Paradigm Biopharmaceuticals LTD (ASX:PAR)

2020 Annual General Meeting (AGM) Presentation

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PARADIGM'S MISSION

Paradigm Biopharmaceuticals Limited (PAR) is a late-stage drug development company

To develop and commercialise pentosan polysulphate sodium (PPS) for the treatment of arthralgia driven by injury, inflammation, aging, degenerative disease, infection or genetic predisposition.

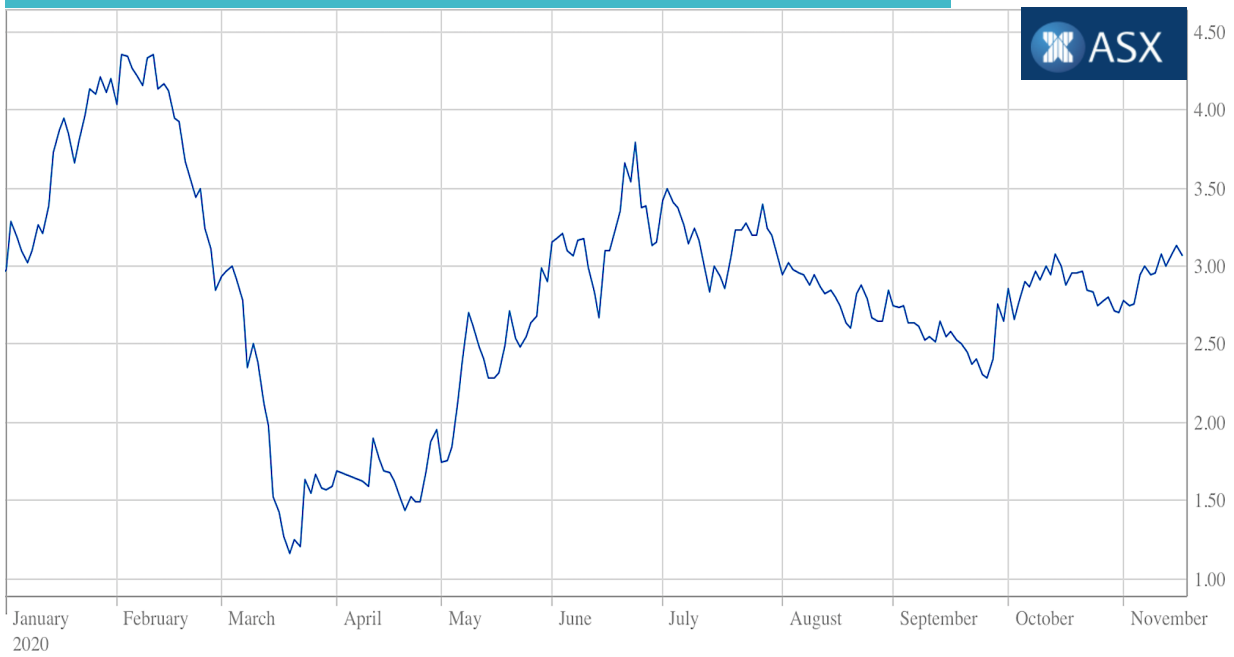
CORPORATE SNAPSHOT

Key Financial Details	Paradigm
Ticker Symbol	ASX:PAR
Share Price (17th Nov, 2020)	~A$3.07
Total Ordinary Shares on Issue	228,019,548
Market Capitalisation (17th Nov, 2020)	~A$700m
Trading Range (12month)	A$1.08 – $4.50
Cash Balance (30th Sept 2020)	A$98.8

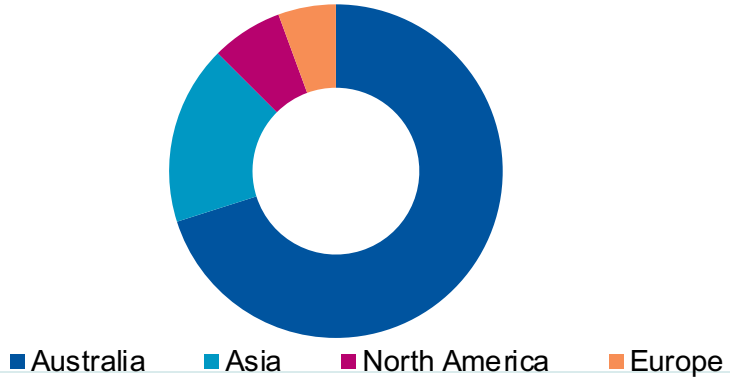
Top Shareholders

Rank	Name	Units	% Units
1	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	17,293,523	7.58
2	KZEE PTY LTD <KZEE SUPERANNUATION FUND A/C>	10,634,408	4.66
3	PAUL RENNIE	7,630,400	3.35
4	CS THIRD NOMINEES PTY LIMITED <HSBC CUST NOM AU LTD 13 A/C>	4,876,284	2.14
5	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	4,791,564	2.10

