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PharmAust

Easy to swallow

- PharmAust (PAA) is a drug development company with a focus on the treatment of motor neurone disease (MND).
- In this report, we outline what the Company does, its major assets, basis for clinical interest, and key catalysts ahead.

What do they do?

- PAA is a clinical-stage biotechnology company that focuses on developing therapeutics for neurodegenerative diseases. Their primary asset is monepantel, a drug currently approved as a sheep and cattle de-worming agent, but is being repurposed for treating human neurodegenerative conditions such as MND.
- PAA have successfully completed a Phase 1 trial for monepantel in treating MND and are now preparing for a larger adaptive Phase 2/3 trial.
- The company is also actively patenting monepantel for cancer and other diseases reliant on the mTOR pathway, as well as analogues with potentially greater potency.

What is the market potential?

- The market potential for MND is significant due to the lack of effective treatments. Monepantel could be used as a monotherapy or in combination with other therapies if successful.
- The company estimates a total addressable drug therapy market of approximately US$3bn per annum. This is based on the incidence rate of MND and the pricing of existing treatments.
- Given the short life expectancy and rapid deterioration of motor functions, the incidence rate of ~1.7 per 100,000 works out to around 130k newly diagnosed patients per annum.

Operational developments

- Over the past few months, there has been a significant overhaul in the management and board, introducing substantial commercial expertise in drug development. Along with the formation of a new scientific advisory board, the team is now entirely dedicated to tackling neurodegenerative diseases.
- The company has entered into manufacturing process development agreements with Syngene International and Catalent Pharma Solutions, both global leaders in the manufacture and commercial supply of pharmaceutical products.
- Syngene is tasked with producing 60 kgs of GMP monepantel, which includes an engineering batch of 15 kg and three process validation batches of 15 kg each. These batches are intended to validate the GMP manufacturing process, aid in product registration, and prepare the company for commercial supply.
- Catalent Pharma Solutions will handle the GMP production of three registration batches, amounting to over 1m tablets. These batches are necessary for supporting product registration.

Catalysts

- The company is currently finalising plans for an adaptive Phase 2/3 trial in the US, Europe and Australia (STRIKE study). They expect to find out in the coming months for its acceptance into the HEALEY ALS Platform Trial inclusion which is designed to accelerate the process of drug development.
- Other upcoming catalysts include potential grant funding, IND submission, and HEALEY ALS Platform Trial acceptance. Interim and full results from the Open Label Extension Study are also anticipated.
- The company also recently appointed Dr. Herbert Brinkman as Head of Manufacturing. Dr. Brinkman brings over 30 years of experience in the pharmaceutical industry to the role. He has successfully launched nine products in the US and has prepared over 25 Chemistry Manufacturing and Control (CMC) sections for various regulatory filings.

KEEPING STOCK

Stock code:	PAA AU
Price:	A$0.185
Market cap:	A$82m
Average daily turnover:	A$0.5m
Index inclusion:	N/A

Price performance

(%)	1M	3M	12M	3Y
Absolute	-9.8	-50.7	134.2	98.9
Rel ASX/S&P200	-10.0	-48.5	127.7	92.7

Source: IRESS

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Analyst(s) own shares in the following stocks mentioned in this report:

– PharmAust

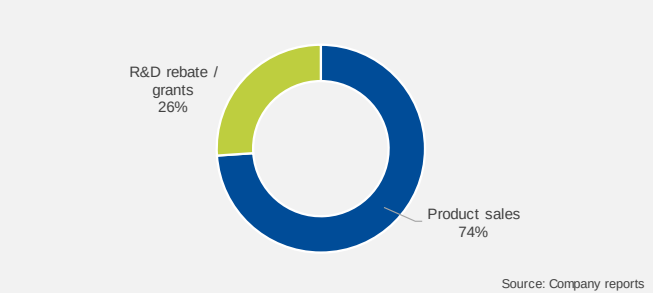
Important disclosures regarding companies that are the subject of this report and an explanation of recommendations can be found at the end of this document. Morgans Financial Limited (ABN 49 010 669 726) AFSL 235410 - a participant of ASX Group.

PharmAust

Price (A$):	0.185	Industry:	Pharmaceuticals
Market cap (A$m):	82	Index inclusion:	N/A

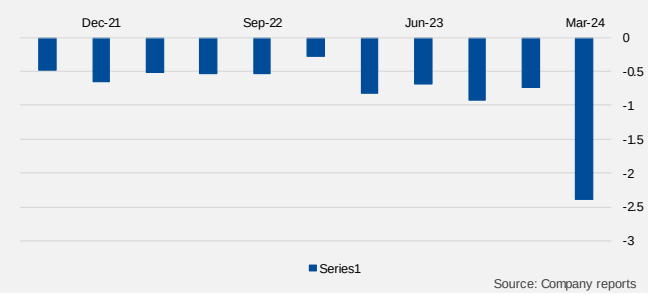
PharmAust is a clinical-stage biotechnology company developing therapeutics for neurodegenerative diseases. The company is focused on repurposing monepantel (MPL) for amyotrophic lateral sclerosis (ALS). ALS is the most common form of motor neurone disease (MND) and affects both upper and lower motor neurons.

