Paradigm BioPharmaceuticals Ltd (PAR)

10 February 2017

RECOMMENDATION

Speculative Buy

Risked Valuation: $1.32

Average daily volume (3M)	30k
12 month share low	$0.26
12 month share high	$0.62
Market Risk	High
Liquidity Risk	High
Infrastructure Risk	Low
Country Risk	Low

IRESS & DJC Research

ISSUED CAPITAL

ASX	PAR
Share price	$0.40
Mkt cap	$40.6m
Ordinary shares on issue	101.6m
Unlisted options & Rights	6.7m

Source: FactSet

DIRECTORS

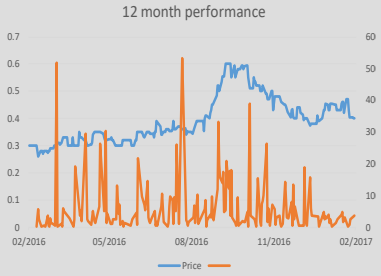
Mr G Kaufmann	Chairman
Mr P Rennie	CEO
Mr C Fullerton	Non-Exec Director
Mr J Gaffney	Non-Exec Director
Mr K Hollingsworth	Co-sec/ CFO

MAJOR SHAREHOLDERS

Paul Rennie	24.6%
MJGD	8.1%
Other Board and Management	8.1%
Irwin Biotech	7.8%

As at December 2016

12 MONTH PERFORMANCE



Source: FactSet

Paul Adams
Head of Research
08 9263 5200

Phase 2 hay fever clinical trial on schedule and budget

Paradigm is an ASX listed biopharmaceutical company focused on repurposing the historic drug pentosan polysulphate sodium (PPS). PPS has non-steroidal anti-inflammatory properties and has potential for its novel use in the treatment of many inflammatory diseases such as (1) Allergic Rhinitis (AR) (also known as hay fever), (2) Alphavirus infection such as Ross River Virus and Chikungunya (CHIKV) and (3) Orthopaedic indications such as Bone Marrow Edema (BME). PAR is approximately 50% through their Phase IIa clinical trial for AR, with results expected as early as late Q2 2017.

Key Points

- **Paradigm Biopharmaceutical Ltd (PAR) Strategy.** Paradigm's strategy is to repurpose pentosan polysulphate sodium (PPS) in three distinct clinical indications. Repurposing means finding new clinical indications for previously approved drugs. Repurposing drugs have the potential to increase the rate of clinical trial success, reduce costs of development and provide shorter lead times to revenue.

- **Phase IIa clinical trial for AR around 50% complete:** By late January 2017 PAR had already recruited all the subjects for its AR clinical trial held in Lund, Sweden. The 40 participants are undergoing a double-blind, placebo controlled, cross-over clinical trial which should provide enough evidence to confirm the efficacy of PAR's novel nasal spray for the treatment of hay fever. Paradigm's product, Rhinosul®, is dual acting which means it inhibits both histamine secretion and inflammation. The trial team is being led by Dr Lennart Greiff at Skane University Hospital, who has conducted similar clinical trials for other large biopharma, including Astra Zeneca.

- **Countdown to results:** Upon completion in late March 2017, the market will potentially have less than three months before the results of the trial are known. We would expect to see an uplift in share price soon after the trial completion as anticipation of the results looms. A positive outcome would launch Rhinosul® firmly on the path to development and will likely be a catalyst for the interest of big biopharma to take a closer look at PAR's innovative approach to this common disease state.

- **PAR fully funded through 2017:** At the end of the Dec Q, PAR had a cash balance of $5.025m, plus a receivable from a government R&D tax incentive of $1.34m. PAR is forecast to spend approximately $1.9m in Mar Q and is fully funded for the completion of the AR clinical trial and through its other programs in 2017.

