

ASX RELEASE

Investor roadshow presentation

20 June 2016, Melbourne, Australia: Paradigm Biopharmaceuticals Limited (ASX: PAR) (**Paradigm** or **Company**) wishes to advise that the following investor roadshow presentation will be shared with investor groups in Australia this week.

- END -

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About the Company

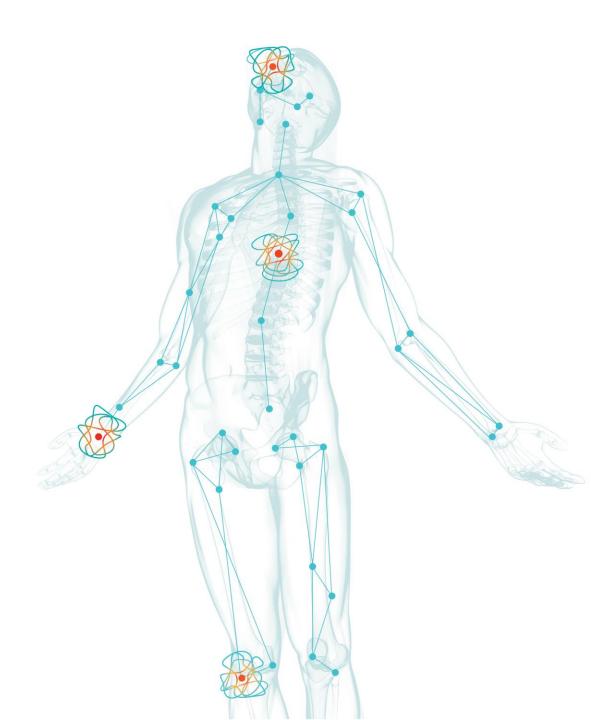
Paradigm Biopharma (PAR) listed on the ASX in August 2015. The Company is focused on repurposing pentosan polysulphate sodium (PPS) for new orthopaedic and respiratory applications. Paradigm addresses conditions that start with and are sustained by inflammation. Lead clinical indications involve treating injury that results in bone marrow edema (BME) and the allergic inflammatory response in allergic rhinitis (AR), which is commonly known as 'Hay Fever'.



Investor roadshow presentation

Paul Rennie, CEO & MD

20 June 2016



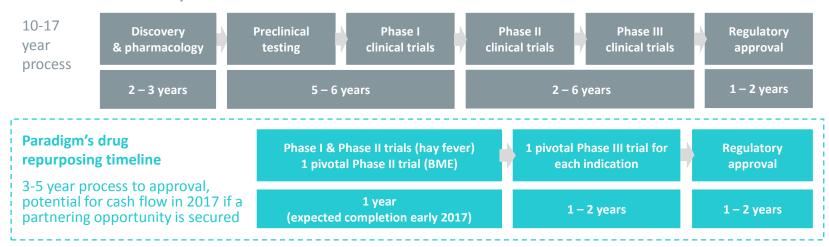
Drug repurposing strategy



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

- Lower cost: average development cost of US\$8-41m 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}



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

Company highlights



- Repurposing a pre-approved drug to reduce clinical costs and accelerate commercialisation
- Pentosan Polysulfate Sodium is a new, multi-acting treatment for bone bruising and hay fever, both of which have very large addressable markets (US\$13.5bn+)
- Highly credentialed Board and management team with top tier experience at CSL and Mesoblast
- Multi-faceted IP strategy and ability to leverage relationships to fast-track time to market
- Strong focus on prudent cash management to enhance shareholder returns
- Fully funded through to the completion of the open label clinical trial for bone bruising
- All short-term operational milestones have been met, with several major clinical trial and development catalysts expected over the next 6-12 months
- Strong platform for growth and growing global interest in bone bruising and hay fever spaces

Operational milestones



Paradigm has met all short term deliverables since IPO

18-Aug-15: IPO

Paradigm lists on the ASX raising A\$8.0m at A\$0.35 offer price Lodge Partners is the underwriter and manager

