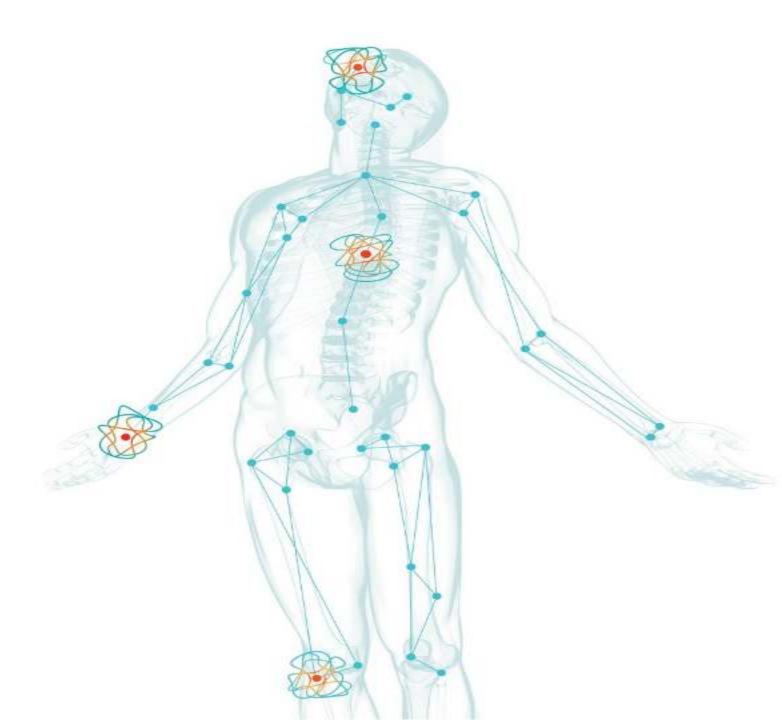


(ASX: PAR)

## Paul Rennie, CEO & MD

**NWR Small Cap Virtual Conference, March 2020** 



# **Paradigm's Mission**



Paradigm Biopharmaceuticals LTD (PAR) is a late stage drug development company focusing on repurposing the drug Pentosan Polysulfate Sodium (PPS).

Paradigm's Aim is to develop and commercialise an ethical, safe and effective Pharmaceutical Agent (PPS) for the treatment of musculoskeletal disorders in humans with degenerative disease driven by injury, viral infection, aging or genetic predisposition.

# Paradigm – COVID-19 Update



- Paradigm Board and staff are observing all recommendations issued by the Australian Federal Government, States and Territories.
- Paradigm staff are working from home and have been for the past 3 weeks, no shutdowns are expected to adversely affect our business.
- Significant work identifying any risks to minimize and any interruptions to the business especially the current FDA submission timelines in wake of COVID-19.
- Risk mitigations strategies in place across business and continue to move forward to our key FDA submissions.
- The company does not believe the impact from COVID-19 is material to the overall business operations
  at this time due to the fact no clinical trials are being undertaken and most Paradigms staff already
  work remotely.
- Strong balance sheet with over A\$70m cash and fully funded for the future expected clinical trials.
- Well positioned and believes overall impact of COVID-19 is unlikely to have a material long term impact on the business.

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# **Executive Summary**



- Repurposing Pentosan Polysulfate Sodium ("PPS," "ZILOSUL®"): FDA-approved, 60-yr track of treating inflammation
- Lead program: Osteoarthritis (OA) –31m sufferers in the US alone
- Seeking joint submission (FDA & EMA) under 505(b)(2) to treat Mucopolysaccharidosis (MPS) in Q2 2020 potential pivotal trial readout in 2021
- Planned FDA IND for Phase 3 trial in OA in 2020, potential US trial readout and regulatory submission in 2022.
- OA Phase 2b trial (n=112) successfully met primary, secondary and exploratory endpoints
  - Primary endpoints reduction in pain from baseline at Day 53
  - Secondary endpoints up to 6-month duration of effect, reduction in volume/size/grade of BML confirmed by MRI
  - Exploratory endpoints reduction in two key OA biomarkers COMP and ADAMTS-5
- Competing treatments (NGF, steroid, opioid) lack combo of safety, subjective/objective efficacy, disease regression and reduction of key biomarkers.
- MoA established and peer reviewed anti-inflammatory, pain reduction, chondroprotective, downregulates Nerve Growth Factor in bone
- Zilosul granted FDA approval under Expanded Access Program (EAP) to treat 10 patients suffering with OA Started dosing February 2020
- Seeking Provisional Approval in Australia with TGA prior to completing Phase 3 trial
  - If successful, Paradigm could be revenue-generating in Australia in Q4 2020 (subject to TGA Provisional Approval).
  - 3m sufferers, revenue potential in Australia / 20% market share: ~AUD\$1.5b TAM
- Revenue potential in US / 10% market share: ~US\$9bn potential TAM
- Meeting with EMA in 2020 to ensure Phase 3 trial will also meet EU regulatory requirements
- Strong portfolio of IP protection and patents on Zilosul patents in all key markets from 2030 to 2039
- Secured scalable manufacturing supply from FDA approved facility exclusive agreement for 20 years
- \$73.63m of cash on balance sheet (a/o DEC 2019) + \$3.19m R&D Tax Incentive Refund: fully funded for all major clinical trials and regulatory submissions in OA and MPS; strong position to negotiate favorable outcome with big pharma post regulatory clearance.