- **Recommendation and Valuation:** We maintain our **Speculative Buy** recommendation. We stress that PAR is significantly under-valued compared to peers who have compounds undergoing Phase II trials. We believe a successful outcome will be a major catalytic event for PAR and is likely to initiate interest from big pharma who are looking to replace revenues from drugs going off-patent. Our valuation remains between A$120M and A$152M which corresponds to share price of A$1.18 and A$1.50 respectively, or a mid-point of $1.34 per share.

PAR's repurposing strategy

- PAR's strategy is to repurpose the well-known compound historic drug pentosan polysulfate sodium, or PPS, for a number of disease states but focusing initially on allergic rhinitis (AR). The global market for AR drugs is extremely large, estimated to be circa US$11 billion annually. The available drugs are dominated by anti-histamines and corticosteroids but market surveys have found a high level of patient dissatisfaction with long-term anti-histamine and steroid use. The application of PPS to AR could provide a solution to patient dissatisfaction.

- PAR is also looking to apply PPS to other disease states such as viral arthritis following mosquito born virus infections such as Ross River Virus and Chikungunya. It also may act as a new treatment for Bone Marrow Edema (BME) following traumatic injury. Further work on both these disease states is scheduled for this year.

- Repurposing a drug has been shown to diminish risks and timeframes compared to traditional new drug development. It has also been shown to substantially lower costs of bringing a drug to market.

Progress on the Phase IIa clinical trial for AR

- On 25 January 2017 PAR announced the recruitment of the subjects required to conduct a Phase IIa clinical trial, numbering 40 in total. The study is an allergen challenge study on subjects with allergic rhinitis (hay fever). It is a double blind, placebo controlled, cross-over clinical trial which should provide enough evidence to confirm the efficacy of PAR's novel histamine stabilising, non-steroidal ant-inflammatory nasal spray product Rhinosul®.

- The clinical trial is being conducted under the leadership of Dr Lennart Greiff at Skane University Hospital, Lund, Sweden. Dr Greiff has conducted similar clinical trials, using the established allergen challenge clinical method for other large pharma companies, including Astra Zeneca. Astra Zeneca produced one of the most widely used steroid-based drugs for treating AR globally.

- PAR have completed approximately 50% of their Phase IIa clinical trial. At the time of writing the first 15 subjects have completed their treatment.

- The second batch of 15 subjects are scheduled to be completed by mid-March and the final 10 subjects by the end of March.

- PAR's trial is therefore on schedule and on budget.

Results expected late Q2 or early 3Q CY17

As soon as the trial is completed work will begin on collating and analysing the results. We anticipate the trial results will be reported by late Q2 or early Q3 2017, but believe the completion of the trial itself marks a milestone in the advancement of PAR's repurposing strategy and for Rhinosul® in particular.

Upon completion in late March, the market will potentially have less than three months before the results of the trial are known. We would expect to see an uplift in share price post the trial completion as anticipation of the results looms. A positive outcome would launch Rhinosul® firmly on the path to development and will likely be a catalyst for the interest of big biopharma to take a closer look at PAR's innovative approach to this common disease state.

Fully funded program

PAR completed an over-subscribed $6.21m capital raise in October 2016 and followed this with a $1.0m share purchase plan for existing shareholders. At the end of the Dec Q, PAR had a cash balance of $5.025m, with a receivable from a government R&D tax incentive of $1.34m.

PAR is forecast to spend approximately $1.9m in Mar Q and is fully funded for the completion of the AR clinical trial and result report and for making further progress on the application of PPS to BME and viral arthritis following mosquito born infections.