23-Nov-15: Bone bruising clinical trial approved

Ethics approval granted from the Human Research Ethics committee

15-Dec-15: Respiratory patents granted

Secured European patent to use PPS to treat respiratory diseases

26-Feb-16: First patient enrolled in bone bruising trial

Open label phase II clinical trial to determine the safety and tolerability of ZILOSUL® in patients with a bone bruise

26-Aug-15: Bone bruising patents granted

Secured US patent to use PPS for the treatment of bone bruising

More recently bone bruising patent secured in Japan

3-Dec-15: Elite athlete successfully treated with ZILOSUL®

Elite athlete in a major Australian sporting code with an ongoing knee issue was treated using ZILOSUL®

Player had an excellent response, was able to do a full pre-season and play the 2016 season

9-Jun-16: Rapid progress in hay fever clinical trial

Safe toxicology report for hay fever clinical trial

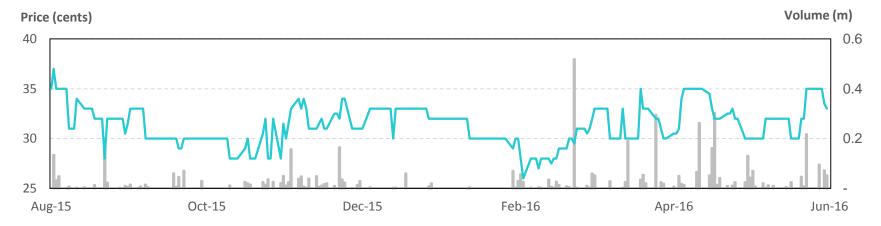
Phase I trial commencing on 20 June, closed out by 30 August

Company overview



Financial information	
Share price (17-Jun-16)	A\$0.33
Number of shares ¹	87.6m
Market capitalisation	A\$28.9m
Cash (31-Mar-16)	A\$4.1m
Debt (31-Mar-16)	No debt
Enterprise value	A\$24.8m

Top shareholders ^{2,3}	Shares (m)	%
Paul Rennie (Managing Director)	21.2	24.6%
MJGD Nominees (technology vendor)	7.1	8.1%
Other Board and management	7.1	8.1%
Irwin Biotech (technology vendor)	6.8	7.8%



Source: IRESS Note:

- 1. Includes 53.4m escrowed shares (19.5m shares escrowed until 7-Aug-16, 33.9m escrowed until 18-Aug-17)
- Blue shading represents Board and management holdings
- MJGD Nominees and Irwin Biotech are select vendors of Xosoma, which was acquired by Paradigm prior to listing

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)
 - ✓ Anti-inflammatory
 - ✓ Anti-histamine
 - Anti-clotting
 - ✓ Prevents necrosis (premature cell death)
 - ✓ Prevents cartilage degeneration

IP protection



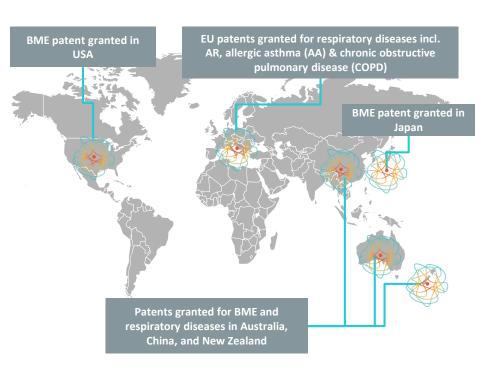
Multi-faceted IP protection increases barriers to entry for potential competitors

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

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

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:



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

Hay fever: the market for RHINOSUL®



RHINOSUL® has the potential to fill the current gap in hay fever treatment options

