

# Paradigm Biopharmaceuticals

## FDA not-so-fast track

**HOLD** (no change)

Current price:	A\$1.69
Target price:	A\$1.74
Previous target:	A\$2.16
Up/downside:	2.7%
Reuters:	PAR.AX
Bloomberg:	PAR AU
Market cap:	US\$203.3m
	A\$334.3m
Average daily turnover:	US\$2.96m
	A\$4.50m
Current shares o/s	224.7m
Free float:	72.2%

- PAR released an update to the market after feedback from the FDA requiring significantly larger trial cohorts as well as additional toxicology studies rather than relying on published safety data.
- The announcement vindicates our long-held view that the trial was likely to require more patients and over longer-time frames to support PAR's original claims.
- As a result, PAR is raising an additional A\$35m to fund and allow for the additional time frames and costs.
- We continue to remain cautious on the name with a large number of unknowns remaining, including enforceability of its patents. Our risk-adjusted DCF reduces to A\$1.74 and we retain a Hold recommendation.

### Meeting with the FDA – old data requires a refresh

PAR has released the meeting minutes from its pre-IND meeting with the FDA. The Company is now required to run two Phase 3 trials, previously under the assumption that it would gain an exception due to the generic status of the drug and use existing literature to confirm efficacy (confirmatory study). The first trial will comprise of a 750 patient cohort with similar primary and secondary endpoints as its Ph2b and expected to last 18-20 months. Questions raised by the FDA in regards to minimum effective dosing and duration of treatment are also expected to be addressed in this trial. Along with the Company now being required to run a confirmatory study, the FDA has requested it run further toxicology prior to the Phase 3 commencing, given the tox studies were conducted prior to GLP guidelines being introduced in the 1970's. The result is a substantial increase in costs from A\$30m (April 2019 corporate presentation) to complete the Phase 3 OA trial to A\$80m (+166%). We note that our Phase 3 trial cost assumptions remains at A\$100m.

### Capital raise to fund increase in trial costs

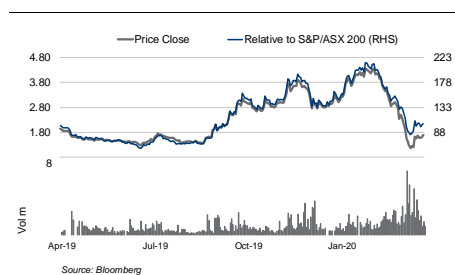
Alongside the FDA release, PAR announced a A\$35m capital raising to fund additional costs of the larger primary and additional secondary trials. The fully underwritten placement to sophisticated and institutional investors is being placed at A\$1.30 per share. The raise results in a pro-forma cash balance as at end of March 2020 of ~A\$108m. Use of funds is expected to be used for Phase 3 OA (A\$80m), Mucopolysaccharidosis (MPS) (A\$9m), and working capital (A\$19m).

### Changes to forecasts

We have only made minor changes to our assumptions including a slightly lower long-term growth rate as a result of diminishing market opportunity due to further delays. The new issuance of shares results in a ~14% dilution.

### Investment view – retaining a Hold

Due to the above changes, our risk-adjusted DCF valuation reduces to A\$1.74 (from A\$2.17). We continue to remain cautious due to a number of issues we have raised previously including final details on trial protocols, IP strength, and patent enforceability. We retain a Hold recommendation. An investment in PAR is appropriate for investors with a higher risk-profile.



Price performance	1M	3M	12M
Absolute (%)	-40.7	-42.3	-16.4
Relative (%)	-22.8	-21.4	-1.4

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– N/A

### Financial Summary

	Jun-18A	Jun-19A	Jun-20F	Jun-21F	Jun-22F
Revenue (A\$m)	2.74	2.98	2.25	5.70	70.20
Operating EBITDA (A\$m)	-6.19	-15.89	-22.10	-48.98	15.17
Net Profit (A\$m)	-6.15	-15.63	-20.50	-47.20	11.24
Normalised EPS (A\$)	-0.04	-0.09	-0.10	-0.21	0.05
Normalised EPS Growth	22681%	115%	5%	114%	
FD Normalised P/E (x)	NA	NA	NA	NA	33.78
DPS (A\$)	-	-	-	-	-
Dividend Yield	0%	0%	0%	0%	0%
EV/EBITDA (x)	NA	NA	NA	NA	22.04
P/FCFE (x)	NA	NA	NA	NA	559.3
Net Gearing	(18.0%)	(87.4%)	(92.7%)	(91.7%)	(75.9%)
P/BV (x)	17.64	3.92	3.96	7.81	6.35
ROE	(45.7%)	(32.4%)	(23.0%)	(65.4%)	20.7%
% Change In Normalised EPS Estimates			(23.7%)	15.6%	(8.5%)
Normalised EPS/consensus EPS (x)			1.64	1.08	-1.11