# **Upcoming Milestones/News Flow**



#### 2020

- Compassionate Use program with NFL 'Pro Players Elite Network'
  - Early 2020: US Trial initiation (n=10) First Patient Dosed Feb, All patients commence dosing March (See ASX ANN 21st Feb, 24th Mar)
  - Q3 CY2020: Results released
- Pivotal Phase 3 OA/BMEL US Clinical Trial
  - Pre-IND meeting meeting with FDA (19<sup>th</sup> Feb 2020)
  - Q4 2020: Submit IND with FDA
  - Late 2020 Early 2021: Commence multi-centre trial /US & EU (n=500)
- Pivotal Phase 2/3 Mucopolysaccharidosis (MPS) trial
  - Mid 2020: Joint Parallel Scientific Advice Submission to FDA and EMA
  - Late-2020: Commence multi-centre Phase 2/3 US & EU under 505(b)(2)
- TGA (i.e. Compassionate Use) Provisional Approval for iPPS to treat OA in Australia
  - Q4 2020/Q1 2021: Potential for approval to begin selling in Australia, initial launch/revenue update
  - Ongoing: Additional release of TGA patient results
- Additional News flow
  - Ongoing assessment of respiratory indication
  - Peer reviewed publication of Phase 2b OA/BMEL Results & peer reviewed publication of Phase 2a Viral Arthritis clinical trial

#### 2021

- Phase 3 OA trial: potential US trial readout and regulatory submission
- Phase 2/3 MPS trial: potential pivotal trial readout
- Zilusol® AUS launch update
- Trial launches in additional pre-clinical indications (e.g. viral arthritis)

# **Background - Pentosan Polysulfate Sodium (PPS) / Zilosul**



#### **Pentosan Polysulfate Sodium**

- Semi-synthetic drug manufactured from beech-wood hemicellulose
- Has been used in humans for more than 60 years
- Oral formulation is FDA approved and sold under the name Elmiron, by Janssen Pharmaceuticals (Johnson & Johnson), for the treatment of interstitial cystitis (painful bladder syndrome). Also used to treat deep vein thrombosis
- Paradigm has been granted patents to use PPS for new indications

#### **Potential biological characteristics**

- ✓ Anti-inflammatory
- ✓ Prevents cartilage degeneration
- ✓ Anti-histamine
- ✓ Anti-clotting
- ✓ Prevents necrosis (premature cell death)
- ✓ Non-performance enhancing (WADA & ASADA Cleared)
- √ Non-addictive

#### **Excellent Safety Profile**

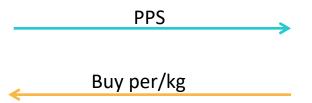
- Well established safety profile with no reported serious adverse events
- FDA Approved 30+ years ago for oral use, 100 m+ injectable doses administered
- Semi-synthetic, complex carbohydrate makes it well tolerated by the human body
- Weak anti-coagulant:  $1/15^{th} 1/20^{th}$  the anti-coagulant activity of Heparin. Data on file with US FDA
- Clearance from the body, as measured by activated partial thromboplastin time (aPTT), is 300 minutes (5 hours).
- Suggested sports physician treatment protocol:
  - Administration at least 48 72 hours before any contact sport is played
  - Blood test prior to contact sport to test coagulation parameters are within the normal range
- Weak anti-coagulant properties should not present any notable issues

# **Exclusive Supply & Manufacturing**



## **Exclusive Supply**

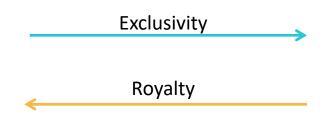






#### License







- Long term exclusive supply agreement with bene pharmaChem GmbH.
- Bene pharmaChem: original developer of PPS and <u>only FDA-approved</u> <u>manufacturer.</u>
- Johnson & Johnson have been sourcing PPS from bene for a different application (bladder pain).

- Agreement grants exclusive supply of only FDA approved PPS for Paradigm's orthopaedic and respiratory programs.
- Paradigm to pay bene pharmaChem small single digit (2% on net sales) royalty on commercial sales.