- The hay fever market is changing with new players, like Meda (MEDA.STO, A\$9.0bn market cap), developing a new class of dual acting treatments
- RHINOSUL[®] is dual acting with multiple mechanisms of action that make it a potentially superior treatment to existing therapies corticosteroid therapies (like Rhinocort [®], Beconase [®]) and antihistamines (like Claratyne [®] and Zyrtec [®])
- If FDA approved, RHINOSUL® would be the first dual-acting hay fever treatment with no undesirable side effects

	paradigm	Zyrtec"	Rhinocort	MEDA
	RHINOSUL®	Anti-histamines (eg. Zyrtec®)	Corticosteroids (eg. Rhinocort®)	Dymista [®]
Treats acute symptoms (histamine release)	✓	\checkmark	√ 1	✓
Treats chronic symptoms (inflammation)	✓		✓	✓
No undesirable side effects	✓			
Anti-inflammatory	✓		✓	✓
Simple to manufacture	✓			

Note

^{1.} Immediate use of corticosteroids do not treat acute hay fever symptoms, however, ongoing use will result in the subsiding of such symptoms

Hay fever: clinical timeline



Paradigm is on track with clinical development timeline and expenditure

- Paradigm is developing RHINOSUL®, the first intra-nasally applied PPS product to be used humans
 - Since this would be the first time PPS would be delivered intra-nasally, Paradigm conducted a bridging nasal toxicology study in Sweden, run by the same team that developed Astrazeneca's Rhinocort®
 - Paradigm also conducted a comparator study comparing RHINOSUL® to Rhinocort®, with results to be published in 'Allergy',
 a leading allergen journal
- The Phase I (safety/tolerability) study will be conducted in June in Perth, followed by the Phase II (placebo controlled, efficacy)
 allergen challenge study in Sweden in November-December 2016

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)	Phase I safety study (n=20)									
Ethics approval for Phase II trial										
Phase II placebo-controlled allergen challenge study										

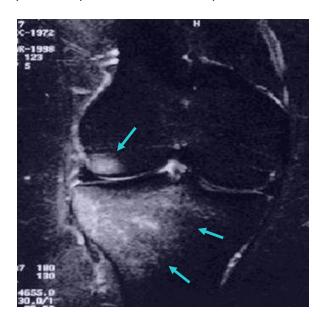
Bone marrow edema (BME)



Currently no approved treatments for bone marrow edema, growing market opportunity

What is bone marrow edema (BME or bone bruising)?

 Bone marrow edema or bone bruising is the accumulation of interstitial fluid or inflammation within the bone marrow, typically a consequence of a direct impact to bone



Addressable market based on acute traumatic injuries:

1.4 MILLION

knee & ankle injuries associated with bone bruising^{1,2,3}



US\$1,750

potential price per ZILOSUL® treatment



US\$2.5+ BILLION

ZILOSUL® market in USA

(Market size could significantly increase with shoulder, elbow and hip injuries as well as chronic injuries)

Source:

- 1. Based on 200k ACL injuries per annum, with 80% being associated with BME Niall D, et al. (2004) and Friedberg R, et al. (2016)
- 2. Based on 1m meniscal injuries per annum, with 80% assumed as being associated with BME Jones C, et al. (2012)
- 3. Based on 600k ankle injuries per annum, with 80% assumed as being associated with BME Waterman B, et al. (2010)

BME: the market for ZILOSUL®



Multi-acting treatment that addresses the underlying pathology of bone bruising

Why focus on bone bruising?

- Untreated BME lesions are 10x more likely to lead to osteoarthritis
 - BME lesions restrict blood supply to the cartilage in the joint, causing the cartilage to break down which can lead to progressive joint degeneration and osteoarthritis
- Currently no effective, regulatory approved, therapeutic treatments available to treat BME treatments from Bayer and Roche
 have limited efficacy
- ZILOSUL® passed a proof of concept trial, with all patients experiencing complete resolution of the bone bruise and associated pain

	paradigm	Bayer Bayer	Roche
	ZILOSUL®	lloprost®	Ibandronate ®
Anti-inflammatory	✓	✓	
Fibrinolytic agent (anti-clotting)	✓	✓	
Prevents cell death and necrosis	✓		
Increase in cartilage synthesis	✓		
High safety profile	✓		✓
Hospitalisation not required	✓		
Not administered intravenously	✓		

