ASX: PAA

Investor Update

17 May 2024

John Clark

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Corporate Overview

Mid-stage biotechnology company targeting human neurodegenerative diseases

Share Price Performance

Board & Management

Mr John Clark	Chief Executive Officer & Managing Director
Mr Sergio Duchini	Chairman & Non-Executive Director
Mr Marcus Hughes	Non-Executive Director

Capital Structure (AUD$)

	16 May 2024
Current Share Price (PAA/PAAOA)	$0.18 / $0.10
52 Week Low / High (PAA)	$0.06/ $0.53
No. of Shares (PAA)	395,013,669
Listed Options (PAAOA)	117,313,521
Market Capitalisation	**$73.24m**
Cash (as at 31-Mar-24)	$3.9 m
Debt (as at 31-Mar-24)	Nil
Net Cash	**$3.94m**
Enterprise Value	**$67.36m**
Unlisted Options (10c/15c/17.5c)	7.34 m
Enterprise Value (fully diluted)	**$74.7m**

Top Shareholders*

Hybrid Holdings Pty Ltd <Darcy Family Super Fund A/C>	5.6%
Mr Gerald James Van Blommestein & Mrs Gillian Van Blommestein <Van Blommestein S/F A/C>	4.6%
Dr Roger Aston	3.8%
Board & Management	3.1%

* As at 16 May 2024

Product candidates for neurodegenerative diseases

Human Health Focus
Mid stage biotechnology company focused on large and growing markets in human health

Repurposing Monepantel
Repurposing an approved veterinary product – monepantel – anthelmintic for sheep

Neurodegenerative Diseases
Exploiting autophagy as a hunter for toxic aggregates, a common pathology in neurodegenerative diseases

Motor Neurone Disease
Lead clinical program for the treatment of motor neurone disease/ Amyotrophic Lateral Sclerosis (MND/ALS)

Strong IP Position
Strong intellectual property with 6 patent families and protection beyond 2030

Pipeline Synergies
Pipeline synergies to leverage commercial infrastructure across development programs

Experienced Management
Experienced world-class Board and management team

Broad Investor Base
Healthy mix of loyal institutional and retail investors

Meet Our Team – Board

John Clark
Managing Director
John has over 20 years of pharmaceutical industry experience in phase I – IV clinical trials across numerous therapeutic areas and multiple geographical regions. John has a thorough knowledge of ICH-GCP and regulatory requirements and held clinical operations leadership roles responsible for implementing global clinical programs.

Sergio Duchini
Chairman & Non-Executive Director
Sergio serves as a Non-Executive Director and Chair of the Audit Committee at Enlitic Inc. Additionally, he holds the position of Chair at Lymphoma Australia, a leading not-for-profit organization. Sergio previously sat on the AusBiotech Board of Directors for nine years. He also served as a Board Director at Deloitte Australia, overseeing the governance, strategy development, and stewardship of the partnership.

Marcus Hughes
Non-Executive Director
Marcus brings more than 20 years' experience with listed companies. He possesses extensive corporate finance experience, having led project financing and capital raisings in the industrial sector. He has held senior managerial, tax and finance roles with multi-national companies including Lend Lease, Fortescue Metals and Rio Tinto

Meet Our Team – Management

John Clark
Interim Chief Executive Officer
John has over 20 years of pharmaceutical industry experience in phase I – IV clinical trials across numerous therapeutic areas and multiple geographical regions. John has a thorough knowledge of ICH-GCP and regulatory requirements and held clinical operations leadership roles responsible for implementing global clinical programs.

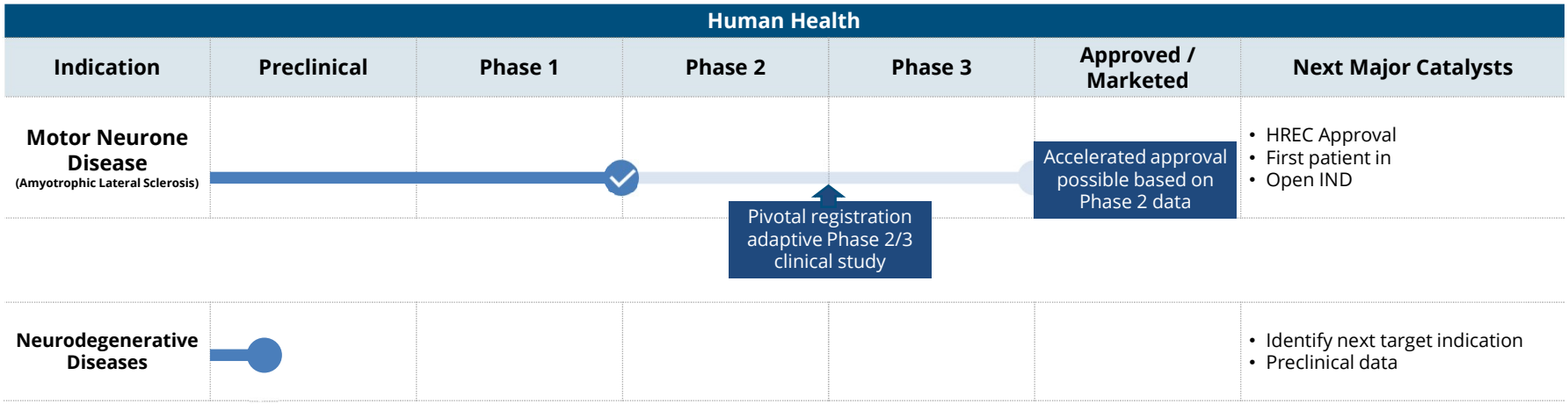
Dr Herbert Brinkman
Head of Manufacturing
Herb has over 30 years of experience in the pharmaceutical industry. He has prepared over 25 Chemistry Manufacturing and Control sections and updates for multiple filings for FDA and EU regulatory agencies. Herb has filed and commercially launched 9 products and contributed to filing 21 ANDAs for various semi-solid and parenteral products. He is also an inventor on 14 patents.

