



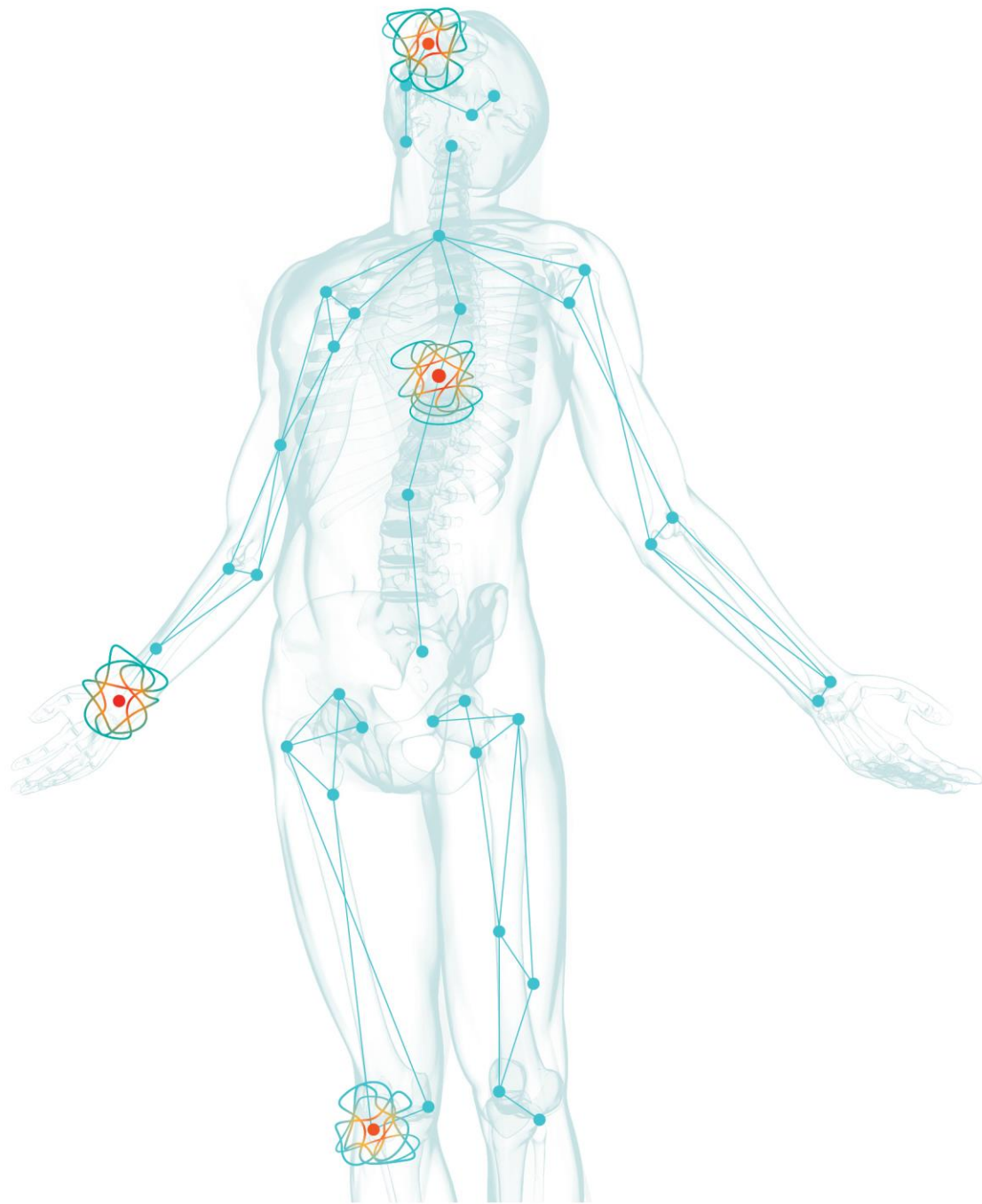
paradigm
BIOPHARMA

AGM

ASX: PAR

Paul Rennie, CEO & MD

30 November, 2016



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Drug repurposing strategy

Much lower cost, accelerated timeline, lower risk and with higher rates of success