Revenue by segment (A$m) - FY23



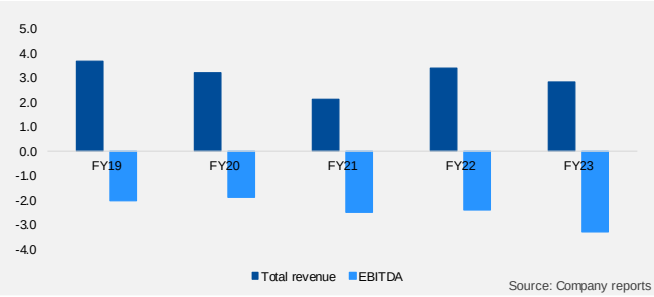
Source: Company reports

Operating cash outflow ex R&D rebates (A$m)



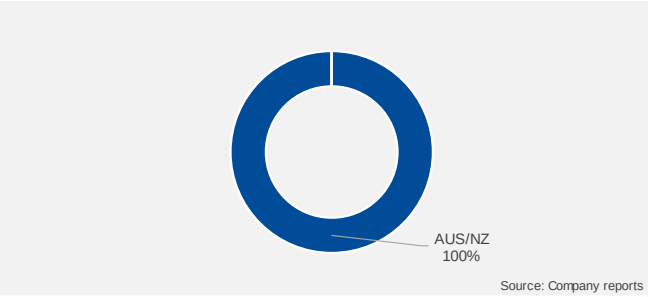
Source: Company reports

Revenue & EBITDA (A$m)



Source: Company reports

Revenue by geography (A$m) - FY23



Source: Company reports

Bull points

Focused on an underserved indication
There are currently only two drug treatments for MND/ALS. Both show no functional improvement over placebo and only minimal improvements in life expectancy.

Rare diseases - high investor interest
Share price performance of several ASX listed rare disease companies following clinical success has placed a spotlight on the sector. Investors are actively looking for these opportunities with reasonable grounds for clinical success.

Bear points

Pre-revenue
PAA is currently clinical stage and pre-revenue. R&D expenses are expected to increase significantly over the next 24 months as its Ph2/3 ALS trial commences.

Capital requirements
Running trials is highly capital intensive. While PAA is currently funded for trial startup and preparations, further capital may be required as the trial progresses.

Environmental, Social and Governance

Exposure
PAA does not own or control any buildings or vehicles, and therefore does not produce Scope 1 or 2 emmissions. While PAA has no specific set targets or actionable details around its environmental impact, the nature of its business being predominately clinical research - the footprint would be limited. PAA also makes a positive contribution to patient outcomes.

Management
PAA has adequate policies in place to ensure ethical conduct of its employees. While PAA have a Diversity Policy Charter, given the size and composition of the organisation it has not currently met its targets and looks to improve its ratios as scale of operations allow. Majority of the board is independent.

Source: Morgans

PharmAust Limited (PAA)

Overview

PAA is a clinical-stage biotechnology company focused on developing therapeutics for neurodegenerative diseases. Its major asset is a drug called Monepantel which is an aminoacetonitrile derivative (AAD) drug currently approved as a sheep and cattle de-worming agent, however the core focus is human neurodegenerative conditions such as motor neurone disease (MND). Following a successful Phase 1 trial in MND, PAA is looking to advance its asset to a larger adaptive Ph2/3 trial.

Upcoming catalysts

- Potential grant funding (FightMND – 1Q25)
- IND submission (1Q25)
- HEALEY ALS Platform Trial acceptance (1Q25)
- Interim OLE study data (ongoing to mid CY25)
- Ph2/3 ALS trial commencement (2Q25)
    - Ph2/3 full recruitment (+6m following commencement: ~mid CY25)
        - Ph2 results (+6m following full recruitment: ~end CY25)
        - Ph3 results (+6m following Ph2 conclusion: mid-late CY26).

About motor neuron disease (MND) / Amyotrophic lateral sclerosis (ALS)

ALS is the most common form subset of a group of neurodegenerative diseases broadly referred to as motor neurone diseases (MNDs). MNDs are rare, but their rapid onset causes severe disability with a high rate of fatality (Disease Control and Prevention, 2020).

The condition affects the cells and nerves in the brain and spinal cord which control the muscles in our bodies. This results in rapid weakness and wasting of the muscles, often progressing to paralysis of the muscles in swallowing and breathing resulting in respiratory failure (National Institute of Neurological Disorders and Stroke, 2021).

The exact cause is not fully understood, with only 10% of cases being inherited (familial), while the remaining 90% having no clear genetic or environmental cause (idiopathic) (Mayo Clinic, 2022).

