



argenica
THERAPEUTICS

AGM PRESENTATION ASX: AGN

MANAGING DIRECTOR PRESENTATION
NOVEMBER 2023



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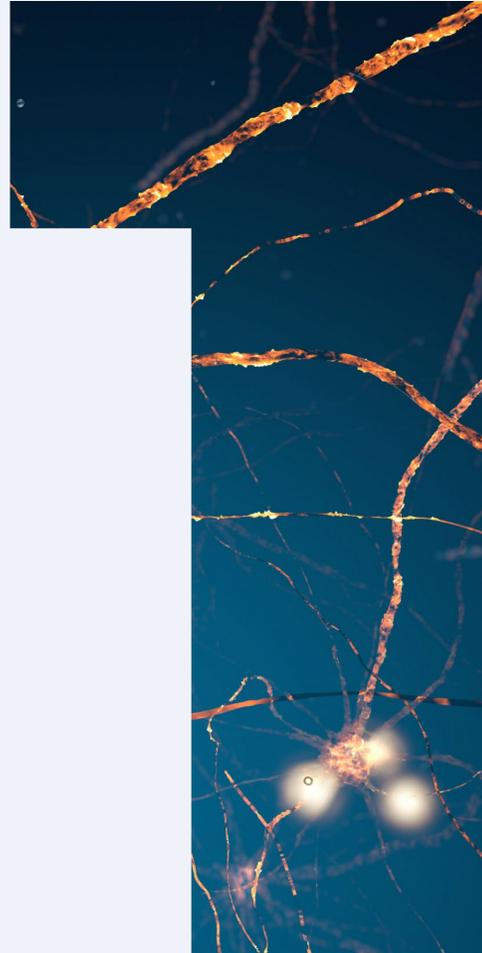
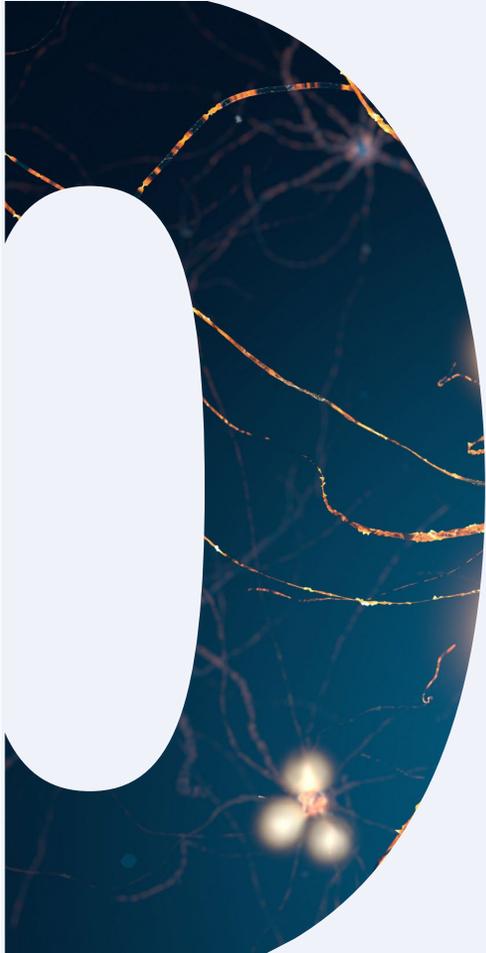
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NEUROPROTECTIVE OPPORTUNITY & OUR ENCOURAGING RESULTS TO DATE



BREAKTHROUGH NEUROPROTECTIVE SOLUTIONS TO REDUCE BRAIN DAMAGE



MISSION

Commercialise breakthrough neuroprotective treatments that minimise brain damage and foster recovery



VISION

Achieve global recognition as the most valuable neuroprotective company, and redefine the standard of care



IMPACT

Create a positive, life-altering impact for millions suffering from neurodegenerative diseases, offering new hope and possibilities



THE OPPORTUNITY IN FRONT OF US

NEUROPROTECTIVE TREATMENTS ARE A NEW FRONTIER IN MEDICINE...

There are **no** marketed drugs that protect the brain after stroke



There is **increasing interest** in neuroprotection from big pharma



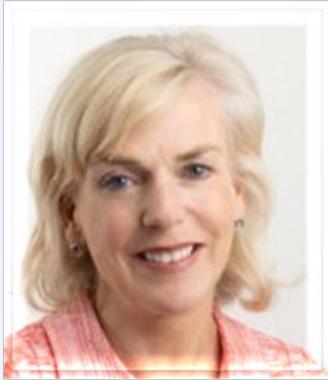
Our drug **ARG-007** aims to fill this urgent and **unmet clinical need**



Untapped commercial opportunity with limited competition



ARGENICA BOARD



Dianne Angus
Non-Executive Chairman

- Senior executive within the biotechnology and healthcare sectors for over twenty years
- Currently serves as non-executive director with Neuren Pharmaceuticals Limited (ASX: NEU), Cyclopharm (ASX:CYC) and Imagination Biosystems (ASX:IBX)
- Experience in driving development paths for novel neurological pre-clinical agents to late-stage clinical assets
- B.Sc. (Hons), M.(Biotechnology) and is a registered patent & trademark attorney
- GAICD



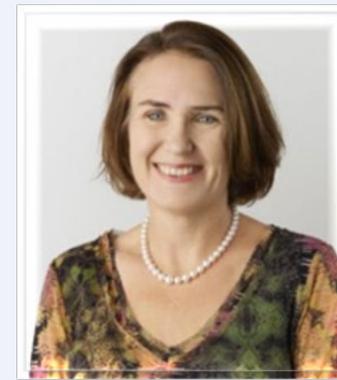
Dr Liz Dallimore
Managing Director

- Over 20 years' experience in R&D, technology commercialisation and management consulting, including at KPMG, EY and PWC
- Extensive background in stroke and spinal cord regeneration research at the Australian Neuromuscular Research Institute, UWA and Oxford University
- BSc (Hons), PhD Neuroscience, MBA (AGSM)
- GAICD