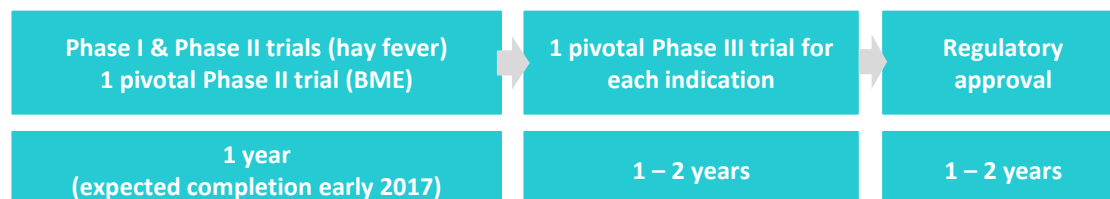
- **Lower cost:** average development cost of US\$28m compared to US\$1.3bn for “de novo” development¹
- **Faster:** FDA 505(b)(2) pathway leveraging previous clinical efforts, which accelerates the development timeline
- **Lower risk:** safety already established so less chance of failure (safety issues account for 30% of clinical failures¹)
- **Higher success rates:** 25% chance of successful commercialisation compared to 10% for “de-novo” drugs¹
- **Repurposed drugs have the same potential** to reach ‘blockbuster drug status’ as de novo drugs

Standard clinical development^{1,2}



Paradigm's drug repurposing timeline

3-5 year process to approval, potential for cash flow in 2017 if a partnering opportunity is secured



Source:

1. Khanaoure A, Chuki P & De Sousa A (2014)
2. Ashurn T & Thor K (2004)

Investment Proposition

- **Reduce clinical trial costs and accelerate commercialisation** by repurposing a pre-approved drug - **505(b)(2)**
- **Several major Phase 2 clinical trial catalysts** expected over the next 12 months
- **With existing drugs, two types of data can be generated**, DBPC Phase 2 clinical trial data and Real-World-Evidence data.
- **Highly credentialed board and management team** with top tier experience at CSL Limited (CSL:ASX) and Mesoblast Limited (MSB:ASX)
- **Strong focus on prudent cash management** to enhance shareholder returns
- **High impact partnering opportunities** – Osteoarthritis, viral arthritis and inflammatory bowel disease all have large unmet clinical need for safe treatments

Company Overview



Financial information

Share price (08-Nov-17)	A\$0.35
Number of shares ¹	121.1m
Market capitalisation	A\$42.41m
Cash (30-Sept-17) Inc Placement	~A\$7.5m
Enterprise value	A\$34.9m

Top shareholders^{2,3}

	Shares (m)	%
Paul Rennie (<i>Managing Director</i>)	21.8 ³	18.0%
MJGD Nominees (<i>technology vendor</i>)	6.9	5.7%
Other Board and management	7.1	5.8%
Irwin Biotech (<i>technology vendor</i>)	6.3	5.2%



Source: IRESS

Note:

1. Includes the Nov 2017 Placement of ~19.17m New Ordinary Shares
2. MJGD Nominees and Irwin Biotech are select vendors of Xosoma, which was acquired by Paradigm prior to listing
3. Mr Paul Rennie subscribed for 333,334 ordinary shares (\$0.30 per share) in the Nov 2017 Placement subject to shareholder approval

Board and Management

High quality Board and management, with top tier pharmaceutical experience

- Board and management are renowned leaders in the biopharmaceutical industry, having held senior management positions with top ASX-listed companies, CSL (CSL.ASX) and Mesoblast (MSB.ASX)
- Extensive experience bringing biopharmaceutical products from clinical development to commercialisation
- Small and highly specialised team focused on product development utilising outsourcing effectively

Board and management

Graeme Kaufman – Non-executive Chairman

- Broad experience in development and commercialisation of pharmaceutical drugs, previously CFO at CSL and executive VP of Mesoblast

Paul Rennie – Managing Director

- Extensive experience in drug development and commercialisation, previously COO & Executive VP, New Product Development of Mesoblast

John Gaffney – Non-executive Director

- 30+ years experience as a lawyer, previously Director of Patrys (PAB.ASX)