Disease statistics

- Incidence rate (# new cases p.a.) of 1.5 - 2 per 100,000 and a prevalence rate ~ 6 in 100,000 (existing cases) (Target ALS, 2022) .
- Deaths vary by geography, sex and age.
- One-third of patients die within 12 months of diagnosis, half dying within 15-20 months of diagnosis (Williams et al., 2023), and the average life expectancy from the time of diagnosis being ~ 2 to 3 years (Taylor et al., 2024).
- Average time from symptom onset to confirmation of diagnosis by a neurologist is 10 to 18 months.

Similar diseases

- Similar neurodegenerative diseases to MND include Alzheimer's disease (AD) and Parkinson's disease (PD). As with MND, these diseases are

characterised by the progressive loss of neurons in the nervous system. There is currently no cure for AD or PD.

Treatment options for MND

- Currently there is no cure for MND.
- Treatment is multidisciplinary and largely symptomatic care; neurology, physical therapy, respiratory therapy, social work/care, and finally palliative care.
- Medications are used as supportive therapy, only delaying the progression of the disease.
- Two main drugs used to treat MND symptoms are Riluzole and Edaravone.
- **Riluzole** was the first drug approved by the U.S. FDA in 1995 to treat MND, however it cannot reverse the damage already done to motor neurons. May extend survival by 3 to 6 months.
    - Needs prescription and limited to patients with MND diagnoses less than 5 years (plus other criteria). Can be prescribed under PBS. PBS price $30, private prescription $180 for a one month supply.
    - Works as a neuroprotective and potentially extends survival and/or time to tracheotomy (assisted breathing). No evidence to suggest improvement in motor function, lung function, muscle twitching, muscle strength, or motor functions.
- **Edaravone** (Radicava®) was originally used to treat stroke patients in Japan and since been approved for use in ALS patients since 2017.
    - The drug works as an antioxidant by suppressing the hydroxyl radical (OH)-dependent and OH-independent lipid peroxidation pathways.
    - The mechanism of action is thought to protect nerve cells by mopping up damaging “free radicals” in the body.
    - Has shown to improve survival in ALS patients by 6 months, but has not shown not affect functional outcomes.
    - Cost is ~US$172k.
- US and Canada granted conditional approval to RELYVRIO® (sodium phenylbutyrate and taurursodiol), developed by Amylyx, for the treatment of adult MND. September 2022 cost was ~US$158k p.a. Subsequent failure of Phase 3 confirmatory trial in March 2024 and has since been pulled from the market.
- QALSODY® was granted accelerated approval in 2023 by FDA for adults with MND associated with SOD1 mutations (~2% of all MND cases). Via spinal injection. Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending a marketing authorisation under exceptional circumstances for QALSODY®.
- Botulinum toxin (Botox) injections may be used to treat muscle stiffness by weakening overactive muscles. They may also be injected into the salivary glands to stop drooling. Excessive saliva can also be treated with medications such as amitriptyline, glycopyrrolate, and atropine.

Monepantel Mechanism of Action

- Monepantel is a veterinary drug that has been repurposed for use in treating MND/ALS. It is a potent inhibitor of the mTOR pathway, which is involved in cell growth, proliferation, and autophagy. Autophagy is a process cells use to recycle abnormal or defective components or molecules.
- In the context of MND/ALS, **misfolded proteins** play a significant role. These proteins, which can be produced by mutant genes, accumulate in motor

neurons, inducing dysfunctions and leading to their death. Misfolded proteins can spread from neuron to neuron, enabling the disease to spread throughout the nervous system.

- Monepantel is believed to help clear these misfolded proteins that build over time in the motor neurons of MND/ALS patients, damaging and killing these cells. By activating the mTOR pathway, monepantel may enhance the clearance of these harmful proteins.
- Recent studies have shown promising results. A Phase 1 MEND study (NCT04894240) showed that monepantel met its primary safety and tolerability endpoints, with slowing in disease progression, in patients with MND/ALS. The trial featured 12 patients with MND/ALS who were given monepantel for a 24-hour single-dose pharmacokinetic study, followed by a 4-week repeated escalating dose study. The estimated rate of decline was –0.74 in ALS Functional Rating Scale-Revised (ALSFRS-R) points per month or a 39% slowing in ALSFRS-R decline when compared with the PRO-ACT database, an external historical control cohort. All patients completed the study, with no dose-limiting toxicities experienced.
- In conclusion, Monepantel's action on the mTOR pathway and its potential to clear misfolded proteins could provide a new therapeutic approach for MND/ALS.