Geoff Pocock
Non-Executive Director

- 20 years' experience in commercialisation of emerging technologies and capital markets
- Non-Executive Director, Osteopore Ltd (ASX:OSX)
- Non-Executive Director of EMVision Medical Devices Ltd (ASX:EMV)
- Co-Founder / Former Managing Director of Hazer Group (ASX: HZR)
- BSc Chemistry, LLB



Liddy McCall
Non-Executive Director

- Over 25 years' experience of senior Board and Management roles and has a strong history of success with early-stage Biotechnology companies
- Co-founded 3 biotechnology companies which have successfully achieved 3 FDA drug registrations and 1 FDA/CE Mark medical device approval
- Co-founder of iCeutica Inc group (acquired in 2011 achieving a ten-fold uplift on the valuation) and Dimerix Limited (ASX:DXB)
- Bcom. LLB, Bjuris,
- GAICD



Terry Budge
Non-Executive Director

- 25 years with National Australia Bank in senior executive roles before serving as managing Director of Bankwest from 1997 to 2004
- Previously Chancellor of Murdoch University, Chair of Landcorp, National Director of AICD, and independent director for Westoz Investment Company (ASX:WIC)
- BEcom, Harvard Advanced Management Program
- GAICD



OUR LEAD DRUG CANDIDATE

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

DISCOVERY PRE-CLINICAL PHASE 1 PHASE 2 PHASE 3

Efficacy Safety / Tox

STROKE

Damage to the brain from interruption of its blood supply



HIE

Hypoxic ischemic encephalopathy (HIE) develops during pregnancy and labour



SEVERE TBI

Trauma to the head or body causes a loss of consciousness



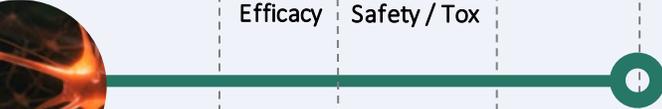
MILD / MOD TBI

Slightly less damaging trauma to the head but still a significant injury



ALZHEIMER'S DISEASE

Progressive neurological disorder that causes brain atrophy





POTENTIAL OF ARG-007

MAIN INDICATIONS

STROKE 

HIE 

TBI 

ALZHEIMER'S DISEASE 

Ability to partner / licence on all indications

ADDRESSABLE MARKET

USD\$12bn
by 2030¹

1. Coherent Market Insights Report – Acute Ischemic Stroke (AIS) Market Analysis, Oct 2023

USD\$1.9bn
by 2030²

2. Data Bridge Market Research Market Analysis Study 2023

USD\$18.6bn
by 2031

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

USD\$13.0bn
by 2031⁶

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

All indications have large addressable markets

SUMMARY OF RESULTS TO DATE

66% reduction
in Brain Tissue Death 24 hours after stroke

70% reduction
in Brain Tissue Death 28 Days after stroke

52% reduction
in total brain injury 4 weeks after injury

60% reduction
compared to hypothermia

52% reduction
in neurofilament heavy protein

51% reduction
in amyloid precursor protein

65% reduction
in Abeta aggregation

84% reduction
in cellular uptake of a-syn

89% reduction
in Tau aggregation

Results to date are exceptional and will drive commercial / partnering interest



ENHANCING **STROKE** RECOVERY WITH ARG-007

SO WHY ARE WE TARGETING STROKE FIRST?

INCIDENCE



ONE IN FOUR

people will suffer a stroke in their lifetime¹

SOCIETAL IMPLICATIONS



ONLY 10%

will recover almost completely, due to the extent of brain cell damage¹

THE IMPORTANCE OF TIME



1.9 MILLION

brain cells are attacked each minute during a stroke²

Current markets cater to treatment & diagnosis of stroke, not protecting brain cells

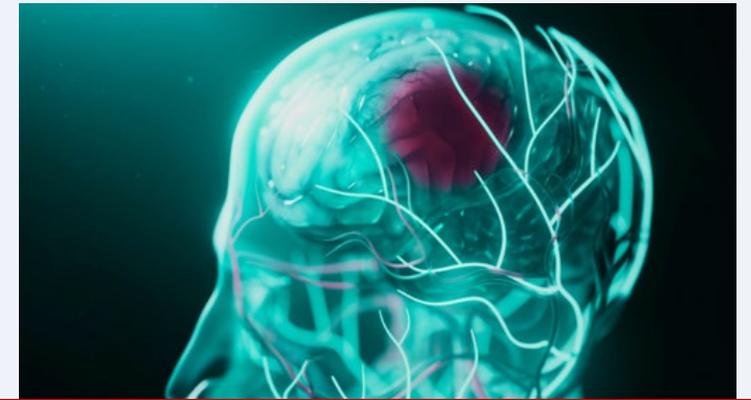
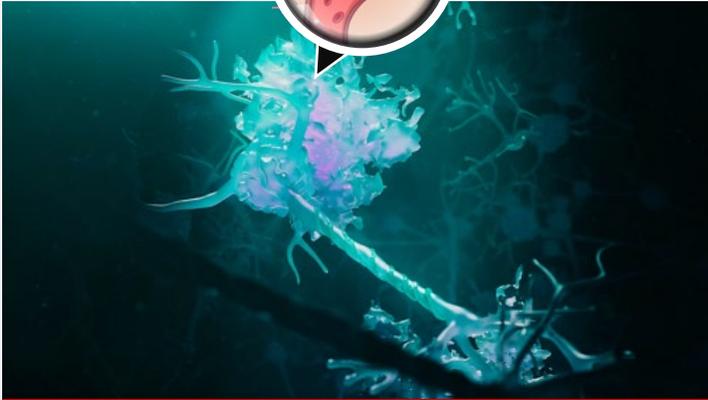
[1] Stroke Foundation