SOURCE: MORGANS, COMPANY REPORTS

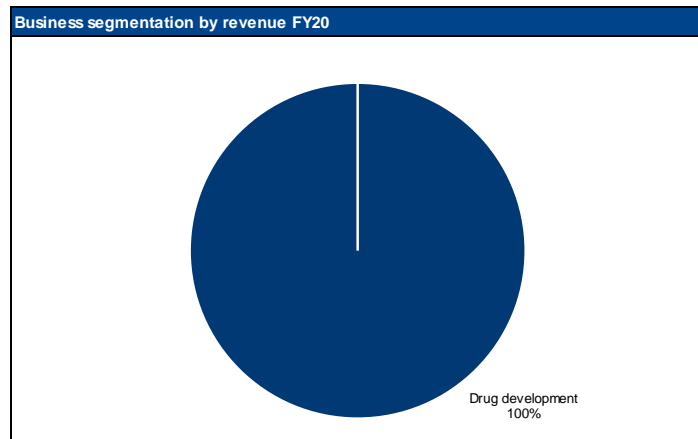
## Paradigm Biopharmaceuticals

as at April 7, 2020

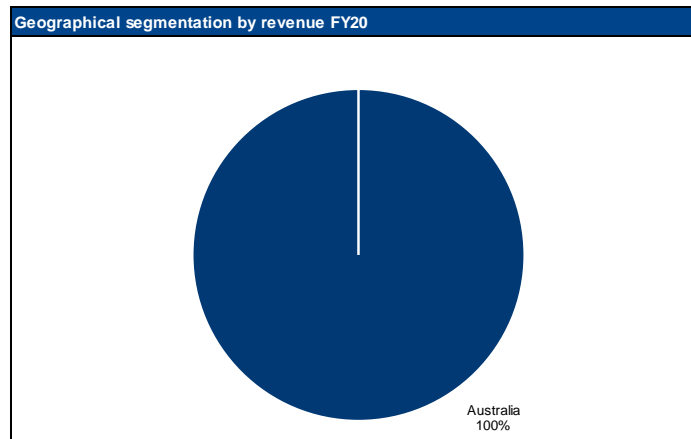
Market cap (A\$m):	334.3	Rating:	HOLD
Shares outstanding (m):	224.7	Price (A\$):	1.69
Free float (%):	72.2	Target price (A\$):	1.74
Website:	<a href="https://paradigmbiopharma.com/">https://paradigmbiopharma.com/</a>	Upside/downside to target price (%):	2.7

### Company description

Paradigm Biopharmaceuticals Limited (PAR) is an Australian biopharmaceutical company focused on repurposing the drug 'pentosan polysulphate sodium' (PPS) for the treatment of bone marrow edema. Paradigm is targeting addressable markets with the aim to use the shortened development pathway utilising repurposed drugs.



SOURCE: MORGANS



SOURCE: MORGANS

### PAR corporate milestones

Milestones for CY2020	
Initiate Compassionate Use program with NFL 'Pro Players Elite Network'	
Peer review publication of Phase 2a Viral Arthritis clinical trial.	
Phase 3 OA/BMEL Clinical Trial:	<ul style="list-style-type: none"> <li>Commence Phase 3 Clinical Trial in USA</li> </ul>
Phase 2/3 MPS Clinical Trial:	<ul style="list-style-type: none"> <li>Commence Phase 2/3 Clinical Trial in USA and EU</li> </ul>
Peer reviewed publication of Phase 2b OA/BMEL Results	
Progress MPS Indication	
TGA Provisional Approval for iPPS to treat OA in Australia	
Ongoing assessment of respiratory indication	

SOURCE: PARADIGM BIOPHARMACEUTICALS

### Catalyst table

Upcoming catalysts:
Peer-reviewed publication of OA/BMEL results
TGA provisional approval results
Release of Ph3 trial protocol (FDA IND)
Ex-NFL player EAP
Partnership transaction discussions
Ph3 commencement

SOURCE: MORGANS

### Market assumptions

MARKET DATA	#
Population of target market	325.70
Prevalence of disease	12.1%
Post-traumatic portion	12.0%
Number of Cases Forecast for Year 1	4.7
Annual Population Growth	0.70%
Peak Market Penetration	10.0%
Revenue Per Unit (\$US)	\$ 1,750
Market Ramp Time to Peak Penetration (Years)	5
Hold peak	5
Life cycle of drug	20