Catalysts Summary

PAR will have a number of catalytic events through CY2017 with significant news flow from a number of trials. In summary:

Hay Fever (AR)

- **Q4 2016-Q1 2017**, Phase II(a) allergen challenge trial commences at Lund University in Sweden.
- **Q1 2017-Q2 2017**, Publication by internationally recognised respiratory researcher, Professor Jonas Erjefält, from Department of Experimental Medical Sciences, Clinical Immunology, Allergy and Pulmonology, of the ***comparator drug research*** paper; "Th2, Neutralisation and *In Vivo* Anti-inflammatory Action of Pentosan Polysulphate Sodium (PPS) in an Allergic Rhinitis Model".
- **Q4 2016-Q2 2017**, Potentially interest from a few key respiratory pharmaceutical companies following the publication of the Professor Erjefält research and or before Phase II trials commence.
- **Q2/Q3 2017,** Completion and publication of Phase II(a) allergy challenge trials.
- Other uses of PPS in respiratory diseases. PAR's respiratory patent includes the use of PPS to treat allergic asthma and chronic obstructive pulmonary disease (COPD).

Alphavirus

- **Q1-Q2 2017** Phase II trials ethics approval and trial initiation for Ross River Virus/Chikungunya virus.
- Potential for PPS to treat other autoimmune inflammatory joint disease states such as Rheumatoid Arthritis.

BME

- **Q4 2016-Q1 2017**, Open label trial may potentially confirm PPS efficacy and optimised dosage in the treatment regime management of BME. This will potentially bring forward the fully funded Phase II(b) closed label trial.
- **Potential for PPS to treat other joint diseases which have bone marrow lesions such as osteoarthritis.**

Corporate Opportunities

- **Q1-Q3 2017,** Potential licensing agreements/ takeover interest in PAR may be sparked by the publication of the Th2, Neutralisation and *In Vivo* Anti-inflammatory Action of Pentosan Polysulphate Sodium (PPS) in an Allergic Rhinitis Model, paper.
- **Q1-Q3 2017,** Potential licensing agreements/ takeover interest in PAR may be sparked by the Phase II(b) closed label trials for PPS in the treatment of BME.
- Development and maturation of existing manufacturing agreements.

Valuation and recommendation

We note that that the Phase IIa trial is well and truly underway with results published as early as late Q2.

We maintain our **Speculative Buy** recommendation. We stress that PAR is significantly under-valued compared to peers who have compounds undergoing Phase II trials. We believe a successful outcome will be a major catalytic event for PAR and is likely to initiate interest from big pharma who are looking to replace revenues from drugs going off-patent.

We also maintain our valuation range between A$120M and A$152M which corresponds to share price of A$1.18 and A$1.50 respectively, or a mid-point of $1.34 per share.

Private Client Dealing		Email	Telephone
Chad South	Head of Retail Advisory	csouth@djcarmichael.com.au	+61 8 9263 5225
Tim Bennett	Private Client Adviser	tbennett@djcarmichael.com.au	+61 8 9263 5351
Matthew Blake	Executive Director - Private Client Adviser	mblake@djcarmichael.com.au	+61 8 9263 5248
Eve Broadley	Private Client Adviser	ebroadley@djcarmichael.com.au	+61 8 9263 5324
Gregory Chionh	Private Client Adviser	gchionh@djcarmichael.com.au	+61 8 9263 5302
Gerry Connolly	Private Client Adviser	gconnolly@djcarmichael.com.au	+61 8 9263 5265
Andrew Cox	Private Client Adviser (Equities & Derivatives)	acox@djcarmichael.com.au	+61 8 9263 5237
Toby Jefferis	Private Client Adviser	tjefferis@djcarmichael.com.au	+61 8 9263 5217
Chris Jones	Private Client Advisor	cjones@djcarmichael.com.au	+61 8 9263 5232
Michael Marano	Private Client Adviser	mmarano@djcarmichael.com.au	+61 8 9263 5238
Zac Paul	Private Client Adviser	zpaul@djcarmichael.com.au	+61 8 9263 5272
Derek Steinepreis	Private Client Adviser	dsteinepreis@djcarmichael.com.au	+61 8 9263 5292
James Titcombe	Private Client Adviser	jtitcombe@djcarmichael.com.au	+61 8 9263 5254
Chris Eccles	Dealers Assistant	ceccles@djcarmichael.com.au	+61 8 9263 5225
Ben Osborne	Dealers Assistant	bosborne@djcarmichael.com.au	+61 8 9263 5251