# **Strong Patents & IP Position**

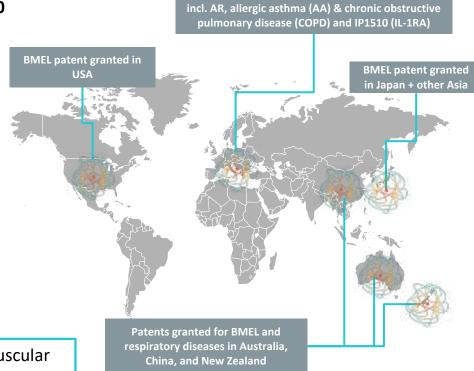
#### Multi-faceted IP protection increases barriers to entry for potential competitors

- Patent protection using PPS for new indications
- Minimum life on patents is 2030 and beyond for more recent patents i.e. 2035 2040
- Established regulatory exclusivity and trademarks
- Patents for MPS (ex Japan) + Orphan Status
- Patent applications for Ross River virus and Chikungunya virus
- Patent applications for osteoarthritis and concurrent BMEL
- Patent for Heart Failure indication
- Prosecuting new patent applications

#### Secure manufacturing and supply

- Exclusive long term supply agreement with bene PharmaChem¹
- bene pharmaChem makes the only FDA-approved form of PPS
- Manufacturing methods are highly complex and a well kept trade secret
- Bene pharmaChem has been supplying J&J for over 20 years for oral use

Patent's claim where treatment is administered by an injection that includes the intra-muscular (IM) or subcutaneous (SC) routes, intra-venously (IV), intra-articularly (IA), peri-articular injections but also includes topical or <u>oral administration</u>. Oral use of PPS, for the indications which Paradigm has patented, is covered under Paradigm's patents and any oral use thereof would be an infringement of Paradigm's patent.



EU patents granted for BMEL, respiratory diseases

# Osteoarthritis – Submission Programs



#### TGA – Provisional Approval

- 3 Stage knockout process.
- Initial meeting (stage 1) with TGA occurred on 11<sup>th</sup> Nov 2019 TGA agreed that there is an unmet clinical need for Zilosul® to treat Knee OA pain with subchondral Bone Marrow Lesions (BMLs).
- Paradigm is proceeding with the provisional determination assessment (stage 2) process (expects submission to occur in Q4 2020)

#### **Extended Access Program (EAP)**

- Treatment program under the EAP began with First Patient Dosing on the 19<sup>th</sup> February (see ASX Ann).
- Paradigm reported on the 24<sup>th</sup> March that all 10 patients have commenced treatment with one patient having completed treatment.
- Results expected to be reported Q3 CY 2020.

#### **FDA Investigational New Drug (IND)**

- Pre IND meeting 19<sup>th</sup> Feb, delivered positive and informative feedback from the FDA.
- Paradigm has submitted its minutes to the FDA and and will provide further information from the Pre-IND meeting to the market once final minutes have been received back from THE US FDA.
- IND submission expected early Q4 CY 2020.

# Osteoarthritis – Special Access Scheme (SAS)



"We need real-world effectiveness data and the analytics to improve access to medicines from real-world data, not just from clinical trials1." CSL Chief Executive, Paul Perreault.

- Paradigm previously reported greater than 50% reduction in pain across 205 patients with Knee Osteoarthritis using the NRS acute pain scale.
- Phase 3 reporting will be measuring WOMAC pain subscale scores.
- The Western Ontario and McMaster Universities Arthritis Index (WOMAC) is widely used in the evaluation of Hip and Knee Osteoarthritis. It is a self-administered questionnaire consisting of 24 items divided into 3 subscales:
  - Pain (5 items): during walking, using stairs, in bed, sitting or lying, and standing upright
  - Stiffness (2 items): after first waking and later in the day
  - Physical Function (17 items): using stairs, rising from sitting, standing, etc.
- Paradigms proposed Phase 3 trial in knee OA will use the industry standard WOMAC reduction of pain as the primary endpoint in the phase 3 trial.
- Paradigm expects to report addition SAS data and a post-hoc analyses of our Phase 2B Clinical trial data against the WOMAC pin scale
- Pain outcome measures at 3 months (week 12 or Day 81) after the initiation of PPS treatment. These are clinically meaningful reduction in pain and function at 3 months since the commencement of PPS treatment.
- To date Paradigm has treated over 450 patients who have Knee OA with iPPS (Zilosul®) via its Clinical Trials and Special Access Scheme.