12-Month Share Price Performance



Top 20 by location



OSTEOARTHRITIS MARKET

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BLOCKBUSTER MARKET OPPORTUNITY

SIGNIFICANT MARKET SIZE WITH UNMET NEED

~72M+
Total prevalence of OA in these markets.

AUS
US
Canada
EU5

81%
Number of OA patients dissatisfied with current treatments[1]

Target uptake: 10% dissatisfied market[1]

Zilosul® Indicative Price: US$2500 per year[2]

A PARADIGM SHIFT IN THE TREATMENT MARKET FOR OA

US$15B+[3] Conservative Estimate Addressable Market for OA

1. National Institute of Health; Emerging drugs for osteoarthritis; Hunter DJ and Matthews G 16(3): 479–491; 2011 September.
2. Pricing elasticity research commenced.
3. This is a company estimate based on Zilosul® receiving registration and several commercial assumptions

GOAL: HARMONISED GLOBAL REGISTRATION

USA

Pre IND meeting February 2020

- Bene pharmaChem product
- Additional pre-clinical studies
- Western PK
- Two adequately sized P3 trials

Type C meeting

- Submitted briefing package to FDA
- Awaiting written response on clinical trial design and associated supporting clinical data

IND

- Harmonisation of clinical trial design for multiple regions
- Type C feedback will ensure Paradigm's trial will have all the necessary components for registration should the Phase 3 trials be successful.

EUROPE

EMA meeting September 2020

- Agree with Clinical Trial design and endpoints
- Confirmation no-comparator arm
- Ability to recruit Eu patients
- Clear path to product registration

AUSTRALIA

Provisional Approval TGA.

- Awaiting feedback from FDA Type-C meeting

Finalising pay-for-use SAS program.

CONFIDENCE: PHASE 3 STUDY DESIGN

CONSISTENT RESULTS ACROSS MULTIPLE PROGRAMS IN PAIN REDUCTION FOR KNEE OA

Phase 2B OA/BML Clinical Trial

- Double-Blinded Placebo Controlled study (n=112)
- Met primary endpoint – Change in KOOS pain score from baseline
- Secondary Endpoint of Patient Global Impression of Change (PGIC) was statistically significant
- 46.2% of patients receiving Zilosul® reported >50% reduction in pain (day 53)
- Confirmed safety profile, target population and informed Phase 3 design

Special Access Scheme (SAS)

- KOOS : >50% mean pain reduction across 205 patients
- WOMAC: 47.3% mean pain reduction across 76 patients

Expanded Access Program (EAP)

- First IND opened with US FDA
- Treatment of 10 Ex-NFL players reported on average a 65% reduction in WOMAC pain from baseline

COMPETITOR FIELD UPDATE

COMPANIES	DRUG	MECHANISM OF ACTION	TARGET	STATUS
Galápagos / GILEAD Creating Possible / SERVIER	GLPG1972, S201086	ADAMTS-5 Inhibitor	• Cartilage Degradation	• Discontinued.
Pfizer / Lilly	Tanezamub	Anti-NGF	• Pain Reduction	• Multiple clinical holds due to Adverse Events • Submitted for Registration
Roche	Tocilizumab	IL- 6 Blocker	• Reduction of Inflammatory cytokine	• Recent failure to meet Primary Endpoint in Hand OA
CENTREXION THERAPEUTICS	CNTX-4975	IA Trans-capsaicin	• Pain Reduction	• Ph 2/3
paradigm BIOPHARMA	Zilosul®	ADAMTS-5 Inhibitor Downregulation of NGF Reduction of Joint Inflammation Reduces BML's Multi-modal activity	• Cartilage Degradation • Pain reduction • Reduction of pro-inflammatory cytokines • Improving vascular blood flow in subchondral bone	• Proven Safety and Efficacy in Ph 2b, SAS and EAP • Harmonised global Phase 3 clinical trial design

Source:
https://www.fiercebiotech.com/biotech/galapagos-osteoarthritis-drug-flunks-phase-2-dashing-hopes-250m-gilead-deal?
https://www.medpagetoday.com/rheumatology/arthritis/85781
https://ard.bmj.com/content/early/2020/10/19/annrheumdis-2020-218547
https://www.medpagetoday.com/meetingcoverage/asipp/88481