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

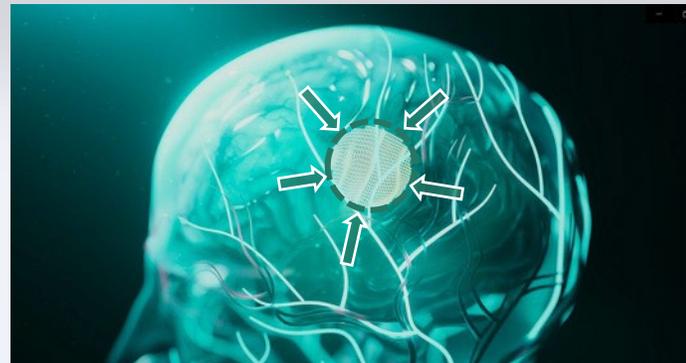
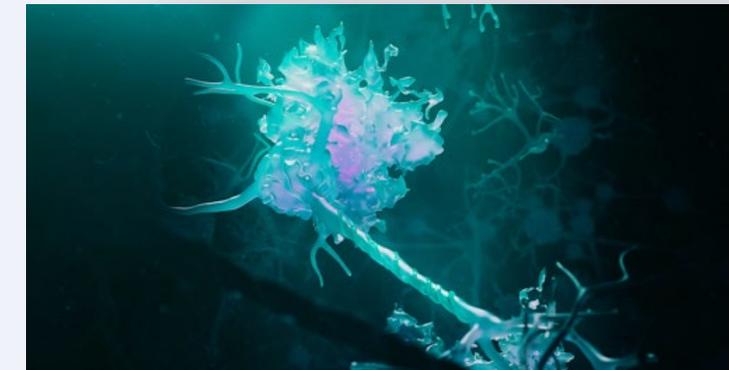


ISCHEMIC STROKE
EXAMPLE

HOW ARG-007 WORKS IN STROKE



INITIAL INFARCTION SETS OFF A CASCADE OF CELL DEATH THAT **WILL CONTINUE SPREADING FROM LOCATION**



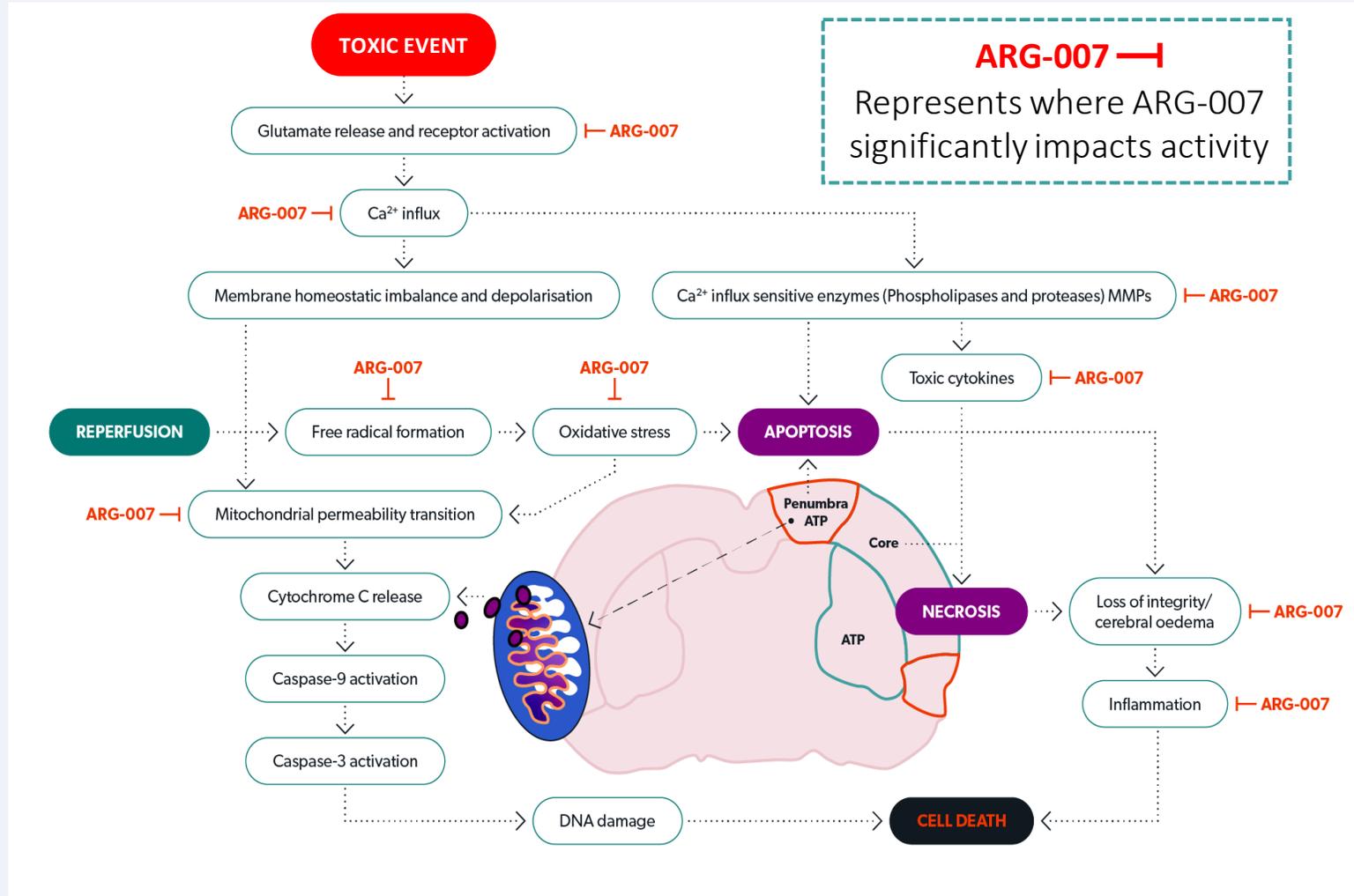
ARG-007 STOPS THE CASCADE OF CELL DEATH & PROVIDES A PROTECTION BARRIER AROUND THE INITIAL INFARCTION