# Osteoarthritis – WOMAC V KOOS (PAIN)



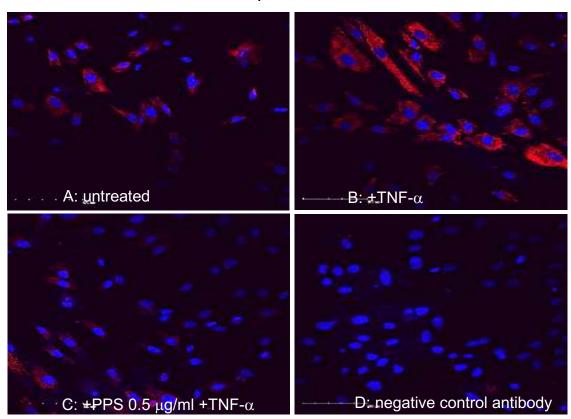
KOOS Pain Questionnaire (9 questions)	Rating Scale WOMAC Pain Questionnaire (5 questions)		Rating Scale
P1 How often do you experience knee pain	0-4, where 0 = never, 4= always	-	-
P2 Pain twisting/pivoting on your knee	0-4, where 0 = no pain, 4= extreme pain	-	-
P3 Pain straightening knee fully	0-4, where 0 = no pain, 4= extreme pain	-	-
P4 Pain Bending knee fully	0-4, where 0 = no pain, 4= extreme pain	-	-
P5* Pain walking on flat surface	0-4, where 0 = no pain, 4= extreme pain	1. Pain Walking on flat surface	0-4, where 0 = no pain, 4= extreme pain
P6* Pain going up or down stairs	0-4, where 0 = no pain, 4= extreme pain	2. Pain Going up/down stairs	0-4, where 0 = no pain, 4= extreme pain
P7* Pain at night while in bed	0-4, where 0 = no pain, 4= extreme pain	3. Pain At night	0-4, where 0 = no pain, 4= extreme pain
P8* Pain sitting or lying	0-4, where 0 = no pain, 4= extreme pain	4. Pain Sitting/lying	0-4, where 0 = no pain, 4= extreme pain
P9* Pain standing upright	0-4, where 0 = no pain, 4= extreme pain	5. Pain Standing upright	0-4, where 0 = no pain, 4= extreme pain
KOOS Pain Score (total)	0-100, where 100 = no pain, 0= extreme pain	WOMAC Pain Score (total)	0-20, where 0 = no pain, 20 = extreme pain

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# **Mechanism Of Action (MOA)**

#### Reduction of NGF as mediator of PAIN.

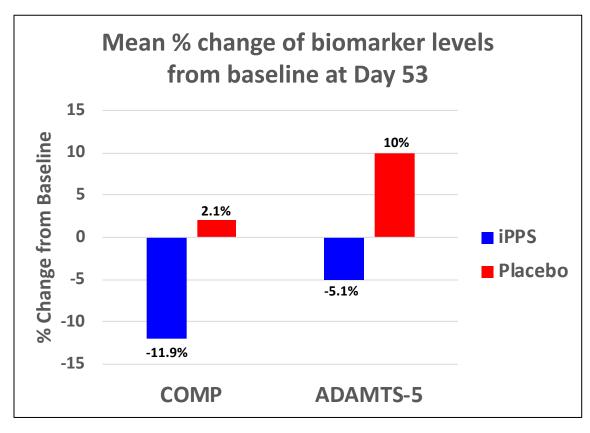
PPS downregulates NGF expression in osteocytes knee OA patients



Confocal microscopy images showing NGF protein expression (red) by freshly harvested human osteocytes. Nuclei (blue) (*Stapeldon et al PLOS One 2019*)

**Inhibition of the cartilage degrading enzymes** that are known to play a key role in the progression of OA.

Reduction in serum **COMP** & **ADAMTS-5** in P2 study of knee OA.



Among subjects with symptomatic knee OA, <u>a single measurement of increased</u>

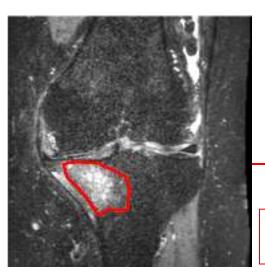
<u>COMP predicted subsequent cartilage loss on MRI.</u> Hunter et al.

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#### **BONE MARROW LESIONS (BML):**