Monepantel in MND/ALS

Clinical studies

- **Phase 1 MEND Study**: This was a multicentre, open label study comprising a 24-hour escalating single-dose pharmacokinetic (PK) study and 4-week repeated escalating dose study to establish the safety, tolerability and PK parameters of monepantel administered orally to patients with MND/ALS. Twelve participants were enrolled in cohorts of 6 patients across 2 sites. Cohort 1 was administered 2 and 6 mg/kg/day dose levels, and Cohort 2 was administered 4 and 10 mg/kg/day dose levels. Upon completing the study, all participants continued receiving monepantel via a special access scheme and opted to enrol on a 12-month open-label extension (OLE) study.
- An **Open Label Extension Study** of Monepantel in Individuals With Motor Neurone Disease: This is a multi-centre, 12-month open label extension study, following Phase 1 MEND Study, with a single dose of monepantel once daily (QD) for the treatment of individuals with MND. A daily dose of 10 mg/kg monepantel (QD) will be studied in the OLE Study (MON-2023-001) to further evaluate long-term safety and efficacy in participants with MND/ALS that completed the Phase 1 Study (MON-2021-001).
    - Further interim data readouts are expected quarterly. Full cut of results anticipated mid CY25.
- PAA is currently finalising plans for an adaptive Phase 2/3 trial in the US, Europe and Australia (STRIKE study).
    - PAA expects to find out in the coming months for its acceptance into the HEALEY ALS Platform Trial inclusion which is designed to accelerate the process of drug development for promising new drugs. See HEALEY ALS Platform Trial section for more detail.

Clinical results

- **Safety and Tolerability Endpoints**: The safety profile of monepantel was favourable with no treatment-related deaths, no dose limiting toxicities, and all 12 patients successfully completing the study. A total of 56 treatment-emergent Adverse Events (AEs) were reported, with only 3 mild AEs considered possibly related to the study drug. Patients remained on daily

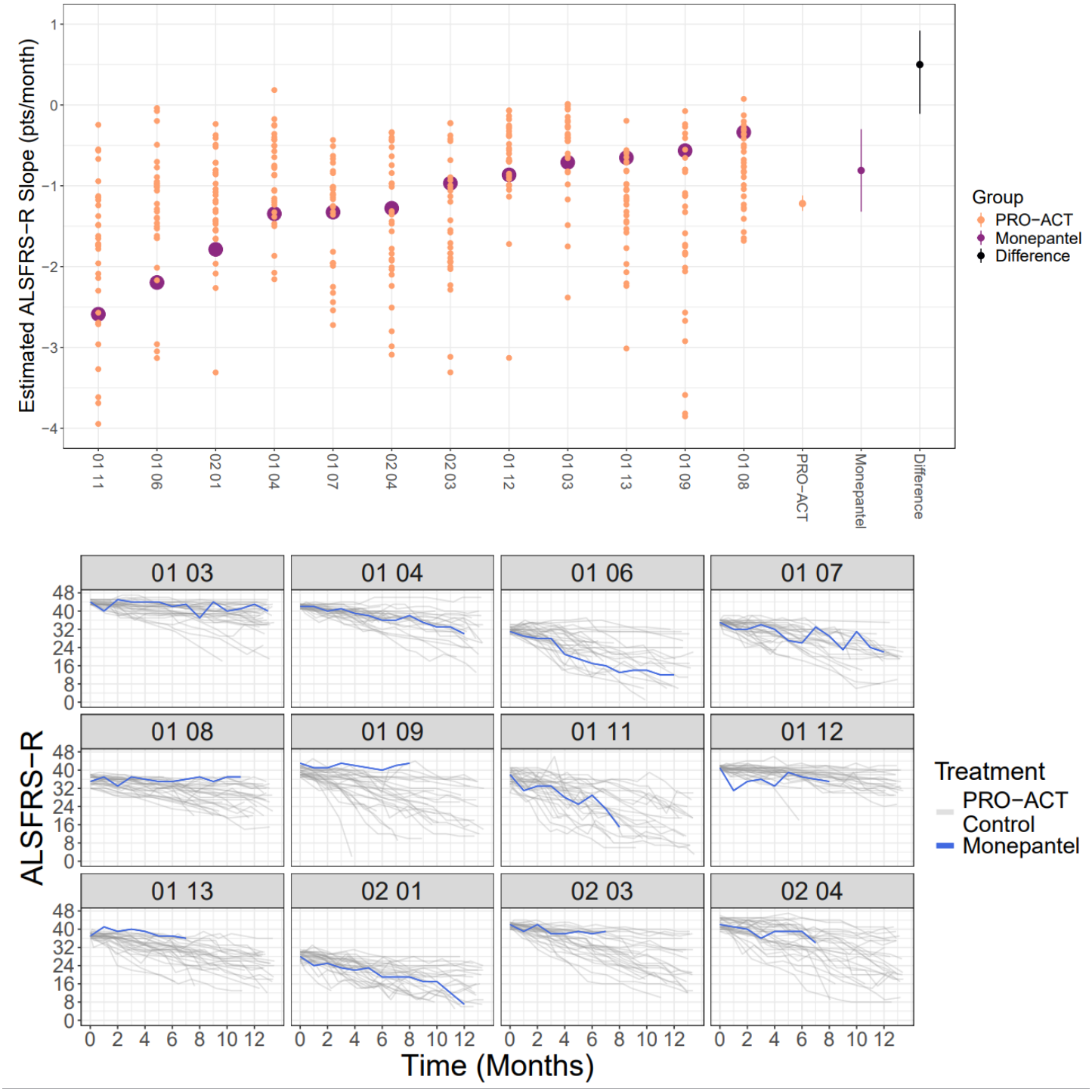
treatment of monepantel for 10 to 16 months, and all participants continued receiving monepantel after the study.