MULTIPLE MECHANISMS OF ACTION: TARGETS CELL TOXICITY

- Reduces calcium influx
- Preserves mitochondrial membrane potential
- NMDA (NR2B) downregulation
- Reduces GFAP and IL-6 expression
- Reduces MMP9 activation

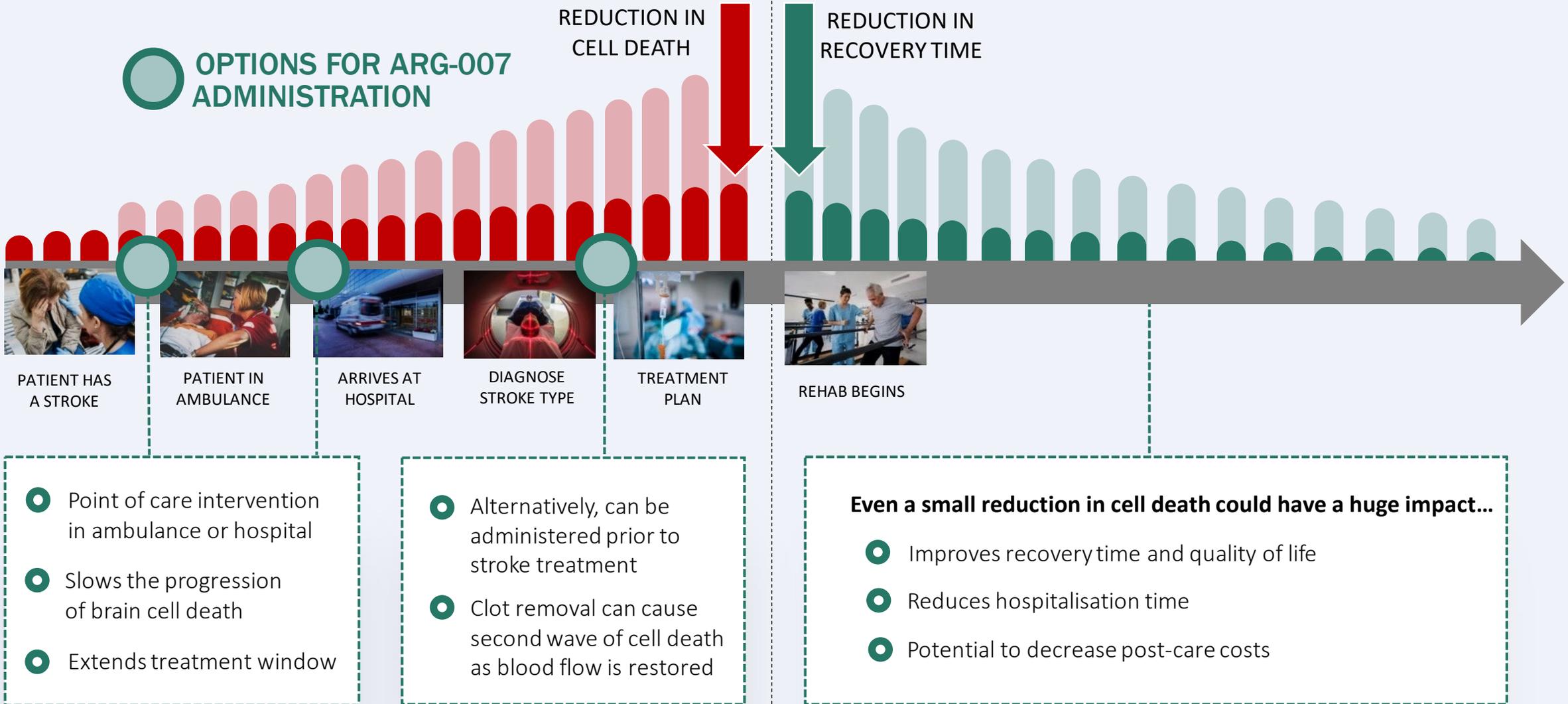
COMBINED MECHANISMS IMPROVES DRUG EFFICACY