Dr Carol Worth
CMC Operations Manager
Carol brings over 30 years of industry experience and a passion for focusing on quality control and quality assurance. She recently served as Quality Manager at Epichem Pty Ltd as Chief Technical Officer at Suda Pharmaceuticals and Solbec Pharmaceuticals. Carol has also led product development programs at Thermalife International Pty Ltd/ Pharmasolv Laboratories Pty Ltd

Pipeline

Multiple synergistic product opportunities in human health by repurposing monepantel

- Single pivotal registration clinical study or MND/ALS
- Targeting accelerated approval from Phase 2 data
- FDA approval in 2026 possible

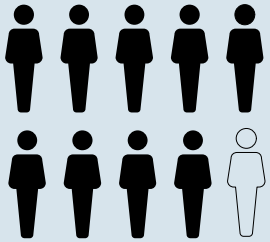


IND – Investigational New Drug
HREC – Human Research Ethics Committee

MND / ALS Statistics & Treatments

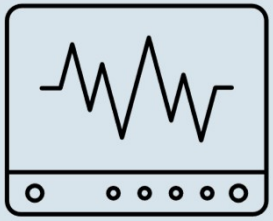
There is no cure and MND/ALS is always fatal

Every **90 minutes** someone is **diagnosed and dies** with MND/ALS



90% of cases occur **without a family history**

Onset is usually between the ages of **40 & 70 years**



Life expectancy on average is just over **2 years**

By **2040 the incidence** of MND/ALS is expected to **increase by 70%**

Current Treatments

Qalsody (tofersen)
Developed to treat ALS associated with a mutation in the superoxide dismutase 1 (*SOD1*) gene. The FDA approved Qalsody to treat *SOD1*-ALS in 2023.

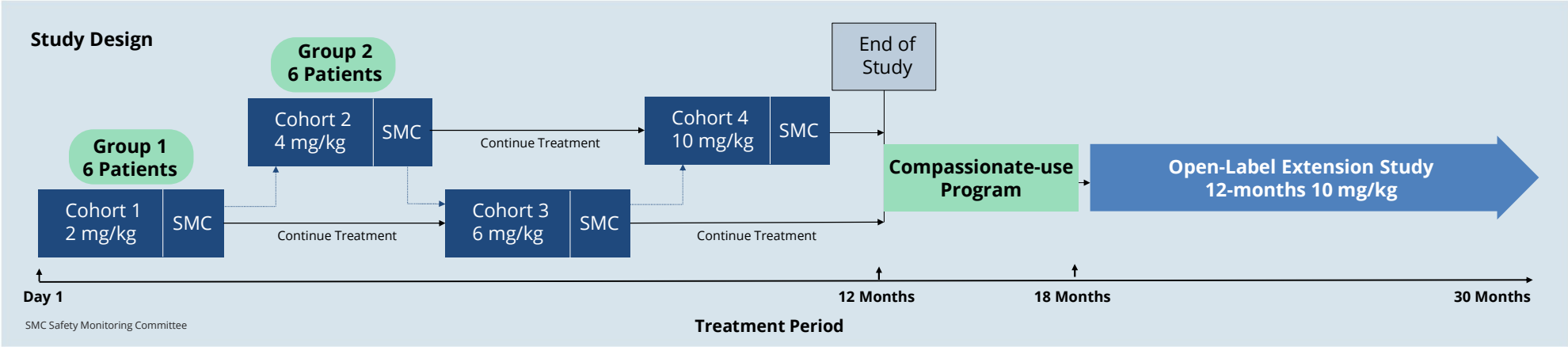
Rilutek (riluzole)
This was the first FDA-approved drug available to treat ALS — in 1995. It inhibits glutamate release and prolongs life ~3 months.