- **Exploratory Efficacy Endpoints:** The study used several clinical efficacy markers including the ALS Functional Rating Scale-Revised (ALSFRS-R), ALSSQOL-R Quality of Life Questionnaire, Edinburgh Cognitive and Behavioural ALS Screen (ECAS), and Slow Vital Capacity (SVC). There were no significant differences in ALSFRS-R scores between pre-dose and end of treatment for all patients, suggesting that treatment with monepantel over 8 – 12 months slowed the rate of disease progression.
    - A comparative analysis of the rate of decline in ALSFRS-R scores against 30 matched controls from the PRO-ACT database highlighted the potential for monepantel to slow disease progression. For all 12 patients, the estimated rate of decline was -0.74 in ALSFRS-R points per month or a 39% slowing in ALSFRS-R decline. PAA's statistical consultants suggested that depending on the current severity of the disease (determined by the pre-treatment slope of decline), monepantel could provide patients with an additional 13.5- 56.5 months in median survival.
    - The results of the additional exploratory efficacy measures of ALSSQOL-R, ECAS, and SVC further supported slowing in disease progression. In addition, the analysis of biomarkers provided supplemental supporting evidence that monepantel slows disease progression with a large reduction in cerebrospinal fluid neurofilament light chain (NfL), a measure of neuronal damage.

Figure 1: ALSFRS-R Results for Pooled Treatment Group

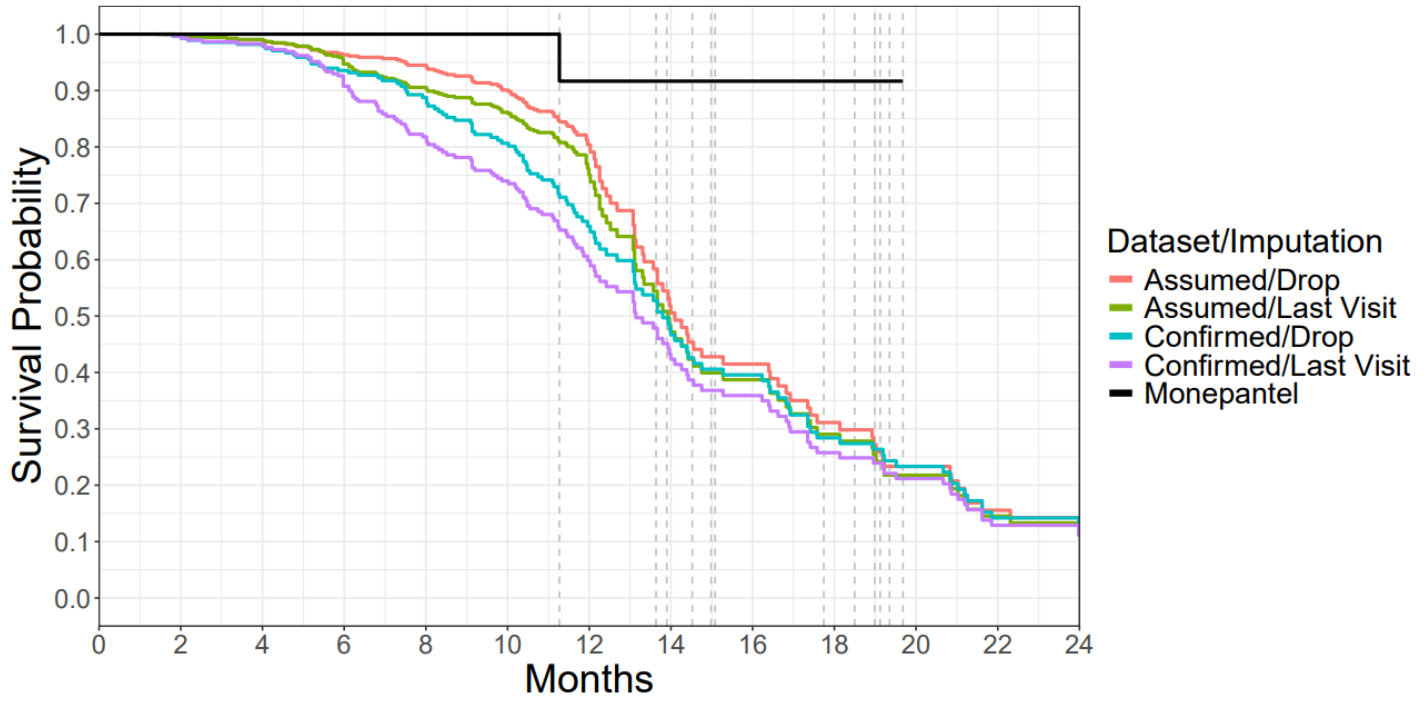
	Estimated Rate of Decline (points per month) *	Slowing in ALSFRS-R Decline *	Additional Life Expectancy **
Combined Cohort 1 + 2	- 0.74	39%	**13.5 – 56.5 months** [1]
Cohort 1 (Low Dose)	- 0.83	23%	
Cohort 2 (High Dose)	**- 0.60**	**58%**	
Relyvrio®	- 1.24	25%	**9 months**