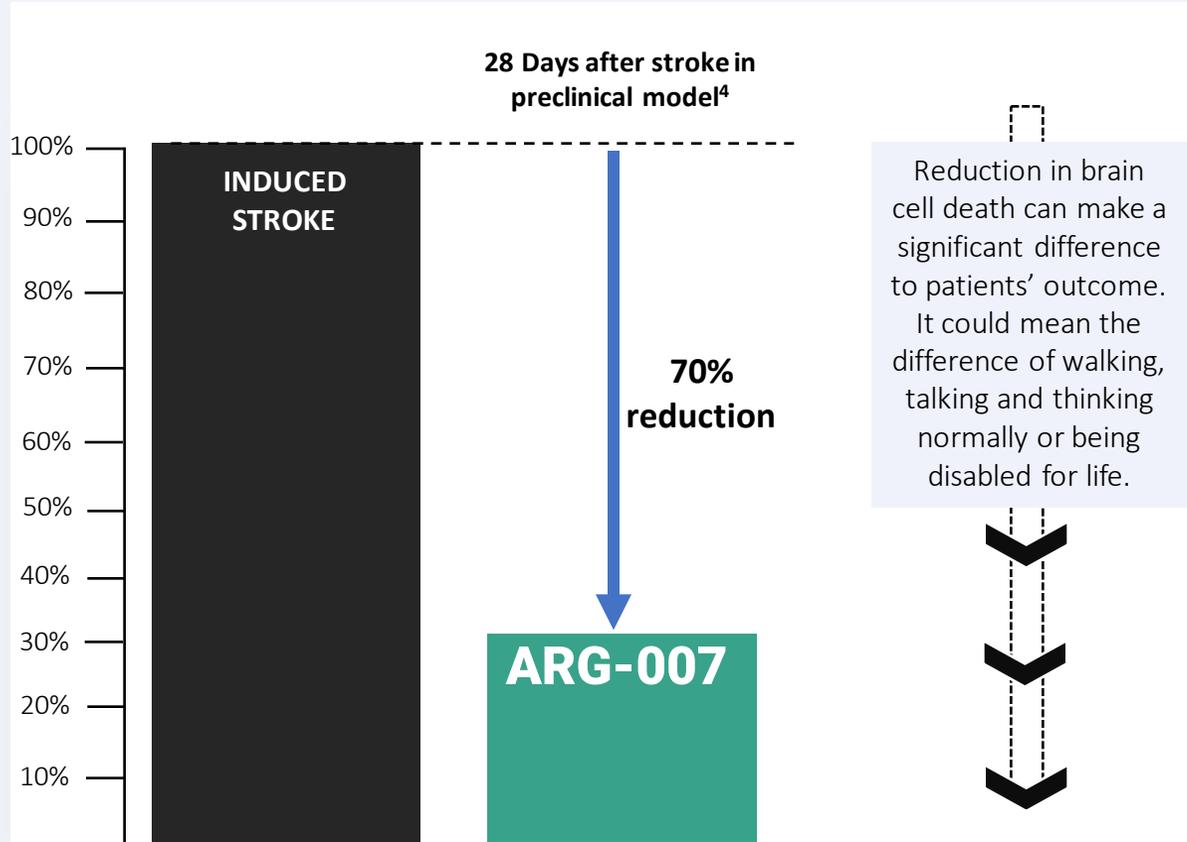
ARG-007 is under development and subject to clinical validation.

IMPLICATIONS FOR STROKE PATIENTS

OPTIONS FOR ARG-007 ADMINISTRATION



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

PRECLINICAL & CLINICAL DATA

SAFE TO ADMINISTER IN THE FIELD¹

CAN BE ADMINISTERED WITH CLOT DISSOLVING DRUG²

DOSES OF ARG-007 SAFE & WELL TOLERATED IN HEALTHY HUMAN PHASE 1³

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 CLINICAL TRIAL IN STROKE

OVERVIEW

- Up to 10 Australian hospitals recruiting up to 92 patients
- 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		★		
First patient dosed			★	
First independent review of patient safety data				★
Patient recruitment update				★



THE OPPORTUNITY FOR ARG-007 IN OTHER INDICATIONS

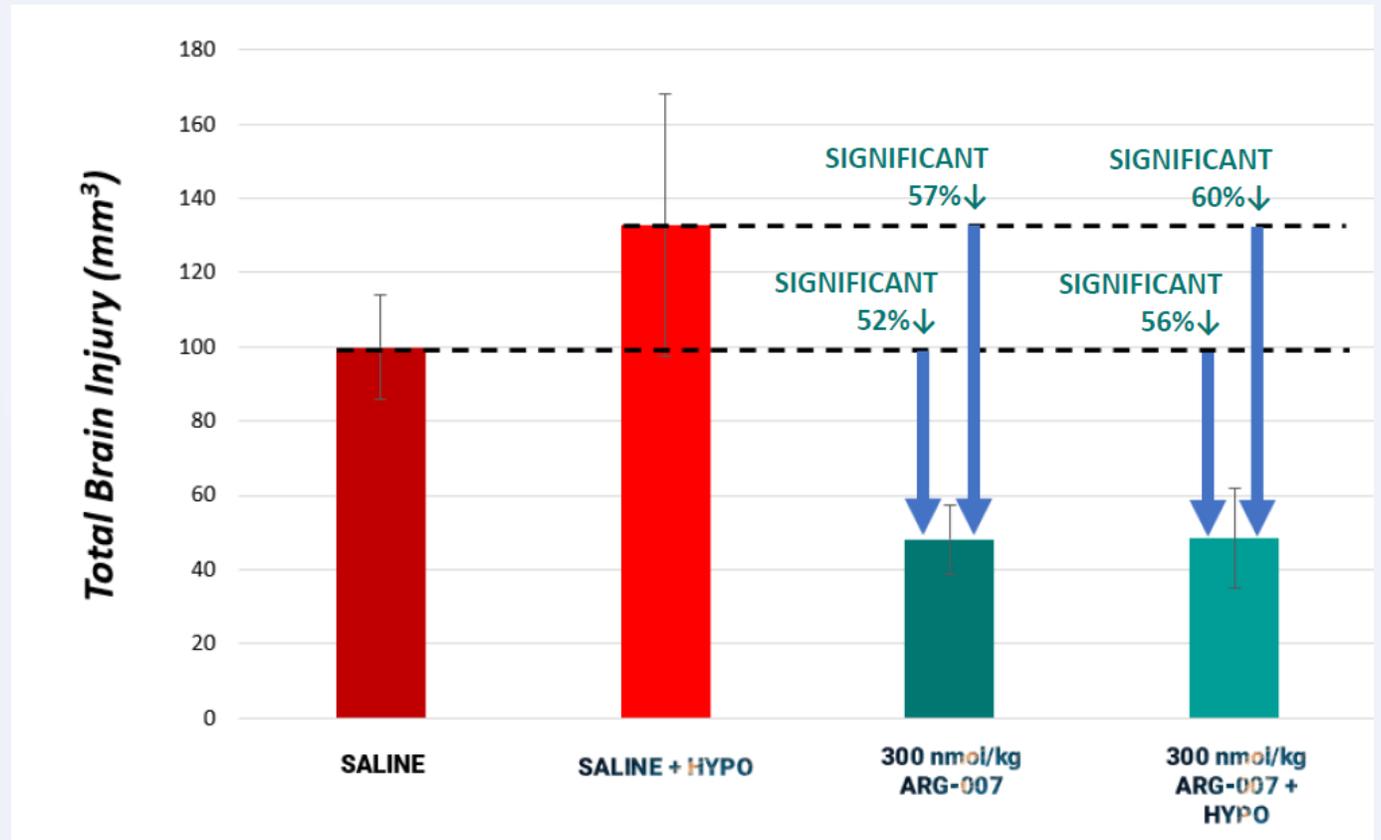


ARG-007 POTENTIAL IN HIE

HYPOXIC-ISCHAEMIC ENCEPHALOPATHY (HIE)