BME: clinical timeline



Opportunity to further accelerate clinical trial development timeline

- Currently conducting an open label clinical trial investigating the safety, tolerability and efficacy of ZILOSUL® in patients with a bone marrow edema from a recent ACL injury
 - Open label design means that dosage levels can be adjusted and optimised due to real time data transparency
- Commencement of closed label clinical trial may be brought forward pending the results of interim analysis
- Paradigm fully funded from IPO until Q2 2017 to complete Phase II open label clinical trial
 - Total expenditure for the Phase II trial is A\$2.1 million which includes funds that have already been spent

Clinical development timeline		2015		2016			2017					
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Proof of concept study (n=5)												
Ethics approval for pilot trial												
Phase II open label clinical trial (n=40)												
Interim analysis (fast-track potential)												
Closed label clinical trial ¹												

Nota

^{1.} Closed label, randomised, double blind, placebo controlled trial commences in Q3 2017, expected to be completed in 12-24 months after commencement

Bone bruising: elite athlete case study



Potential to open new market opportunities by treating chronic BME with ZILOSUL®

Overview

- Elite athlete in a major Australian sporting code successfully treated for a chronic orthopaedic injury by ZILOSUL®
 - Successfully completed pre-season in 2016 and has continued playing during the season
- Treatment permitted under TGA's Special Access Scheme; consisted of 6 intramuscular injections over 3 weeks
- Results highlight the potential for ZILOSUL® to be used as a treatment for both chronic and acute bone bruising

Before: Pre-treatment wellbeing



After: post-treatment results

- Un-resolving bone bruise multiple unsuccessful therapeutic and surgical interventions
- Fluid had to be drained from the knee after every training session

- ✓ Significant improvement in pain score and joint function, no adverse events
- ✓ Patient has not had to drain fluid from knee since the treatment in November 2015

	Pre treatment	Post treatment	Change
Pain	8.5 (very bad)	3.2 (mild)	↓ 62%
Joint function	69 (fair/poor)	95 (excellent)	↑ 37%

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Undervalued compared to peers



Attractive investment given low risk development and large market opportunity

Paradigm appears undervalued compared to similar stage, drug repurposing peers given its platform for successful
development, secure industrial scale manufacturing and the size of its addressable markets

Peer	Ticker and exchange	Market cap (A\$m) ¹	Rationale	Clinical stage of key product	Addressable market size
Medical Developments International	MVP.ASX	351	Developing new markets and applications for Penthrox, recent focus on respiratory diseases, significant manufacturing IP	Commercialisation	US\$1.5bn+
starpharma	SPL.ASX	251	Commercialising an old technology of synthetic branching polymers (dendrimers), with lead product VivaGel in Phase III trials	Phase III & commercialisation	US\$3bn+
AXSOME	AXSM.NASDAQ	164	Developing novel therapies for the management of central nervous system disorders, focusing on treatment of BME	Phase III	US\$2.5bn+²
verona pharma	VRP.LN	55	Focused on commercialising an old compound for respiratory diseases, with dual inhibition of key enzymes	Phase I/II(a)	US\$12bn+ ³
paradigm BIOPHARMA	PAR.ASX	29	Focused on the clinical development of PPS as a multi-target treatment for complex conditions, such as BME and AR	Phase II(a)	US\$13.5bn+ ⁴

Source: Bloomberg, company filings

Note:

- 1. Market data as at 17 June 2016, exchange rates of GBPAUD 1.94 and AUDUS 0.74
- 2. Based on BME addressable market size, excludes CRPS addressable market due to lack of available information and thus likely understates true market size
- 3. Only includes the market size for COPD which is US\$12b+, excludes market sizes for other respiratory disease indications
- 4. Includes AR market of US\$11bn+ and BME market of US\$2.5bn+, excludes COPD addressable market size of US\$12bn+ and Asthma addressable market size of US\$15bn+

