

Paradigm Biopharmaceuticals Ltd

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Paradigm Biopharmaceuticals targets 2019-20 milestones for OA-MPS-BMEL pipeline

- Victorian youngster Paradigm has other indications in mind besides OA, including BMEL, MPS and respiratory conditions.
- The late-stage biotech has an active clinical trial program for its pipeline, with the various indications being investigated at various stages.
- A number of peer-reviewed publications will be published next year, as the company follows a regulatory approval pathway for its lead pentosan polysulfate sodium asset Zilosul.

Paradigm has made excellent progress with the filing of a number of submissions to the regulatory authorities in the USA, Europe and Australia.

The briefing pack to support the US FDA pre-IND meeting has been prepared and is pending submission upon FDA's confirmation of the meeting date.

Paradigm Biopharmaceuticals managing director and CEO Paul Rennie, October 25, 2019

What does Paradigm Biopharmaceuticals do?

Paradigm Biopharmaceuticals Ltd (ASX:PAR) is a late-stage Melbourne biotechnology company hoping to take an investigational new drug (IND) application to the US Food and Drug Administration (US FDA) early next year.

The Victorian company's lead asset is the repurposed therapeutic pentosan polysulfate sodium, Zilosul (PPS, iPPS).

Paradigm has been pursuing OA indication for the target, to target patients across the world diagnosed with a painful bone condition.

Paradigm has other indications in mind for its pipeline, including: bone marrow edema-like lesions (BMEL); the rare disease of malfunctioning of lysosomal enzymes, mucopolysaccharidoses (MPS); and respiratory conditions.

The company's corporate strategy is to repurpose existing drugs and develop therapeutics that can target multiple pathways.

Who leads Paradigm Biopharmaceuticals?

The Victorian biotech is led by founder, managing director and CEO Paul Rennie.

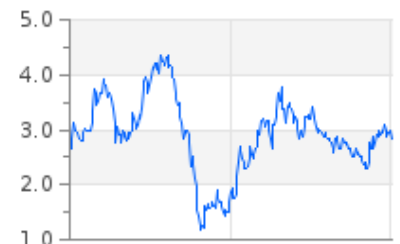
Rennie established the company near on 5 years ago and is a lawyer and scientist with more than 38 years' experience in industry.

The significant Paradigm shareholder comes from a background at a variety of

Price: 2.85

Market Cap: \$650.01 m

1 Year Share Price Graph



October 2019 April 2020 October 2020

Share Information

Code: PAR

Listing: ASX

52 week	High	Low
	4.5	1.08

Sector: Pharma & Biotech

Website: www.paradigmbiopharma.com

Company Synopsis:

Paradigm Biopharmaceuticals Ltd (ASX:PAR) is listed on the Australian Securities Exchange.

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respected pharmaceutical industry companies and respected research organisations.

These biotechs include Australian shining star Mesoblast Limited (ASX:MSB), Roche Holding Ltd. Genussscheine (SWX:ROG) (OTCMKTS:RHHVF) (FRA:RHO6) (OTCMKTS:RHHBY) when it was Boehringer Mannheim, Merck & Co., Inc. (ETR:MRK) (NYSE:MRK) (IDX:MERK) and SolTech Energy Sweden AB (FRA:7ST), then FH Faulding Ltd.

Rennie also previously led the commercialisation of the novel biopharmaceutical spin-out from University of Melbourne dental school, Recaldent.

What does Paradigm Biopharmaceuticals own?

Paradigm's lead asset is the repurposed therapeutic pentosan polysulfate sodium (PPS).

The drug is being investigated in a painful arthritic bone condition, OA, with a flagship trial drug Zilosul (iPPS).

About 31 million people have OA in the key US market, with Paradigm seeing its potential market size as up US\$9 billion a year (A\$13.1 billion annually) or 10% of the market.

The company holding ongoing partnering discussions with big pharma has three other indications in mind for its pipeline.

It has an active clinical trial program in multiple regions to investigate the indications with its pipeline.

These indications include bone marrow edema-like lesions (BMEL), which can predict rapid cartilage degeneration.

BMELs are often seen in sportspeople and physically-active individuals with anterior cruciate ligament (ACL) injuries.

Another indication is the orphan disease mucopolysaccharidoses (MPS), where lysosomal enzymes malfunction.

A third, broader additional indication is in respiratory conditions.

Paradigm had A\$75.4 million at the end of September 2019 and is sitting at a market capitalisation of about A\$542.7 million.

Its shares were up 15 Australian cents, or up to 5.4%, to A\$2.96 during intraday trading by lunchtime, following its annual meeting today.

Inflection points

The company's inflection points include a number of 2019 and 2020 milestones. Among these are:

- Imminent results of OA treatments in Australia under the TGA special access scheme
- Results of a TGA-related provisional approval meeting at the end of calendar year 2019 — a potential approval to sell could be the outcome
- A pre-IND meeting with the US FDA for OA at the end of 2019
- A 10-patient compassionate use program with the NFL for its Pro Players Elite Network — the treating of a first patient is expected in December 2019 and results mid-2020
- An early 2020 OA IND filing with the US FDA
- A joint US FDA and EU EMA scientific advice documents filing for an MPS indication in early 2020, with a pivotal MPS trial to also start in the US in 2020
- First revenues in March quarter 2020 for a TGA-approved OA therapeutic, if it is green-lighted in 2019
- A June 2020 quarter OA meeting with the US FDA
- Peering reviewing of a phase IIa viral arthritis clinical trial
- A start to a phase III trial in OA-BMEL indications in the US in mid-2020
- Commencement of a phase II/III MPS trial in the US and European Union (EU)
- The publication of a peer-reviewed phase IIb results for OA-BMEL indications
- Progression of an MPS indication, including possible treatment of Australian patients under a special access scheme in 2020
- An Australian TGA provisional approval for iPPS Zilosul in OA for the Australian market
- Continued assessment of a respiratory indication

Paradigm plans to follow up its IND activities with the FDA for iPPS Zilosul in OA with an eventual new drug application (NDA) filing for the therapeutic.

The company's active discussions with big pharmaceutical companies may also prove a further inflection point for the Australian biotech.

Paradigm Biopharmaceuticals held its annual general meeting in Melbourne today and shared its outlook with investors in an AGM presentation by MD & CEO Paul Rennie that is **available at the company's website**.

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