#### CLINICAL IMPLICATIONS FOR KNEE OA AND DISEASE REGRESSION WITH iPPS THERAPY





BML appear as increased signal intensity within the bone marrow

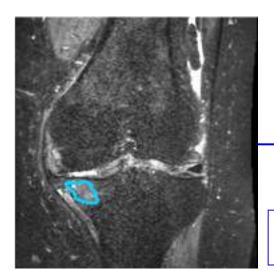
INCREASING PAIN<sup>1</sup>

**INCREASED CARTILAGE LOSS<sup>2</sup>** 

HIGH RISK OF JOINT DESTRUCTION<sup>3</sup>

HIGH RISK OF TOTAL KNEE REPLACEMENT<sup>4,5</sup>

Grade 3 medial tibial BML at baseline



REDUCED PAIN<sup>1</sup>

REDUCED CARTILAGE LOSS<sup>2</sup>

REDUCED RISK OF JOINT DESTRUCTION<sup>3</sup>

REDUCED RISK OF TOTAL KNEE REPLACEMENT<sup>4,5</sup>

Grade 2 medial tibial BML at follow-up

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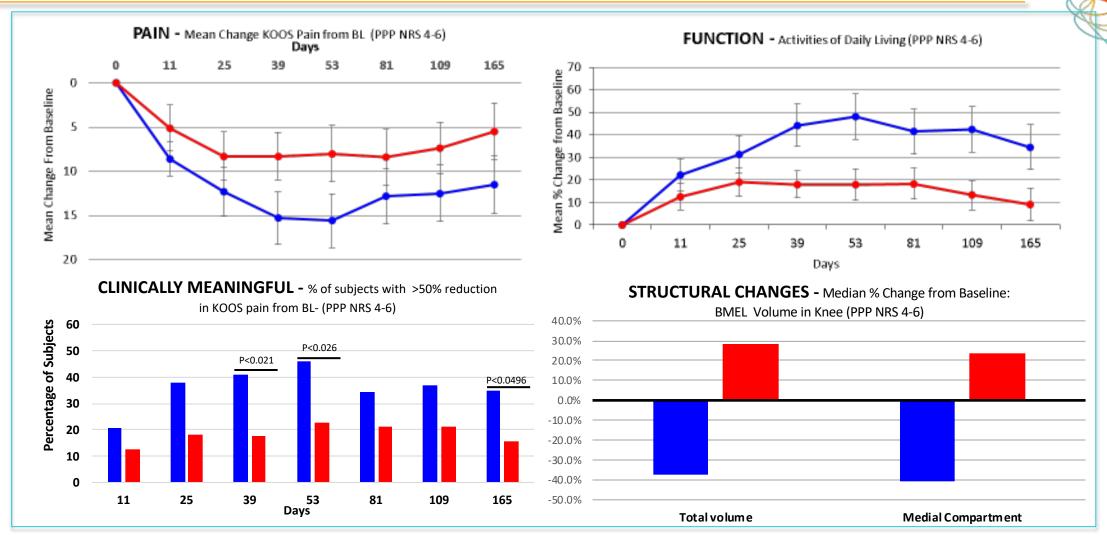
# **OA PHASE 2B TRIAL RESULTS**



# PRIMARY & SECONDARY ENDPOINTS MET



#### **SUMMARY PHASE 2B DATA – PPP NRS 4-6**



 Paradigm also achieved statistically significant and clinically meaningful result in Patient Global Impression of Change (PGIC) (p=0.0062)



# Phase 2b OA/BML Clinical Trial – Primary And Secondary Endpoints

iPPS was safe, effective and clinically meaningful in a Phase 2b randomised, double-blind, placebo-controlled, multi-centre clinical trial

- **Primary endpoint met** change in KOOS pain score from baseline at Day 53 for total trial population (p < 0.0001)
- Number of subjects with >50% Reduction from Baseline in KOOS Pain Score at Day 53 Clinically meaningful and stat sig results (p<0.026)</li>
- Patient Global Impression of Change (PGIC): total iPPS population vs placebo was stat sig (PGIC, p=0.0062)
- BML data confirms iPPS has potential to reduce progression of OA
- Decreasing serum levels of COMP and ADAMTS-5 consistent with iPPS preservation of cartilage

- ✓ Reduction in BML grade, volume and area confirms iPPS reduces rate of progression of OA
- **✓** Decreased serum levels of COMP and ADAMTS-5 confirm iPPS reduces cartilage loss