*Berry Consultants analysis. ** Duration is dependent upon disease severity at baseline.*



Source: Company data

Figure 2: OLE survival results



Kaplan-Meier curves for each of the matched-control PRO-ACT datasets as well as the MPL treatment group. Vertical dashed lines represent the exposure time for all patients.

Source: Company data

- **Pharmacokinetics**: Concentrations of monepantel sulfone (MPLS), the active metabolite of monepantel, increased proportionally with the higher doses of monepantel. MPLS was found in the cerebrospinal fluid indicating that both monepantel and MPLS have the ability to cross the blood brain barrier.
- **Target Engagement (mTOR Pathway):** Target engagement of the mTOR pathway in the peripheral mononuclear blood cells was confirmed at all dose levels.

Market Potential

The market potential for MND/ALS is significant due to the lack of effective treatments. Given the different mechanism of action versus existing treatments, Monepantel could be used as a monotherapy or in combination with other therapies if successful.

In order to put some crude market potential numbers around monepantel in the US alone, it would be fair to peg Monepantel to Amylyx's Relyvrio® market expectations prior to its Ph3 failure.

- Relyvrio® had a list price of US$158k and based on an estimated 38k diagnosed MND patients in the US, this equates to ~US$6bn fully penetrated market for a new and promising treatment.
    - This married up with Relyvrio® peak sales expectations of US$2.6bn @ 50% market penetration prior to being withdrawn from the market.
    - Prior to being withdrawn from the market, Amylyx had generated US$381m in the first 12 months of its ALS drug being conditionally approved for sale.

Intellectual Property

PAA actively patents monepantel for cancer and other diseases reliant on the mTOR pathway, as well as analogues with potentially greater potency. Key patent going forward is the patent granted in the US (US 9,790,176) for "Compounds For The Treatment of mTOR Pathway Related Diseases", providing the company with a broad patent protection over use of monepantel as well as analogues across all mTOR pathway-related diseases out to 2033 including neurodegenerative diseases.

In addition to its patent portfolio of which five patent families have been granted across most major jurisdictions, PAA also has the benefit of being granted orphan drug designation (ODD) for the treatment of ALS which grants 7 years of market exclusivity upon approval by the US FDA.

Manufacturing capabilities

- Syngene International and Catalent Pharma Solutions, both global leaders in the manufacture and commercial supply of pharmaceutical products, have entered into manufacturing process development agreements.
    - Syngene is tasked with producing 60 kgs of GMP monepantel, which includes an engineering batch of 15 kg and three process validation batches of 15 kg each. These batches are intended to validate the GMP manufacturing process, aid in product registration, and prepare the company for commercial supply.
    - Catalent Pharma Solutions will handle the GMP production of three registration batches, amounting to over 1m tablets. These batches are necessary for supporting product registration and facilitating commercial scale-up activities. The manufactured product will be utilised in the forthcoming adaptive Phase 2/3 trial.
- These manufacturing process development agreements are expected to be succeeded by a commercial supply agreement.
- PAA also recently (April 2024) appointed Dr. Herbert Brinkman as Head of Manufacturing. Dr. Brinkman brings over 30 years of experience in the pharmaceutical industry to the role. He has successfully launched nine products in the US and has prepared over 25 Chemistry Manufacturing and Control (CMC) sections for various regulatory filings. He has also filed 21 Abbreviated New Drug Applications (ANDAs) and is an inventor on 14 patents.

Other items

HEALEY ALS Platform Trial

The HEALEY ALS Platform Trial is an US initiative designed to accelerate the process of drug development and the path for effective treatment for ALS/MND. This is achieved by testing multiple drugs simultaneously and adaptively. This study design approach has been seen to be successful for cancer trials.

Compared to traditional drug development, the platform trial is estimated to find an effective therapy more quickly (average 3.4 vs. 8.5 years), with fewer total participants (average 880 vs. 1400), and fewer participants on placebo (average 220 vs. 700). Participants will have an equal chance to be randomised to all regimens that are active at the time of screening. Once randomised to a regimen, participants will be randomised in a 3:1 ratio to either study drug or placebo. (MND Association)

New regimens will be continuously added as new investigational products become available. The HEALEY ALS Platform Trial will enrol additional participants as each new regimen is available. This trial is recruiting in the US only.

The HEALEY ALS Platform Trial, like similar platform studies in cancer drug development, is testing multiple drugs at the same time, using specialised statistical tools. There is only one placebo group, however, meaning that 80% of patients receive a treatment rather than a placebo.