Christopher Fullerton – Non-executive Director

- Chartered Accounting and investment banking expertise, previously Non-executive Chairman of Bionomics and Cordlife (now Life Corporation (LFC.ASX))

Dr Ravi Krishnan – Chief Scientific Officer

- Significant experience in experimental pathology and investigating novel compounds with immune modulatory effects and anti-inflammatory properties

Kevin Hollingsworth – CFO & Company Secretary

- Previously CFO and Co-Sec of Mesoblast and Patrys (PAB.ASX)

Pentosan Polysulfate Sodium

PPS has a long safety history and is currently being sold in the US and Europe

Pentosan Polysulfate Sodium

- Pentosan Polysulfate Sodium (PPS) has been used in humans for more than 60 years
- First approved by FDA more than 30 years ago
- Since approval, there have been in excess of 100 million injectable doses of PPS administered
- Paradigm has been granted patents to use PPS for new indications

Current treatment uses

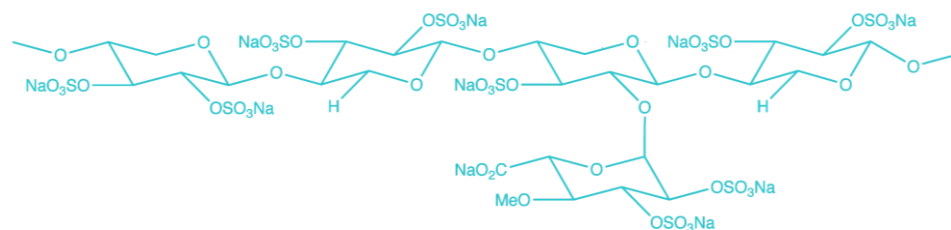
- The oral formulation is FDA approved and sold under the name Elmiron, by Janssen Pharmaceuticals, for the treatment of interstitial cystitis (painful bladder syndrome)
- Also used to treat deep vein thrombosis

Current distributors



Ideal biological characteristics

- PPS is an anti-inflammatory and an anti-histamine with biological characteristics that make it ideally suited for treating hay fever (allergic inflammation in the nasal passage) and bone marrow edema (inflammation in the bone) & viral arthritis
- ✓ Anti-inflammatory
- ✓ Anti-histamine
- ✓ Anti-clotting
- ✓ Prevents necrosis (premature cell death)
- ✓ Prevents cartilage degeneration



IP Protection

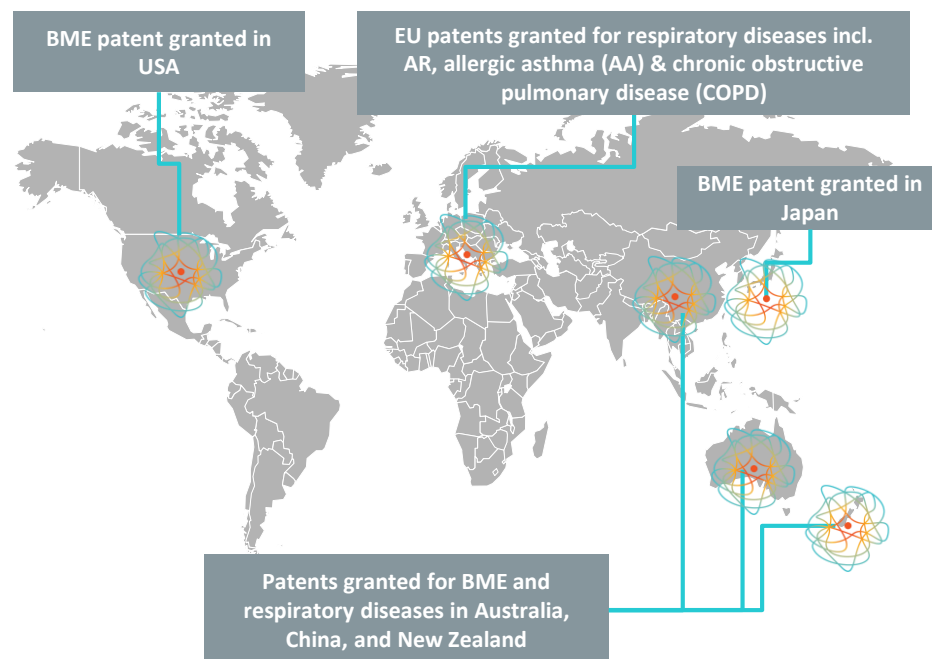
Multi-faceted IP protection increases barriers to entry for potential competitors