All data will be the subject of a peer-review publication

# **Recent OA Transactions - Highlights Pharma Interest In OA**



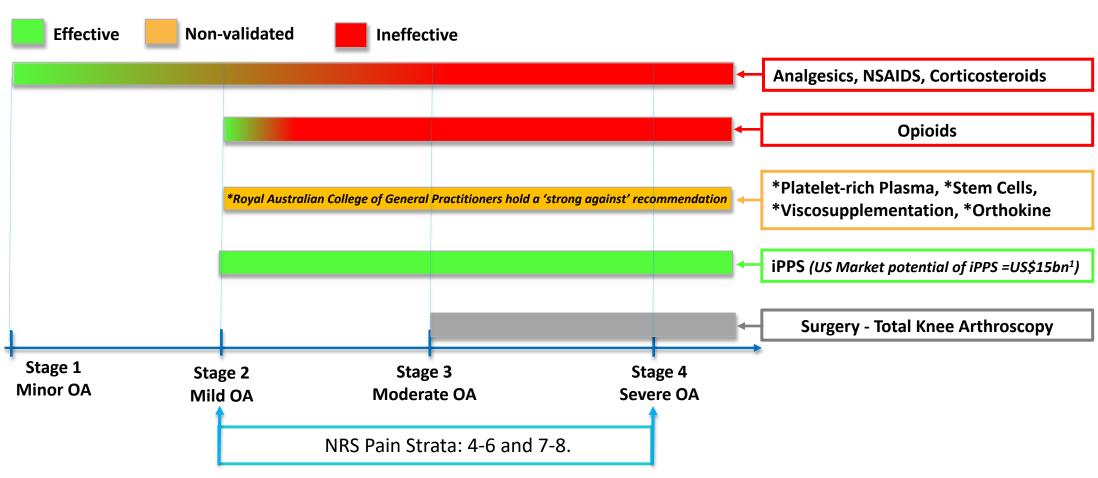
COMPANIES		COMPOUND	REGION	UPFRONT	TOTAL VALUE	STATUS
Pfizer	Lilly	Anti-NGF	Global	US\$200m	US\$1.8bn	Phase 3 (Failed)
REGENERON	teva	Anti-NGF	Global	US\$250m	US\$1.25bn	Phase 3
flexion	SANOFI	Corticosteroid	Global	Take-over*	US\$1.0bn*	Commercialised
AMGEN	janssen 🕽	Anti-NGF	Global (ex Japan)	US\$50m	US\$435m	Discontinued
		GLOBAL AV	/ERAGE	US\$166m	US\$1.12bn	
Galápagos Galápagos	* SERVIER	ADAMTS-5 Inhibitor	EU	Unknown	US\$346m	Phase 1
TissueGene, Inc.	Mitsubishi Tanabe Pharma	Gene therapy	Japan	US\$24m**	US\$434m**	Handed Back
TissueGene, Inc.	mundipharma	Gene therapy	Japan	US\$27m	US\$591m	Phase 3
REGENERON	Mitsubishi Tanabe Pharma	Anti-NGF	Asia	US\$55m	US\$325m	Phase 3
		REGIONAL	AVERAGE	US\$35m	US\$424m	

**Safety Issues** 

# **Market Demand – OA Stages And Treatments**



#### There are no effective treatments for Moderate to Severe OA



<sup>1. 14</sup>m American have symptomatic knee OA – 7m are eligible for knee replacement (late stage 3/stage 4) – PAR Estimate – 5m x US\$3,000 per iPPS treatment = US\$15bn p.a. - https://www.arthritis.org/Documents/Sections/About-Arthritis/arthritis/arthritis-facts-stats-figures.pdf

# **Successful Re-Purposed Drugs**



BRAND NAME	ORIGINAL INDICATION	NEW INDICATION PHARMA COMPANY		PEAK ANNUAL SALES
SPRAVATO	Anaesthetic (Ketamine)	Treatment Resistant Depression	Janssen/J&J	Approved March 2019
REVLIMID	Structural Analogue of THALOMID (below)	Multiple Myeloma	Celgene	\$9.7B (2018)
TECFIDERA	Psoriasis	Multiple Sclerosis	Biogen/IDEC	\$4.0B (2017)
VIAGRA	Angina	Erectile Dysfunction	Pfizer	\$2.05B (2008)
GEMZAR	Anti-viral	Various Cancers	Lilly	\$1.72B (2008)
RITUXAN	Various Cancers	Rheumatoid Arthritis	Biogen & Roche	\$7.1B (2015)
EVISTA	Osteoporosis	Invasive Breast Cancer	Lilly	\$1.07B (2011)
PROSCAR	Hypertension	ВРН	Merck	\$741.4M (2005)
THALOMID	Anti-Nausea	Leprosy Multiple Myeloma	Celgene Celgene	\$535.2M (2008)
REVATIO	Angina/ED	PA Hypertension	Pfizer	\$525.0M (2008)
PROPECIA	Hypertension	Male Pattern Baldness	Merck	\$429.1M (2008)
ELMIRON (PPS)	DVT	Interstitial cystitis	Janssen/J&J	US\$280m (2015)

# Mucopolysaccharidoses (MPS)

#### MPS – An Orphan Indication in need of new treatments

In November 2018, Paradigm in-licensed the MPS indication from the Icahn School of Medicine at Mount Sinai, New York. **The License includes successful Phase 2a safety and efficacy data** 

#### What is MPS?

The mucopolysaccharidoses (MPS) are a family of Orphan Diseases. The cumulative rate for all types of MPS is around 3.5 in 100 000 live births and generally the patients present in one of three ways:

- 1. As a **dysmorphic syndrome** (MPS IH, MPS II, MPS VI) often with early onset middle ear disease, deafness, or upper airways obstruction
- 2. With **learning difficulties**, behavioural disturbance and dementia and mild somatic abnormalities (MPS III)
- 3. As a severe bone dysplasia (MPS IV)<sup>1</sup>

The current standards of care are not adequate in treating pain associated with joint inflammation and musculoskeletal issues and these drugs currently equate to a market size of around US\$1.4b per annum, BioMarin's ERT treatments cost US\$300k – US\$600k p.a. Paradigm believes iPPS may be an effective adjunct/combination therapy with current ERT treatments.