This is a multi-center, double-blind, placebo-controlled, perpetual, adaptive platform trial testing multiple investigational products in parallel to find safe and effective treatments for people living with ALS.

Potential grant

- FightMND is an Australian charity organisation founded in 2014 by former AFL player Neale Daniher. The organisation is dedicated to fighting MND and has invested more than A$55m into MND research since 2014. FightMND supports projects focused on overcoming key barriers preventing the advancement of potential treatments through to clinical trial.
    - PharmAust and FightMND have collaborated previously. In June of 2022, FightMND pledged $900k to PharmAust to conduct research into MND. Following the first $200k grant, PharmAust proceeded to a Phase 1 clinical trial.

Financials

Figure 3: Historical financial statements

Historical data	FY19	FY20	FY21	FY22	FY23
Income Statement (A$m)					
Total revenue	3.7	3.2	2.1	3.4	2.8
Growth (%)	*27.8*	*-12.9*	*-33.0*	*58.0*	*-16.5*
Gross Income	n.a.	n.a.	n.a.	n.a.	n.a.
Growth (%)		n.a.	n.a.	n.a.	n.a.
Gross Margin (%)	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT	-2.2	-2.2	-2.8	-2.7	-3.6
Growth (%)	24.7		-28.5	1.5	-31.8
EBIT Margin (%)	-59.9	-67.9	-130.3	-81.3	-128.3
EBITDA	-2.0	-1.9	-2.5	-2.4	-3.3
Growth (%)	27.7	6.4	-31.4	2.3	-35.4
EBITDA Margin (%)	-55.2	-59.3	-116.4	-72.0	-116.7
Net Income	-1.6	-1.4	-1.3	-1.7	-6.2
Growth (%)	38.5	12.2	1.8	-27.7	-263.6
Balance Sheet (A$m)					
Cash & STI	2.1	2.9	3.0	2.4	2.7
Total Assets	8.6	10.7	11.0	10.1	6.1
Total Debt	0.3	1.5	1.3	1.4	1.0
Net Debt	-1.8	-1.4	-1.7	-1.0	-1.7
Total Liabilities	1.1	2.2	2.1	2.2	2.2
Total Shareholders' Equity	7.5	8.5	8.9	7.8	3.9
Cash Flow (A$m)					
Net Operating Cash Flow	-1.6	-1.3	-0.9	-1.3	-1.6
Capital Expenditures	-0.1	0.0	-0.1	0.0	0.0
Net Investing Cash Flow	-0.1	0.0	-0.1	0.0	0.0
Net Financing Cash Flow	1.9	2.1	1.2	0.8	1.9
Free Cash Flow	-1.7	-1.3	-1.0	-1.4	-1.6
Profitability (%)					
Gross Margin	6.8	-13.3	-36.0	-6.6	-32.9

Period	FY19	FY20	FY21	FY22	FY23
Profitability					
Operating Margin	-59.9	-67.9	-130.3	-81.3	-128.3
Net Margin	-42.3	-42.6	-62.5	-50.5	-220.0
Return on Assets	-18.3	-14.1	-12.3	-16.2	-76.6
Return on Equity	-21.3	-17.0	-15.4	-20.4	-105.9
Return on Invested Capital	-21.0	-15.8	-13.6	-18.1	-90.9
Coverage (x)					
Net Debt/EBITDA	0.0	0.0	0.0	0.0	0.0
Valuation					
Sales per Share	0.0	0.0	0.0	0.0	0.0
EPS (diluted)	0.0	0.0	0.0	0.0	0.0
Growth (%)	*54.5*	*35.2*	*8.7*	*-28.6*	*-259.3*
Dividends per Share	0.0	0.0	0.0	0.0	0.0
Growth (%)	*0.0*	*0.0*	*0.0*	*0.0*	*0.0*
Book Value per Share	0.0	0.0	0.0	0.0	0.0
Growth (%)	*-18.2*	*6.1*	*-0.7*	*-11.7*	*-54.8*
Shares					
Diluted Shares	219.3	296.0	315.7	316.9	321.0
Ratios (x)					
Price / Sales	2.3	14.4	13.4	6.6	8.5
Price / Earnings	-	-	-	-	-
Price / Book Value	1.4	5.5	3.2	2.8	6.7
Price / Tangible Book Value	2.4	8.6	5.0	4.7	33.3
Price / Cash Flow	-5.4	-36.1	-30.6	-16.6	-15.4
Price / Free Cash Flow	0.0	0.0	0.0	0.0	0.0
Dividend Yield (%)	0.0	0.0	0.0	0.0	0.0
Dividend Payout Ratio (%)	0.0	0.0	0.0	0.0	0.0
Enterprise Value / EBIT	-4.0	-20.9	-9.7	-7.7	-6.7
Enterprise Value / EBITDA	-4.4	-23.9	-10.9	-8.7	-7.4
Enterprise Value / Sales	2.4	14.2	12.7	6.3	8.6
EBIT / Interest Expense	-46.0	-18.3	-35.3	-31.1	26.5