PROTECTION: ACHIEVED SECURE SUPPLY

PARADIGM STRENGTHENED IP IN 2020

Exclusive Supply Agreement with only FDA approved PPS Manufacturer

Secure manufacturing and supply – Extension

- Includes all major pharmaceutical markets (excluding Japan which is covered under a separate arrangement).
- 25 years from the date of marketing approval.
- Exclusive supply of PPS for all indications in Paradigm's pipeline
- Manufacturing methods are highly complex and a well-kept trade secret
- Bene pharmaChem remains the only FDA approved manufacturer/supplier of PPS

Strong Patent & IP Position

Multi-faceted IP protection

- Patent protection using PPS for new indications
- Minimum life on patents is 2030 and beyond for more recent patents
- Prosecuting new patent applications.
- Significant IP in Paradigm's process of turning PPS into its injectable form.

Regulatory Exclusivity* on Approval

Exclusivity on Registration

- MPS : Orphan Drug Exclusivity (ODE), 7 years
- OA: 505b2 pathway, 3 years of exclusivity

*Paradigm plans to commence its Ph3 clinical program in 2021

MUCOPOLYSACCHARIDOSES (MPS)

Paradigm's investigation of PPS for MPS seeks to establish whether PPS may be an effective combination therapy with current Enzyme Replacement Therapy treatments

- Orphan Designations for MPS-I and MPS-VI in the US and EU
- Parallel Scientific Advice meeting for MPS-VI provided clarification in both the clinical trial design and regulatory path forward
- Initiated Phase 2 clinical trial for MPS-I with first patient dosed at Adelaide WCH

PREPARATION FOR COMMERCIALISATION

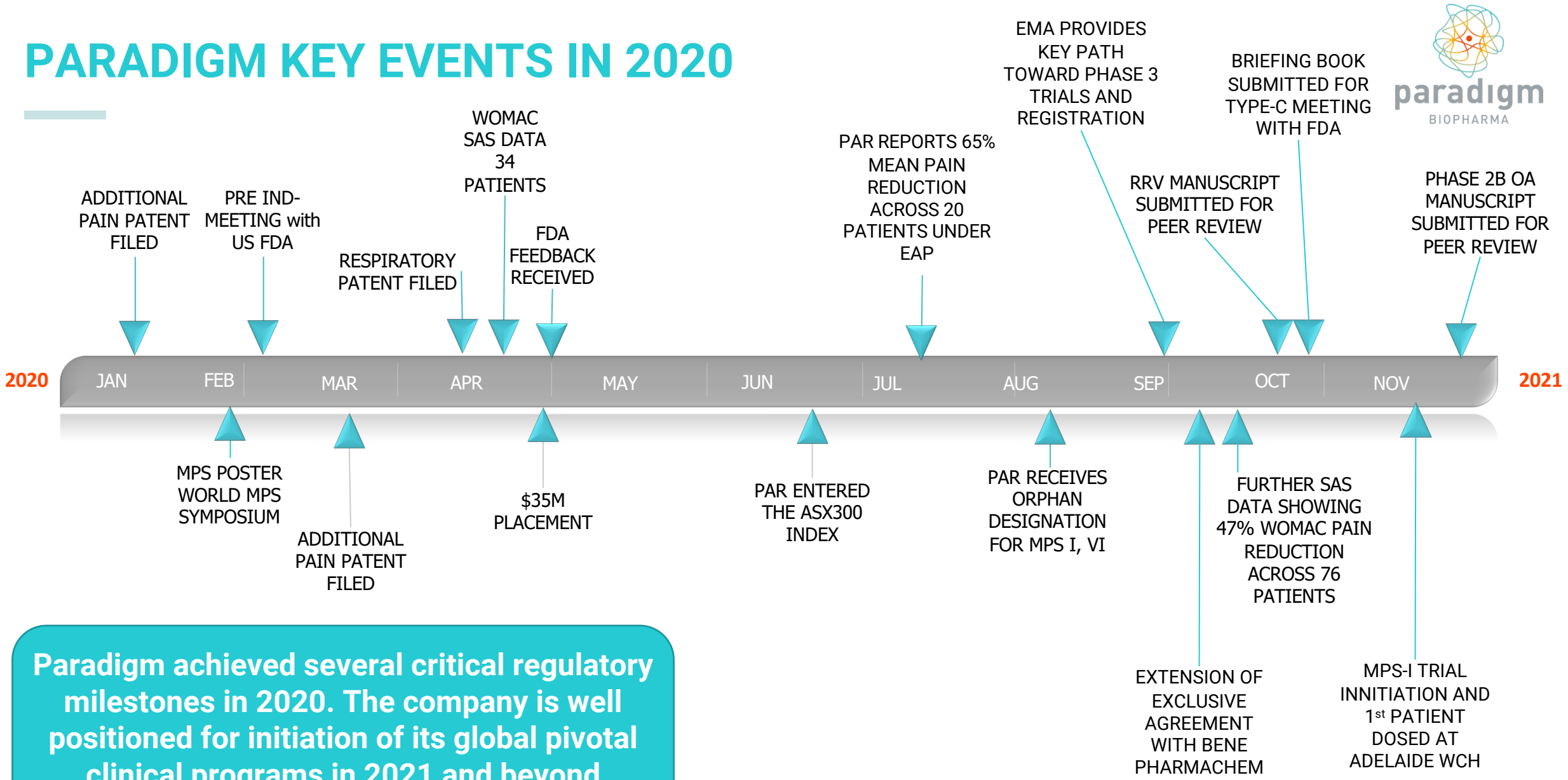
- Gathering and consolidating feedback from US, EU and AU regulators