Compelling Phase 2a data suggests iPPS may be an effective adjunct therapy for various types of MPS

#### **MPS Market Facts:**

13,000+ patients in US

#### **Potential iPPS treatment cost:**

US\$50k - \$100k p.a.

#### **Potential iPPS Market Share:**

US\$650m - US\$1.3bn

#### Three MPS-VI patients



1. https://www.sciencedirect.com/topics/agricultural-and-biological-sciences/mucopolysaccharidosis

**PAR Investor Update** 

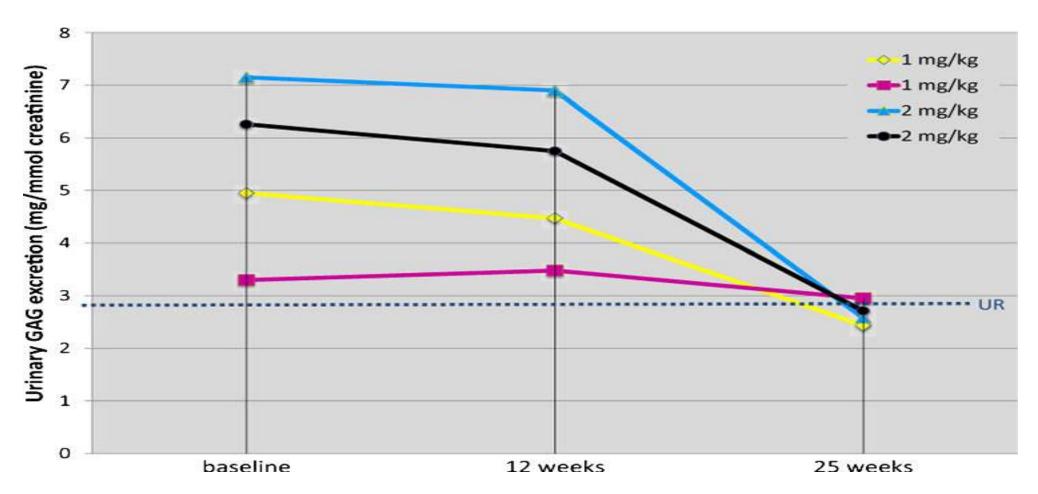
# Mucopolysaccharidoses (MPS) – Patient Centric Program



- Paradigm presented it's MPS VI poster at the MPS World Symposium in Orlando, Florida on the 11<sup>th</sup> Feb.
- Poster presented outcomes of patient focus group which aimed to identify and validate clinical development program endpoints and measurements.
- The FDA and EMA have agreed to a joint Parallel Scientific Advice Submission, the procedure commences in March.
- MPS 1 Clinical trial to begin Q3 CY2020 in Adelaide.
- Joint submission to both FDA and EMA expected Q3 2020.
- Commence multi-centred Phase 2/3 US & EU under 505(b)(2) expected late 2020.

# Mucopolysaccharidosis (MPS) <u>Objective</u> Clinical Data – Phase 2 PPS In Subjects With MPS Type 1. PPS Administered Concomitantly With Aldurazyme (ERT).





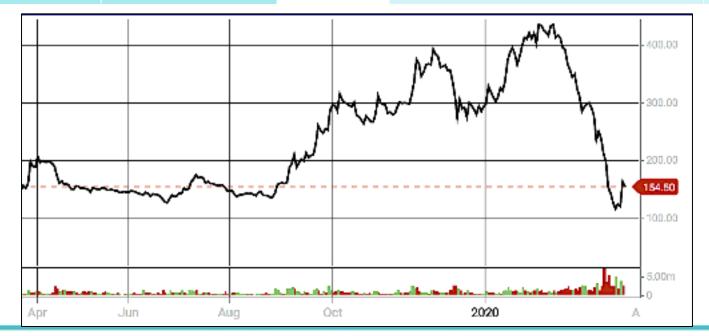
Hennermann J et al "Treatment with pentosan polysulphate in patients with MPS I: results from an open label, randomized, monocentric phase II study" J Inherit Metab Dis (2016) 39:831–837

# **CORPORATE SNAPSHOT - UPDATE**

#### **Financial Information**

Share price (25-MAR-2020)	A\$1.54
52W Low – High	A\$ 1.08 - \$ 4.50
Number of shares	197.8m
Number of Options	~ 1.2 m
Market capitalisation	A\$322m
Cash Dec-19	A\$72m
Current QTR cash inflow   outflow	\$4.49m   \$3.61m