Radicava™ (edaravone)
The FDA approved Radicava™ in 2017, making it the first new treatment specifically for ALS in 22 years. Prolongs life ~6 months.

These drugs provide limited relief are controversial and slow disease progression by only months

Phase 1
MND/ALS MEND Study

The Phase 1 MEND Study was an open label, multicentre study involving 12 patients with MND/ALS with the goal of determining the recommended Phase 2/3 dose based on safety and preliminary efficacy



Study Update

- Positive top-line data released in Q1 CY24
- 12 patients continued treatment with monepantel under a compassionate-use program
- 10 patients have rolled-over into 12-month Open-Label Extension Study. Treatment continues to be very well-tolerated
- 11th patient has confirmed they would like to continue to the OLE study. Anticipated to be fully enrolled by mid-late May 2024
- Updated ALSFRS-R and Survival Analysis to be generated by Berry Consultants. Update expected in coming weeks
- First group of 6 patients are entering their 19th month of continuous treatment with monepantel
- Phase 1 and baseline OLE data used to design global registration adaptive Phase 2/3 Study, to commence in H2 CY24

Orphan Drug Designation Granted

The FDA has today granted monepantel orphan drug designation (ODD) status for the treatment of ALS.

The FDA has authority to grant orphan drug designation to a drug or biological product to prevent, diagnose or treat a rare disease or condition.

The ODD status is in place to assist and encourage companies to develop safe and effective treatments for rare diseases and disorders (impacting less than 200,000 persons in the US).

Designation qualifies PharmAust for incentives including:

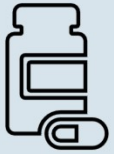
- Tax credits for qualified clinical trials
- Exemption from user fees
- Potential for seven years of market exclusivity after approval

Phase 2/3
ALS STRIKE Study

The pivotal, adaptive Phase 2/3 STRIKE Study will be a multicenter, randomized, placebo-controlled, parallel adaptive clinical study evaluating the safety and efficacy of Monepantel in subjects with ALS

MAIN INCLUSION CRITERIA:

- Adults with Familial or Sporadic ALS
- Time since onset of weakness due to ALS ≤ 24 months at the time of Screening Visit
- Seated Slow Vital Capacity ≥ 50% of predicted value
- Not take riluzole or be on a stable dose of riluzole for ≥ 30 days prior to the Screening visit
- Not take edaravone or have completed at least one cycle of edaravone prior to Screening visit



STUDY PLAN:

- Pivotal registration study
- Adaptive 24/48-week design
- Interim analysis at Week 24 for success or futility
- 210 participants to be enrolled
- Participants randomised 2:1
- 1st SAB meeting conducted to discuss study design

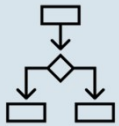
STUDY OBJECTIVES:

- Evaluate the efficacy of MPL, as compared to placebo, on ALS disease progression
- Evaluate the effect of MPL on selected secondary measures of disease progression
- Evaluate the safety of MPL for people with ALS
- Evaluate the effect of MPL on selected biomarkers and endpoints

GEOGRAPHIC LOCATIONS:

~30 sites globally

- 20% AUS
- 40% US (NEALS)
- 40% EU (TRICALS)



PRIMARY & SECONDARY EFFICACY ENDPOINTS:

- Change from baseline through Week 24/48 in disease severity as measured by ALSFRS-R total score & survival
- Change from baseline through Week 24/48 in respiratory function as assessed by slow vital capacity
- Change from baseline through Week 24/48 in disease severity as measured by the ALSFRS-R subdomain scores
- Quality of life from baseline through Week 24/48 as measured by the ALSAQ-40 questionnaire

ALSFRS-R - ALS Functional Rating Scale-Revised; SAB – Scientific Advisory Board; NEALS - Northeast Amyotrophic Lateral Sclerosis Consortium; TRICALS - Translational Research in ALS;

R&D timeline

Timeline

Q2 CY2023

- Orphan Drug Designation
- OLE Update (Survival and ALSFRS-R Analysis)
- Board & Management Hires
- Pipeline Expansion

Q3 CY2024

- STRIKE Study HREC Approval
- EMA CTA
- Open IND
- OMPD
- CMC Validation Batches
- 1st STRIKE Patient Dosed

CTA – Clinical Trial Application; EMA – European Medicines Agency; HREC – Human Research Ethics Committee; IND – Investigational New Drug; OMPD – Orphan Medicinal Product ; OLE – Open Label Extension;

ASX: PAA

Registered Address:
Suite 116, 1 Kyle Way, Claremont WA 6010
Australia

Phone: +61 (8) 9202 6814
Email: investorenquiries@pharmaust.com