Source: Factset, company data

Board and management

Figure 4: Key management personnel

Name	Position	Brief bio
Dr Michael Thurn	MD & CEO	Dr Michael Thurn brings broad experience in drug discovery, development, regulation and commercialisation, acquired through leadership roles in research organisations and industry, including early stage, fast-growing, private and publicly listed biotechnology companies. His previous responsibilities have included leading a variety of US Food and Drug Administration (FDA) Investigational New Drug (IND) applications across a range of therapeutic areas and the evaluation of drugs and vaccines for registration in Australia as a part of the Drug Safety Evaluation Branch (DSEB) of the Therapeutics Goods Administration (TGA).
Mr John Clark	COO	John Clark joined PharmAust with over 20 years of pharmaceutical industry experience in phase I – IV clinical trials across numerous therapeutic areas and multiple geographical regions. Most recently, John served as Senior Project Manager at a Global CRO, leading the Clinical Operations team and providing cross-functional oversight on a national CNS trial. Before that, John held various clinical operations leadership roles responsible for implementing clinical programs. John has a proven project management and stakeholder engagement record, with a thorough knowledge of ICH-GCP and regulatory requirements.
Dr Nicky Wallis	CSO	Dr Wallis is a neuroscientist and brings over 12 years of global expertise in clinical development, spanning pre-clinical through to Phase 3 drug and device development. She has a proven track record in managing multi-site, international clinical studies across the US, Europe, Australia, and New Zealand, with a strong focus on regulatory submissions and compliance, cross-functional collaboration, and vendor management. Prior to joining PharmAust, Dr Wallis provided clinical development consulting services to both private and public biotechnology companies in Australia, with a focus on central nervous system diseases. Her extensive experience includes roles such as Clinical Trials Program Specialist at the Australian Clinical Trials Alliance, Vice President of Clinical Operations at Lateral Pharma Biotech, and Clinical Project Manager at Orygen Youth Mental Health Research. Dr Wallis holds a PhD from The University of Melbourne/The Florey, where her research focused on understanding the pathogenesis of MND/ALS and Alzheimer's Disease.
Dr Herbert Brinkman	Head of Manufacturing	Dr Herbert Brinkman, based in Denver, Colorado, has over 30 years of experience in the pharmaceutical industry. Dr. Brinkman has prepared over 25 Chemistry Manufacturing and Control (CMC) sections and updates for multiple Investigational New Drug (IND), New Drug Application (NDA), supplementary NDA (sNDA), Investigational Medicinal Product Dossier (IMPD), and Abbreviated NDA (ANDA) filings for United States Food and Drug Administration (FDA) and European regulatory agencies. Dr Brinkman has filed and commercially launched nine products encompassing oncology, metabolic, dermatology, and endocrinology therapeutic areas and contributed to filing 21 ANDAs for various semi-solid and parenteral products. He is also an inventor on 14 patents. His expertise includes current Good Manufacturing Practice (cGMP) systems applied to API manufacture / Drug Product manufacture and addressing regulatory issues. Dr Brinkman's previous position was Executive Director of Product Development at NASDAQ-listed company Arcutis Biotherapeutics, Inc. (NASDAQ: ARQT), where he was responsible for the successful commercial launch of ZORYVE (roflumilast).

Source: Company data

Figure 5: Board of directors

Name	Position	Brief bio
Mr Sergio Duchini	Chairman	Mr Duchini brings over a decade of board-level experience with expertise spanning professional services, life sciences, biotechnology, banking, finance, and the not-for-profit sector. His extensive background includes roles such as Chair, Executive and Non-Executive Board Director, Risk & Audit Committee Chair, and Chief Strategy Officer. Mr Duchini has previously sat on the AusBiotech Board of Directors for nine years, where he played a pivotal role in the development of two national life science industry strategies. Mr Duchini's executive experience includes 23 years at Deloitte Australia where he held multiple senior positions as an equity partner.
Dr Michael Thurn	MD & CEO	As in KMP
Dr Katie MacFarlane	NED	Dr Katie MacFarlane has over 30 years of experience in the development and commercialisation of pharmaceutical products and devices. She is the Founder and President of SmartPharma, a commercial and strategic consulting firm that specialises in market and product assessments, market sizing and forecasting, pre-launch preparation and launch and marketing of pharmaceutical products for biopharmaceutical companies. Katie also currently is the Head of Commercial for Arkayli Biopharma, a startup developing a treatment for a rare pediatric disease. Previously, she was Chief Commercial Officer at Agile Therapeutics, Vice President of Marketing, Sales and New Product Planning at Warner Chilcott, and Senior Director of Marketing at Parke-Davis (now Pfizer). Dr MacFarlane is a member of the Board of Directors of Mayne Pharmaceuticals
Mr Marcus Hughes	NED	Mr Hughes 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.

Source: Company data

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