Top Shareholders	Volume Shares (m)	
Paul Rennie	23.4m	12.12%
Other Board and Management	7.45m	3.86%
Citicorp Nominees	7.78m	4.03%
JP Morgan Nominees	5.47m	2.83%



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# Appendix





#### **REVENUE POTENTIAL – OA**



#### **Key Assumptions:**

- 31m OA sufferers in the US
- 3m OA sufferers in Aus.
- Annual dosing/treatment assumed 12 month duration of effect as observed in TGA special access scheme
- Pricing is <u>indicative</u> only

		US MARKET – aiming for approval 2021			
		10% Market Penetration	20% Market Penetration	30% Market Penetration	
INDICITATIVE POTENTIAL PRICING	US\$1.5k p.a	US\$6.2bn p.a	US\$12.4bn p.a	US\$18.6bn p.a	
	US\$2.0k p.a	US\$7.7bn p.a	US\$15.5bn p.a	US\$23.2bn p.a	
	US\$2.5k p.a	US\$9.3bn p.a	US\$18.6bn p.a	US\$27.9bn p.a	

		AUS MARKET – aiming for provisional approval 2020			
		10% 20% 30%  Market Penetration Market Penetration Market Pene			
	A\$1.0k p.a	AUD\$ 450M	AUD\$ 900M	AUD\$ 1.3b	
INDICITATIVE POTENTIAL PRICING	A\$2.0k p.a	AUD\$ 600M	AUD\$ 1.2b	AUD\$ 1.8b	
	A\$2.5k p.a	AUD \$ 750M	AUD\$ 1.5b	AUD\$ 2.25b	

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# **Current Indication Pipeline**



Indication	Phase 1	Phase 2	Phase 3	Status
Osteoarthritis (OA)			2020*	<ul> <li>Pre-Ind meeting with FDA (19/2/20).</li> <li>Further update on Pre-IND meeting once official minutes receipted from FDA.</li> <li>IND Submission by Q4 2020.</li> <li>TGA Provisional Approval Submission 2020.</li> </ul>
Mucopolysaccharidosis (MPS)			2021*	<ul> <li>Joint Parallel Scientific advice procedure with FDA/EMA commencing March.</li> <li>Joint submission Mid – 2020.</li> <li>2021: Commence multi-centred Phase 2/3 US &amp; EU under 505(b)(2).</li> </ul>
Viral Arthritis - Alphavirus (RRV/CHIKV)				<ul> <li>Primary end point met in Phase 2a clinical trial in participants with Ross River virus (RRV).</li> <li>The secondary end points demonstrated iPPS reduced RRV disease symptoms compared to placebo.</li> </ul>
Allergic Rhinitis (Hay Fever)				<ul> <li>Pre-clinical safety and efficacy in guinea pig model.</li> <li>Safety confirmed in Phase 1b clinical trial (n:18).</li> <li>Paradigm to reassess Phase 2b clinical trial (n:40).</li> </ul>

\*Indicative Timing only



#### Paradigm hosts a deep clinical pipeline

	Indication(s)	Clinical Status	Market Size
IL-1RA Peptide	<ul> <li>Inflammatory bowel disease ("IBD")</li> <li>Cancer-related cachexia</li> <li>Ulcerative colitis</li> <li>Crohn's disease</li> </ul>	Safety and efficacy confirmed in Phase 1/2 clinical trial (n:26)	Inflammatory Bowel Disease Medicines predicted to reach US\$9.3 Billion <sup>1</sup>
Cardiovascular	Heart Failure	Demonstrated beneficial effects in an established preclinical heart failure model	US\$18+ Billion²
Respiratory	<ul><li>Hay Fever</li><li>COPD</li><li>Allergic Asthma</li></ul>	See Previous Slide	US\$11+ Billion³

<sup>1.</sup> https://www.visiongain.com/Press\_Release/932/The-World-Market-For-Inflammatory-Bowel-Disease-Medicines-will-reach-9-3-billion-in-2019

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<sup>2.</sup> Forbes – The best selling drugs since 1996 (2012) 2. Heart failure: preventing disease and death worldwide, P.Ponikowski et al (2014) 3. Sales of six leading compounds – Figures between 2014 & 2016 - Statins \$13.2bn (Research and Markets - Global Statin Market 2015-2016), Clopidogrel bisulphate \$1.8bn, Beta-blockers \$1.5bn, Ace inhibitors 0.47bn, Aspirin \$0.54bn, Vitamin K antagonist \$0.5bn (<a href="https://www.pharmacompass.com">www.pharmacompass.com</a>)

<sup>3.</sup> Visiongain: Allergic Rhinitis Drugs Market Forecast 2015-2025

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