- HIE occurs in 1.5 to 2.5 births per 1000¹
- Current standard of care is hypothermia
- Awarded **A\$2.5m** grant to advance pre-clinical studies²

TOTAL BRAIN INJURY AT 4 WEEK POST HIE WITH ARG-007 TREATMENT OR ARG-007 WITH STANDARD OF CARE HYPOTHERMIA³



1. Hypoxic Ischemic Encephalopathy: Pathophysiology and Experimental Treatments Kimberly A. Allen, MSN, RN and Debra H. Brandon, PhD, RN, CCNS, FAAN
 2. ASX Announcement titled 'Significant non-dilutive funding to Complete preclinical hypoxic ischaemic Encephalopathy studies' dated 30 March 2023
 3. ASX Announcement titled 'ARG-007 is an effective stand-alone therapy in preclinical study of term hypoxic ischaemic encephalopathy' dated 18 October 2023



FDA HAS GRANTED ODD STATUS FOR HIE

Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) status to ARG-007 for the treatment of Hypoxic Ischaemic Encephalopathy (HIE).

- ODD qualifies AGN for incentives including:
 - Tax credits for qualified clinical trials
 - Exemption from user fees
 - Potential seven years of market exclusivity after approval
- Granting of Orphan Drug Designation for ARG-007 in HIE forms a key pillar of Argenica's commercialisation strategy
- The potential for extensive market exclusivity following approval of ARG-007 is an extremely compelling commercial driver for the Company



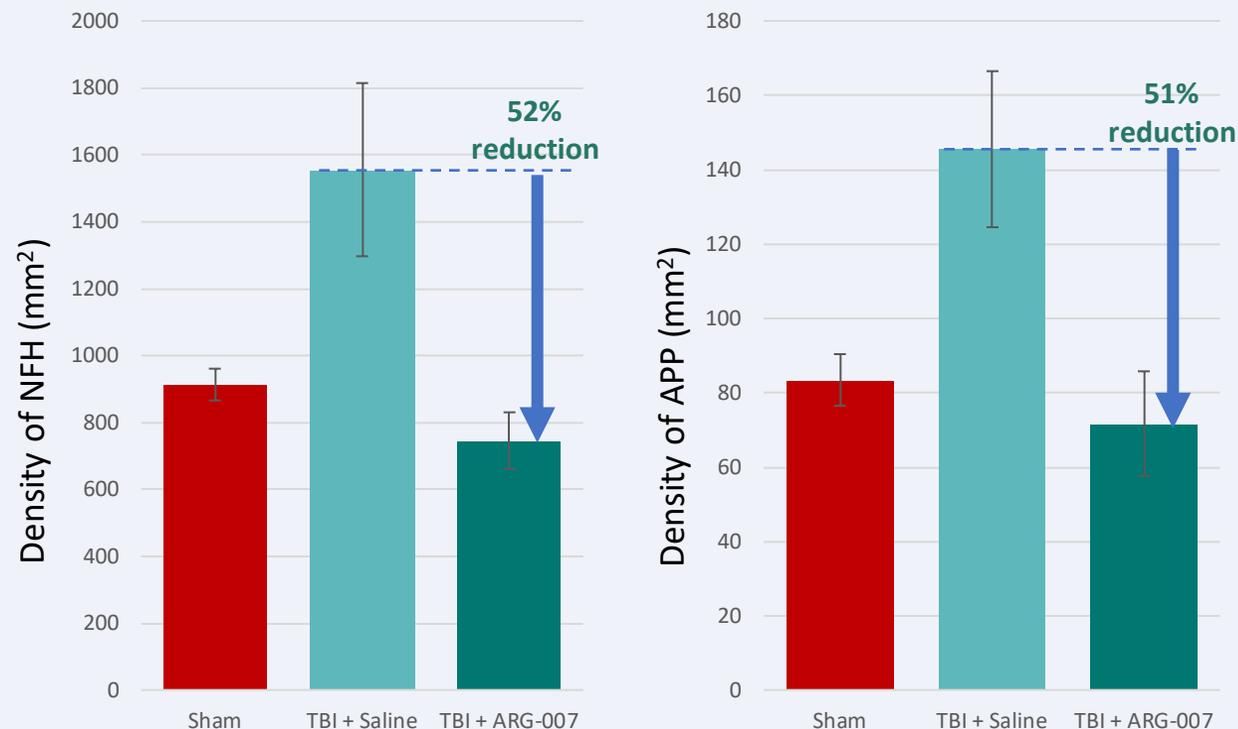


ARG-007 POTENTIAL IN TBI



- Estimated **USD\$18.6bn** market size by 2031¹
- ARG-007 has shown efficacy in pre-clinical studies²
- Awarded **A\$1.2m** grant to advance pre-clinical studies³

ARG-007 SIGNIFICANTLY REDUCES NFH PROTEIN AND APP FOLLOWING TBI²



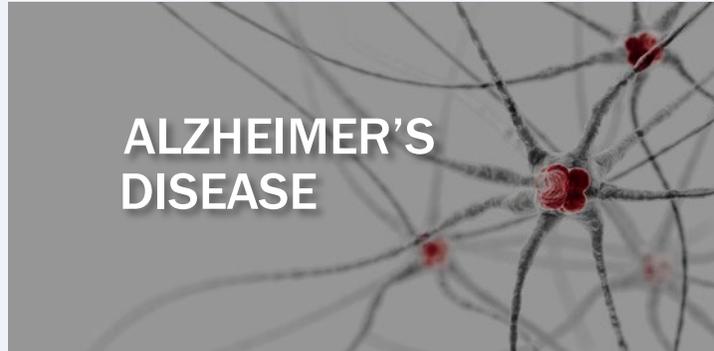
ARG-007 was found to protect brain cells in the injured brain by significantly reducing the accumulation of proteins that contribute to brain cell injury and death following TBI, specifically neurofilament heavy protein (NFH) and amyloid precursor protein (APP).