  Aim: To have a pivotal protocol acceptable to all major jurisdictions
  Benefit: Faster approval globally

- Assembled high calibre and experienced globally focussed team in USA and AUS to obtain and deliver on pivotal studies
- Commercial lead appointed to ensure we have data for global pricing/reimbursement ; conduct patient research ; explore product delivery and patient convenience
- Seeking clarification from the US FDA on any additional information required for label and registration
- Obtain further pre-clinical and clinical data to define MOA for the treatment of arthritic disease states ; continue to explore additional indications
- Package for attracting potential regional/global partnering discussions

PARADIGM KEY EVENTS IN 2020



Paradigm achieved several critical regulatory milestones in 2020. The company is well positioned for initiation of its global pivotal clinical programs in 2021 and beyond

KEY APPOINTMENTS

Team Additions in 2020

- Dr Donna Skerrett - Executive Director
- Dr Jeannie Joughin – Chief Operating Officer
- Justin Cahill – Chief Financial Officer
- Dr Michael Imperiale – Global Head of Safety & MPS
- Beverley Huttmann – Commercial Head
- Simon White – Director Investor Relations
- Dr Catherine Stapledon – R&D Translation Scientist
- Samantha Williams – Business Operations
- Mitch Marrow – US Investor Relations
- Andrew Trigwell – Project Manager
- Dr Robert Hindes – Global Head of OA
- Katie Lodge – Document Publisher
- Dr Julie Monk – Senior Medical Writer
- Melissa Tinworth – HR Lead

Strategic Partners

- Bene pharmaChem
- Siegfried
- Premier Research
- Cytel
- Quality Metric
- PCI Pharma Services
- Bellwyck
- Pharmalex
- Camargo Pharmaceutical Services
- CTI
- Synteract
- Charles River
- Nucro Technics

UPCOMING PRESENTATION FOR INVESTORS

R&D DAY, 21ST / 22ND DEC 2020 (DATE TBC)
PRESENTATIONS FROM, DR DONNA SKERRETT (CMO) AND DR RAVI KRISHNAN (CSO)

- Share feedback from Type-C Meeting written response
- Detail on OA and MPS trial designs and timelines
- Update on scientific research pipeline

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OUTLOOK FOR REMAINDER OF FY21

Osteoarthritis	▪ Feedback from Type-C meeting with US FDA ▪ Paradigm to host R&D Day detailing all clinical programs the company is planning to undertake ▪ Additional TGA SAS patient WOMAC data ▪ Commence Phase 3 Clinical Trial ▪ Peer reviewed publication of Phase 2b OA/BMEL Results
MPS	▪ MPS VI clinical program update ▪ Further updates on patient recruitment and dosing of MPS-I patients in open label Phase 2 clinical trial at the Adelaide WCH
Additional News Flow/Events	▪ Peer reviewed publication of Phase 2a Viral Arthritis clinical trial ▪ Data presented from research program investigating the safety and efficacy of PPS in a viral induced respiratory disease model ▪ Further collaboration with Bene pharmaChem ▪ Several Domestic and International presentations including the JP Morgan Healthcare Conference 2021

For more information please visit: www.paradgimbiopharma.com or email any queries to investorrelations@paradigmbiopharma.com

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