Valuable patent portfolio

- Paradigm has patent protection because it is using PPS for new indications
- Patents granted for specific indications
- Established regulatory exclusivity and trademarks
- Patent applications for Ross River virus and Chikungunya virus

Secure manufacturing and supply

- Exclusive 20 year supply agreement with bene PharmaChem¹
- bene pharmaChem makes the only FDA-approved form of PPS
- Manufacturing methods are a well kept trade secret
- Reduces risks associated with manufacturing and supply



Note:

1. bene pharmaChem is a private company located in Germany and manufactures the only officially approved and clinically tested medicinal PPS in the USA, Europe and Australia

Broad Product Pipeline



Drug Candidate	Indication(s)	Preclinical	SAS Pilot/Phase 1	Phase 2	Milestones (next 12 months)
Orthopaedic - Bone Marrow Edema/Lesions (Bone Bruising)					
PPS	BME with acute injuries (ACL etc)			~10 ACL Patients	ACL-BME Phase 2a results read out
	BME with Osteoarthritis (OA) - placebo controlled			100 OA patients	Commenced Phase 2b BME/OA Trial
	BME with Osteoarthritis (OA) - RWE Open Label			100 OA patients Open Label/RWE	25 patient groups reported qrtly
Viral Arthritis – Alphavirus					
PPS	Ross River Virus (RRv)		30 SAS RRv Patients	24 RRv Patients	Complete Phase 2
	Chikungunya virus (CHIKV)				Enter Phase 2 + other pilot studies
Respiratory					
PPS	allergic rhinitis (hay fever)		20 Phase 1 safety	40x2 patient crossover	Analyse trial data and reformulate
	Chronic Obstructive Pulmonary Disease (COPD)				Develop formulation & partner
	allergic asthma				Develop formulation & partner
Cardiovascular					
PPS	heart failure				Conduct 24 person placebo controlled Phase 1/2
Inflammation & autoimmune					
Novel Anti IL-1 RA inhibitor peptide	auto-immune disorders (IBD, Crohns’ disease, GVHD), oncology, complications from cytotoxic drugs (mucositis) and cancer cachexia		26 patients phase 1/2		Reformulate into oral compound Finalise data pack & partner or progress human clinical trials

The AGM – the Company Scoreboard



Company Scoreboard – Milestones achieved CY2016

Milestones Achieved CY2016

1. US Patent granted for treatment of Bone Marrow Edema with PPS;
2. Ethics Approval for Open Label Pilot Phase 2 Bone Marrow Edema clinical trial;
3. 1st Patient treated under the Open Label Pilot Bone Marrow Edema trial;
4. 1st Patient treated under the TGA's Category B Special Access Scheme for Bone Marrow Edema;
5. Finalize Nasal Formulation for Allergic Rhinitis;
6. ✗ Peer review scientific publication of preclinical Allergic Rhinitis study; ✓
7. Ethics Approval for Phase 1 clinical trial Allergic Rhinitis;
8. ✗ 1st Patient treated with PPS Nasal Spray; ✓
9. Granted Allergic Rhinitis patent in at least one major market, USA, Japan or Europe.

Additional Milestones Achieved CY2016

New acute injury BME clinical trial centre initiated.

Ten BME patients treated under Therapeutic Goods Administration (TGA) Special Access Scheme (SAS). This has created interest in two pilot clinical trials (1) BME in patients with osteoarthritis and (2) BME in newly diagnosed rheumatoid arthritis.

New IP acquired from Griffith University (PPS to treat viral arthritis arising from Alphavirus Infections).

Ten Ross River Virus patients treated under TGA SAS.

Ross River and Chikungunya clinical trial preparation has commenced.

Over subscribed capital raise (\$6.2M) and R&D Tax (\$1.25M).