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

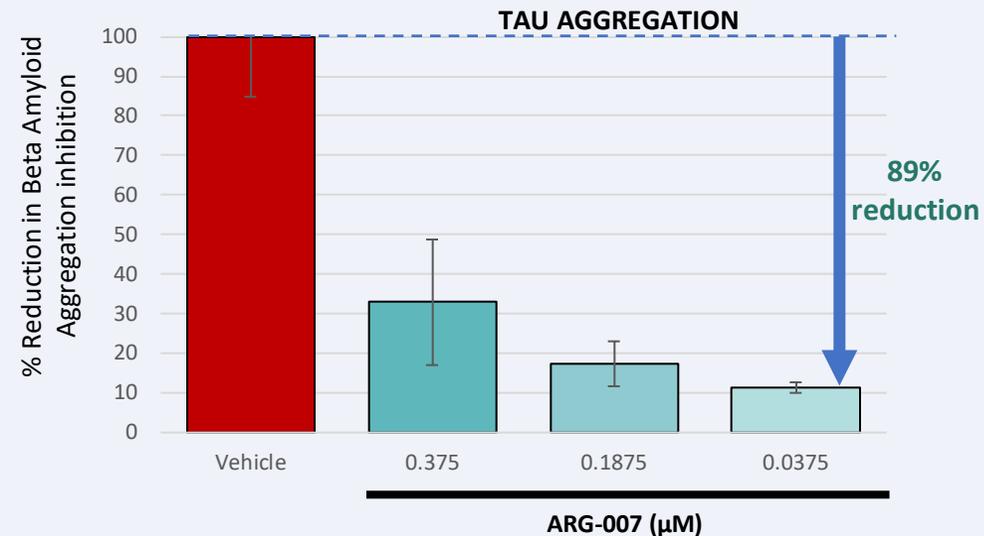
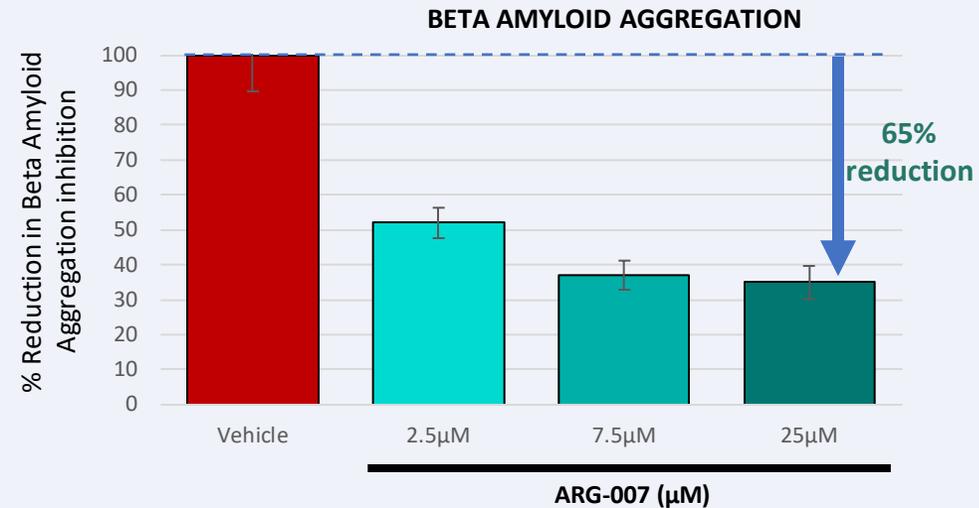
2. ASX Announcement titled 'ARG-007 protects brain cells in moderate traumatic brain injury model' 22 June 2023

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

ARG-007 POTENTIAL IN ALZHEIMER'S DISEASE



- Alzheimer's therapeutics market **USD\$13bn** by 2031¹
- Preclinical data shows ARG-007 inhibits **beta amyloid and tau aggregation**, a key cause of Alzheimer's^{2,3}
- Awarded **A\$350,000** grant to advance pre-clinical studies⁴



SIGNIFICANT INHIBITION OF NEURODEGENERATIVE PROTEIN AGGREGATION

1. Alzheimer's Therapeutics Market Global Opportunity Analysis 2021-2031 – Allied Market Research
2. Announcement titled 'Preclinical data shows arg-007 inhibits one of The main causes of Alzheimer's disease' Dated 9 Feb 2023
3. ASX Announcement titled 'Preclinical data shows ARG-007 inhibits a second main cause of Alzheimer's Disease' dated 3 Nov 2023
4. ASX Announcement titled 'Non-dilutive funding received to progress Alzheimer's disease studies' dated 22 Feb 2023

