome measure that a patient would consider of value, if the treatment producing the outcome was simply implemented, safe and inexpensive.



# POST PHASE 2 STRATEGY AND COMMMERCIAL OPPORTUNITIES



## THE STROKE OPPORTUNITY

Category	Australia	United States
Number of strokes per year	~45,000 annually <sup>1</sup>	~795,000 annually <sup>2</sup>
Cost of stroke to healthcare system per year	AUD\$5.5 billion in healthcare costs in 2023 <sup>1</sup>	USD\$71.55 billion in 2012  expected to increase to  USD\$184.13 billion by 2030 <sup>3</sup>
Estimated costs associated with stroke per year	AUD\$9+ billion annually (including healthcare and indirect costs) <sup>1</sup>	USD\$67 billion in 2020 expected to increase to USD\$423 billion by 20504

#### THOMBOLYTIC DRUG AS A COMPARABLE MARKET

ONLY <u>9%</u> OF ACUTE ISCHAEMIC STROKE PATIENTS ARE ELIGIBLE FOR THOMBOLYTICS<sup>5</sup>
THROMBOLYIC DRUGS CAN SELL FOR = USD\$10k - 12k PER ADMINISRATION<sup>6</sup>
GLOBAL MARKET IN 2022 = <u>USD 1.1B<sup>7</sup></u>
PROJECTED MARKET IN 2030 = <u>USD 3.8B<sup>7</sup></u>

ARG-007 TARGETS OVER 30% OF ISCHAEMICA STROKE PATIENTS, THEREBY CREATING APPROX 3X CURRENT MARKET SIZE

#### IF AGN IS SUCCESSFUL = MULTI BILLION DOLLAR OPPORTUNITY

- 1. https://strokefoundation.org.au/media-centre/media-releases/2024/09/new-report-highlights-number-of-strokes-hits-all-time-high
- US Centers for Disease Control and Prevention (CDC)
- 3. https://www.ahajournals.org/doi/10.1161/str.0b013e31829734f2
- . https://www.precedenceresearch.com/stroke-diagnostic-and-therapeutic-market

- 5. Gaukel et al. Utilization rates of intravenous thrombolysis for acute ischemic stroke in Asian countries:: A systematic review and meta-analysis. Medicine (Baltimore). 2023 Oct 20;102(42)
- 6. Kleindorfer D et al. Cost of Alteplase Has More Than Doubled Over the Past Decade, Stroke, 2017 Jul:48(7):2000-2002.
- 7 https://www.verifiedmarketresearch.com/product/thromholytic-drug-market/



# **POST PHASE 2 STRATEGY**



#### 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 global channels to commercialise in acute ischaemic stroke.



#### **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 of 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.

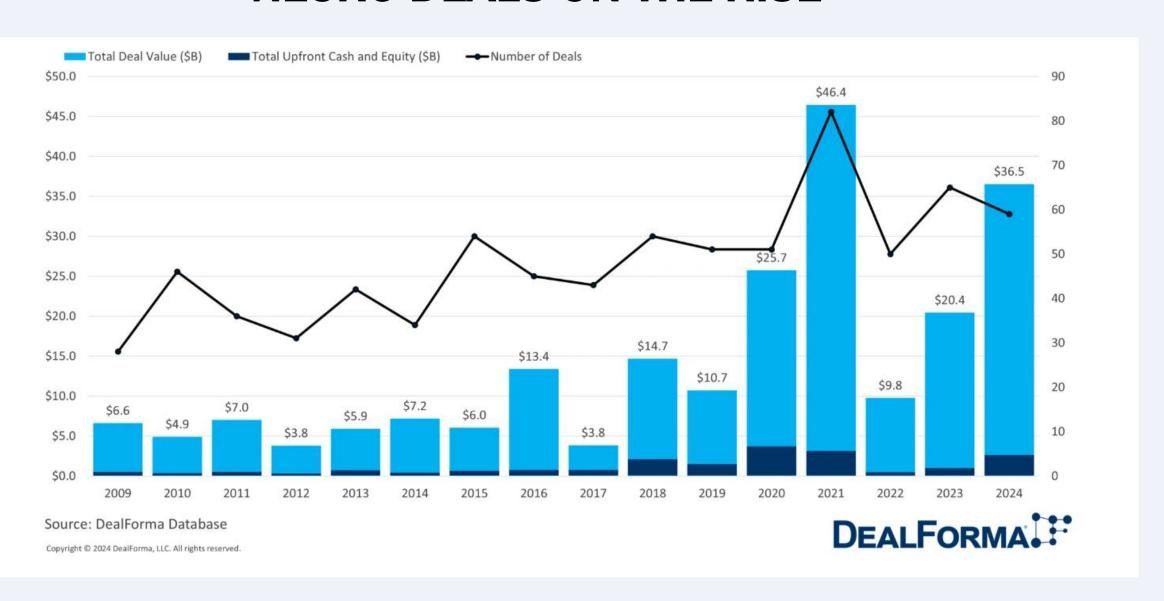
**OR...** 

CREATE GREATER
SHAREHOLDER VALUE BY
MOVING TO PHASE 3
ALONE AND DOING A
DEAL ON INTERIM DATA

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# **NEURO DEALS ON THE RISE**



# NEAR-TERM CATALYSTS

Phase 2 acute ischaemic stroke trial results imminent. Further regulatory and preclinical milestones in the next 12 months.

# INVESTMENT HIGHLIGHTS

#### 1#

# SOLVING LARGE UNMET NEEDS

Nervous system disorders are the biggest cause of poor health globally<sup>1</sup>. Currently there are <u>no</u> marketed safe, early intervention therapeutics capable of protecting the brain from damage following stroke<sup>2</sup>. Argenica is one of the furthest progressed clinical drug development companies globally focused on this indication.

#### 2#

#### SIGNIFICANT PRE-CLINICAL DATA

ARG-007 (R18D) has amassed a huge amount of preclinical data scientifically validating the efficacy, safety and mechanism of action of the drug. There are over 25 peer reviewed publication, as well as the Phase 1 clinical trial data, derisking ARG-007.

#### 4#

# PARTNERING OPPORTUNITIES

Given the focus on neurology assets and blockbuster indications by pharmaceutical companies, Argenica is well positioned to partner post Phase 2.