Global interest in respiratory and BME



Recent transactions highlight big pharma interest in respiratory and BME spaces

- Mylan's takeover offer of Meda earlier this year was at a 92% premium to last close and Dymista® is RHINOSUL®'s closest comparative product
- AstraZeneca's transactions highlight big pharma's interest in respiratory businesses units and the potential value attributed to them

Date ↓	Target	Acquirer	Deal value (US\$m)	Relevance
Feb-16	MEDA	Mylan	7,200	 Meda's third biggest product is Dymista®, which is a dual acting AR product Transaction not yet complete
Dec-15	Takeda	AstraZeneca	575	 Acquired Takeda's respiratory business only Acquisition includes expanded rights to roflumilast, used to treat COPD
Jul-14	E Almirall	AstraZeneca	2,100	 Acquired Almirall's respiratory products only Products focused on asthma and COPD
May-13	A STATE OF THE STA	ZIMMER BIOMET	Undisclosed	 Zimmer Biomet acquired Knee Creations for its Subchondroplasty procedure, designed to treat BME

Source: Bloomberg, company filings

Partnering with Big Pharma



Paradigm will likely seek to partner with a Big Pharma company in the future

Big Pharma continues to acquire and partner with junior biotechs to replenish its R&D pipeline and transactions are done
increasingly in the earlier R&D stages

- Co-development/partnership opportunities									
	Phase I	> Phase II	Pha	se III	Regulatory				

Date ↓	Australian company	Big Pharma	Deal type	Deal value	Phase
May-16	Phosphagenics	Undisclosed Japanese healthcare company	Licensing agreement	Undisclosed	Phase I
Apr-16	Phosphagenics	Undisclosed Japanese healthcare company	Licensing agreement	Undisclosed	Phase IIa
Sep-15	starpharma	AstraZeneca	Licensing agreement	US\$219m incl. milestone payments	Phase I
Jan-15	spinifex	NOVARTIS	Acquisition	US\$200m upfront excl. milestone payments	Phase II

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Enhancing shareholder returns



Strong ongoing focus on prudent cash management

- Paradigm maintains a highly specialised and nimble team through effective outsourcing
- Paradigm's focus is to use cash for clinical development rather than administration and overheads
 - Paradigm's clinical and R&D expenditure is significantly higher than industry average
 - ✓ This expenditure is also eligible for the R&D tax refund

Expenditure ratios	paradigm BIOPHARMA	ASX-listed health care universe
R&D expenditure / total operating expenditure (%)	78%	29%
Staff, marketing & advertising expenditure / total operating expenditure (%)	9%	35%

✓ Paradigm's staff, marketing and advertising expenditure is significantly **lower** than industry average

Clear alignment of interests and strong focus on shareholder returns

Source: IRESS, company filings

Note:

- 1. Total operating expenditure is exclusive of "interest and other costs of finance" and "income taxes paid"
- 2. ASX-listed health care universe figures are reflective of companies that reported quarterly cash flows via an Appendix 4C for the quarter ending 31 March 2015

Share price catalysts



Upcoming milestones should drive strong shareholder returns

BME TRIAL Phase II(a) trial	 Open label trial anticipated to confirm efficacy together with optimal dosing of ZILOSUL® and clinical endpoints Potential to bring forward next clinical trial to 3Q 2016
HAY FEVER Initiating human trials	 Phase I trial commencing on 20 June 2016, expected completion on 30 August 2016 Publication of comparator study in "Allergy" expected in 2H 2016 Phase II 'allergen challenge' trial to begin in Sweden in December 2016
MULTIPLE USES Multiple indication available	 Potential for PPS to treat other joints (hips, ankles, shoulders and elbows) Further potential indications in other respiratory diseases Second generation versions of PPS under investigation
CORPORATE OPPORTUNITIES Potential partners	 Demonstrated interest from major pharmaceuticals companies in treatments for bone bruising and hay fever Value accretive partnership with world-class manufacturers
EXPANSION Market share	 Expansion of bone bruising market beyond acute orthopaedic therapy Respiratory expansion of PPS for allergic asthma (AA) and chronic obstructive pulmonary disease (COPD) Preliminary stage review of novel IP

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