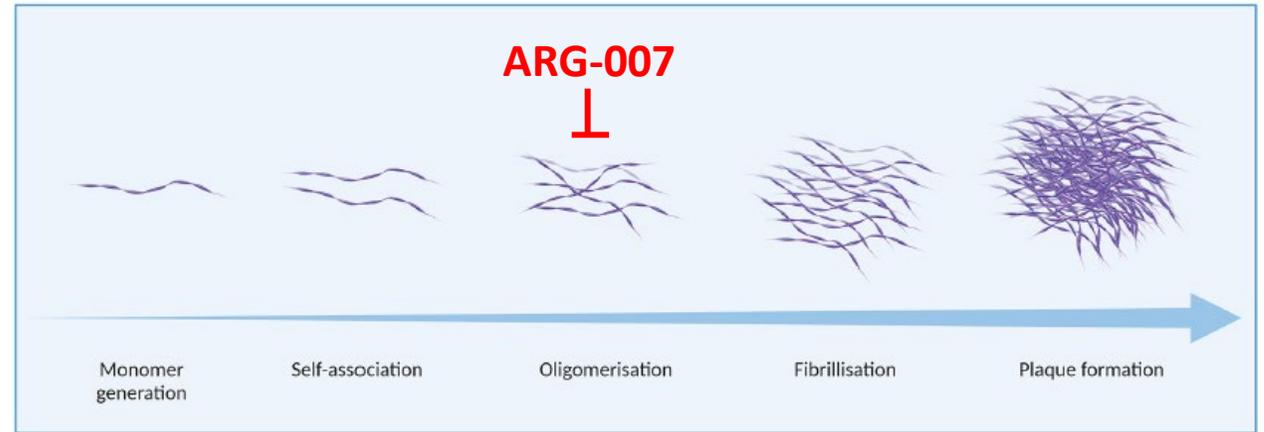


MULTIPLE MECHANISMS OF ACTION: TARGETS PROTEIN AGGREGATION

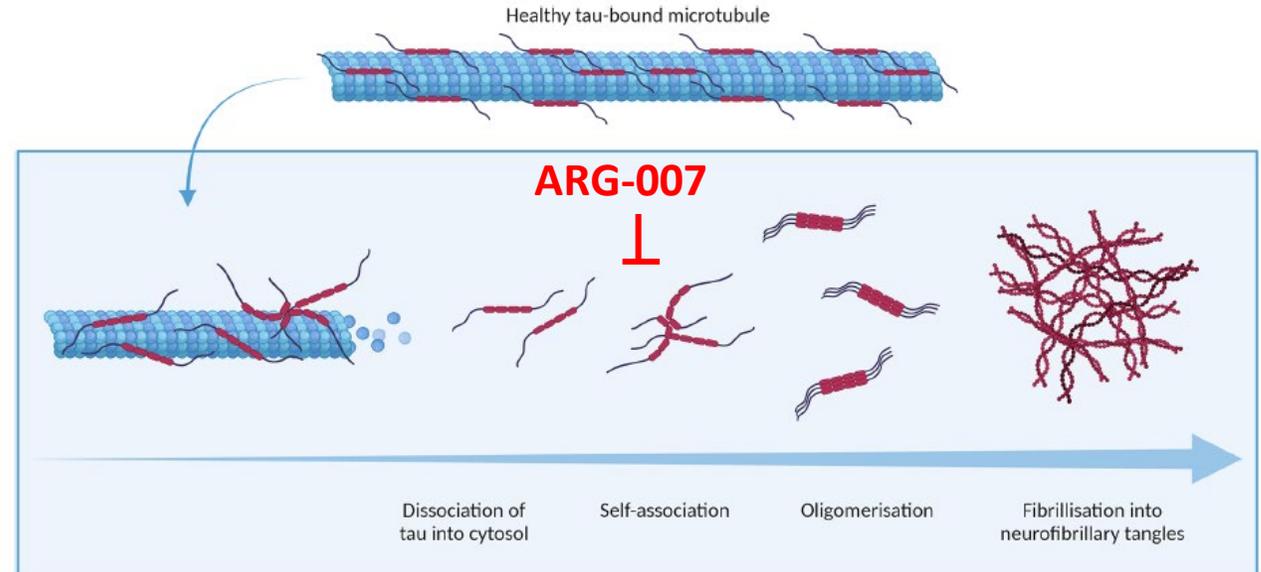
ARG-007 reduces aggregation of key neurodegenerative proteins which cause disease progression:

- Reduces aggregation of beta amyloid
- Reduces aggregation of tau
- Reduces aggregation of alpha-synuclein

Amyloid-beta aggregation



Tau protein aggregation





WE HAD A VERY SUCCESSFUL 2023

- ✓ SUCCESSFUL PHASE 1 CLINICAL TRIAL
- ✓ ETHICS APPROVAL FOR PHASE 2 IN STROKE
- ✓ SUCCESSFUL FDA PRE-IND MEETING FEEDBACK
- ✓ SECURED +\$4M IN NON-DILUTIVE FUNDING
- ✓ ENCOURAGING PRE-CLINICAL ALZHEIMER'S DATA
- ✓ ADDITIONAL HIE DATA SHOWING EFFICACY
- ✓ FDA GRANTED ORPHAN DRUG DESIGNATION FOR HIE
- ✓ EXCITING PRE-CLINICAL DATA IN MODERATE TBI





2024 WILL BE EQUALLY EXCITING...

Our core areas of focus will be:

- Initiating our Phase 2 clinical trial in stroke patients
- Receiving initial patient safety data from Phase 2
- Continuing our engagement with global pharmaceutical companies
- Completing all required pre-clinical studies for other indications
- Expanding the board and management team



KEY COMPANY METRICS

\$7.4M
CASH @ BANK¹

R&D REFUND RECEIVED Q4
+\$2.09M

+\$4M
NON-DILUTIVE GRANTS²

98.3M
SHARES ON ISSUE

\$42M
MARKET CAP³

FUNDED
TO COMMENCE PHASE 2

1. Cash balance as @ 30 September 2023

2. Various ASX Announcements dated 20 January 2023, 22 March 2023, 30 March 2023, 12 September 2023

3. Calculated with closing price on @ 28th November being \$0.43



For further information please contact:

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CEO & Managing Director

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