Publication drafted for BME case report.

R&D undertook DD on four new projects

Company Scorecard –Milestones for CY2017.



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BME Milestones for CY2017

Close-out open-labelled acute BME study Q2 2017. ✓ Results Q4 CY2017 or Q1 CY 2018.

Commence Phase 2b randomised, double-blind placebo-controlled clinical trial in subjects with osteoarthritis and concurrent BML (n=100) ready out CTQ4 2018 – CYQ1 2019. ✓

Respiratory Milestones for 2017

Complete Phase 2 clinical trial with read-out Q3 2017. ✓

Commence commercial partnership opportunities. ✓

Product development for a new product to treat other allergic conditions. ✗

Alphavirus Milestones for 2017

Commence RDBPC Phase 2 clinical trial Ross River. ✓

Commence Chikungunya Phase 2 clinical trial (Brazil) (Planning has commenced). ✓

Additional Milestones Achieved CY2017

Twenty-Four Doctor's patients with advanced OA treated with PPS under the TGA SAS. ✓
83% response rate to reduction in pain;
80% response rate to improved knee function.
Another Twenty-Five Doctor's patients treated under the TGA SAS expected to be reported in Q1CY 2018.

Ross River Phase 2A commenced – expected readout Q2 or Q3 CY 2018. ✓

Over subscribed capital raise (\$5.75 Million) ✓
R&D Tax (\$1.7M). ✓

Publication peer-reviewed and published for Patient with OA and concurrent BML – A case study. ✓

Implemented a Company Quality System ✓

Replaced E-DMS ✓

R&D undertook DD on four new projects. ✓

Company Scorecard –Milestones for CY2018.

Milestones for CY2018

Phase 2 RDBPC Clinical Trial Viral Arthritis Q2 or Q3 CY2018.

Phase 2 RDBPC Clinical Trial Degenerative Arthritis Q4 CY2018 or Q1 CY2019.

RWE Date Acute Injuries Throughout CY2018.

RWE Data Degenerative Arthritis Throughout CY2018.

RWE CLBP and RA.

Continue to develop commercial partnerships.

Ongoing R&D and product development.

Ongoing assessment of hay fever product.



Hay Fever: Clinical Timeline

Paradigm is on track with clinical development timeline and expenditure

- Nasal formulation, intra-nasal toxicology and Phase 1 clinical trial complete.
- Ethics and Swedish Regulatory approval.
- Participant screening and recruitment has commenced.
- Successful Phase II results are expected to result in a significant licensing opportunity



Clinical development timeline

	2015				2016				2017	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Bridging nasal toxicology study										
Nasal formulation development										
Nasal spray product development (Aptar device)										
Phase I safety study (n=20) - COMPLETED										
Ethics approval for Phase II trial										
Phase II placebo-controlled allergen challenge study										

Hay Fever

Hay fever is a very common condition that is poorly treated at present

What is hay fever (allergic rhinitis)?

- Allergic inflammation of the nasal airways, when an allergen is inhaled by a sensitised individual

Why focus on hay fever?

- Strong need for more effective treatment options
 - **More than 50% of patients are dissatisfied with current medication and 60% have said they would be interested in new treatments¹**
 - Long term use of corticosteroids proven to be harmful to certain sufferers
- Clear need for safer, superior and cheaper treatments
- Hay fever associated with growing economic burden

Addressable market for hay fever:



600
MILLION

Estimated number of people who suffer from hay fever worldwide²

US\$11+ BILLION
size of the therapeutic market for hay fever in 2014³

Source:

1. 2005 survey conducted by Asthma and Allergy Foundation of America
2. Mullol J, et al. (2008)
3. Visiongain: Allergic Rhinitis Drugs Market Forecast 2015-2025

Share Price Catalysts

Upcoming milestones should drive strong shareholder returns

Arthritis

- Phase 2 RDBPC Clinical Trial Viral Arthritis Q2 CY 2018
- Phase 2 RDBPC Clinical Trial Degenerative Arthritis Q4 2018
- RWE Data Acute Injuries Throughout CY 2018
- RWE Data Degenerative Arthritis Throughout CY 2018