Wealth Management		Email	Telephone
Brad Clarke	Wealth Adviser	bclarke@djcarmichael.com.au	+61 8 9263 5224
Paul Elkington	Wealth Adviser	pelkington@djcarmichael.com.au	+61 8 9263 5285
Domenic Macri	Wealth Adviser	dmacri@djcarmichael.com.au	+61 8 9263 5263
Mark Meacham	Wealth Adviser	mmeacham@djcarmichael.com.au	+61 8 9263 5247
Nick Casale	Portfolio Administration Manager	ncasale@djcarmichael.com.au	+61 8 9263 5215
Jason Murray	Business Associate	jmurray@djcarmichael.com.au	+61 8 9263 5260

Research		Email	Telephone
Paul Adams	Director - Head of Research and Natural Resources	padams@djcarmichael.com.au	+61 8 9263 5234
Michael Eidne	Director - Head of Industrials	meidne@djcarmichael.com.au	+61 8 9263 5213
Michael Ron	Research Analyst	mron@djcarmichael.com.au	+61 8 9263 5264

Corporate Finance		Email	Telephone
Davide Bosio	Managing Director - Head of Investment Banking	dbosio@djcarmichael.com.au	+61 8 9263 5210
Scott Robertson	Director – Corporate Finance Executive	srobertson@djcarmichael.com.au	+61 8 9263 5218
Matthew Hall	Associate Director - Corporate Finance	mhall@djcarmichael.com.au	+61 8 9263 5291
Adam Russo	Associate Director - Corporate Finance	arusso@djcarmichael.com.au	+61 8 9263 5290
Hugo McChesney	Institutional Client Manager	hmcchesney@djcarmichael.com.au	+61 8 9263 5214
Carly Circosta	Manager - Corporate Finance Executive	ccircosta@djcarmichael.com.au	+61 8 9263 5268
Julie Martino	Executive Secretary	jmartino@djcarmichael.com.au	+61 8 9263 5257

Administration		Email	Telephone
Cadell Buss	Chief Executive Officer	cbuss@djcarmichael.com.au	+61 8 9263 5204
Belinda Roychowdhury	Administration Manager	broychowdhury@djcarmichael.com.au	+61 8 9263 5216
Gabrielle Bouffler	Head of Risk and Compliance	gbouffler@djcarmichael.com.au	+61 8 9263 5221
Janelle Whyte	Chief Financial Officer	jwhyte@djcarmichael.com.au	+61 8 9263 5241
Michelle Perrett	Assistant Accountant	mperrett@djcarmichael.com.au	+61 8 9263 5220
Kerry Morrice	Administration Assistant	kmorrice@djcarmichael.com.au	+61 8 9263 5279
Brenda Woodenberg	Reception	bwoodenberg@djcarmichael.com.au	+61 8 9263 5200

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The contact person for this report has an interest in less than 50,000 shares in **Paradigm Biopharma Limited (PAR-ASX).**

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The Author of this report made contact with the **Paradigm BioPharmaceuticals Ltd** for assistance with verification of facts, admittance to business sites, access to industry/company information. No inducements have been offered or accepted by the company.

The recommendation made in this report is valid for four weeks from the stated date of issue. If in the event another report has been constructed and released on **Paradigm BioPharmaceuticals Ltd**, the new recommendation supersedes this and therefore the recommendation in this report will become null and void.

Recommendation Definitions

SPECULATIVE BUY – 10% or more outperformance, high risk
BUY – 10% or more outperformance
HOLD – 10% underperformance to 10% over performance
SELL – 10% or more underperformance
Period: During the forthcoming 12 months, at any time during that period and not necessarily just at the end of those 12 months.

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