SOURCE: MORGANS

### Key drivers / risks

Key Drivers
Licensing deal value for late stage assets
Potential for early commercialisation
Key risks:
Timing / execution risks
Trial risks
Value of intellectual property
API supply
Alternative therapies
Quality of trial data to date

SOURCE: MORGANS

Figure 1: Financial summary

Income statement	2018A	2019A	2020F	2021F	2022F	Closing price (A\$)	1.69	Price target (A\$)	1.74
Milestone payments	0.0	0.0	0.0	0.0	70.2	Valuation metrics			
Royalty	0.0	0.0	0.0	0.0	0.0	Methodology -DCF-PER Comp		Target Price	\$1.74
R&D rebate	2.7	3.0	2.3	5.7	0.0	DCF valuation inputs			
<b>Total revenue</b>	<b>2.7</b>	<b>3.0</b>	<b>2.3</b>	<b>5.7</b>	<b>70.2</b>	Rf	3.00%	10-year rate	5.25%
<b>EBITDA</b>	<b>-6.2</b>	<b>-15.9</b>	<b>-22.1</b>	<b>-49.0</b>	<b>15.2</b>	Rm-Rf	5.50%	Margin	2.0%
Associate income	0.0	0.0	0.0	0.0	0.0	Beta	1.80	Kd	5.00%
Depreciation	0.0	0.0	0.0	0.0	0.0	CAPM (Rf+Beta(Rm-Rf))	12.9%	Ke	14.9%
EBITA	-6.2	-15.9	-22.1	-49.0	15.2	E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (A\$m)	386.4
Amortisation/impairment	0.0	0.0	0.0	0.0	0.0	Equity (E/EV)	96.5%	Minority interest (A\$m)	0.0
<b>EBIT</b>	<b>-6.2</b>	<b>-15.9</b>	<b>-22.1</b>	<b>-49.0</b>	<b>15.2</b>	Debt (D/EV)	3.5%	Net debt (A\$m)	0.0
EBIT(incl associate profit)	-6.2	-15.9	-22.1	-49.0	15.2	Interest rate	5.00%	Investments (A\$m)	0.0
Net interest expense/FX	0.0	0.0	0.3	1.6	1.8	Tax rate (t)	30.0%	Equity market value (A\$m)	386.4
<b>Pre-tax profit</b>	<b>-6.3</b>	<b>-15.6</b>	<b>-20.5</b>	<b>-47.2</b>	<b>16.1</b>	WACC	12.9%	Diluted no. of shares (m)	224.7
Income tax expense	0.0	0.0	0.0	0.0	4.8			DCF valuation	\$1.72
After-tax profit	-6.3	-15.6	-20.5	-47.2	11.2				
Minority interests	0.0	0.0	0.0	0.0	0.0	<b>Multiples</b>			
<b>NPAT</b>	<b>-6.3</b>	<b>-15.6</b>	<b>-20.5</b>	<b>-47.2</b>	<b>11.2</b>	Enterprise value (A\$m)	377.4	2018A	307.5
Significant items	0.0	0.0	0.0	0.0	0.0	EV/Sales (x)	n.a.	2019A	291.0
NPAT post abnormals	-6.3	-15.6	-20.5	-47.2	11.2	EV/EBITDA (x)	-61.0	2020F	335.2
						EV/EBIT (x)	-60.9	2021F	334.4
						PE (pre-goodwill) (x)	-38.9	2022F	334.4
						PEG (pre-goodwill) (x)	-0.2		
<b>Cash flow statement</b>	<b>2018A</b>	<b>2019A</b>	<b>2020F</b>	<b>2021F</b>	<b>2022F</b>	<b>At target price</b>	<b>2018A</b>	<b>2019A</b>	<b>2020F</b>
EBITDA	-6.2	-15.9	-22.1	-49.0	15.2	EV/EBITDA (x)	-60.9	-19.3	-13.2
Other cash items	0.0	0.0	0.0	0.0	0.0	PE (pre-goodwill) (x)	-39.9	-21.4	-19.0
Net interest (pd)/rec	-0.1	-0.3	-1.6	-1.8	-0.9				
Taxes paid	0.0	0.0	0.0	0.0	-4.8				
Change in working capital	0.1	9.8	3.5	2.8	-10.6				
<b>Cash flow from ops (1)</b>	<b>-6.1</b>	<b>-6.4</b>	<b>-20.2</b>	<b>-48.0</b>	<b>-1.1</b>				
Capex (2)	0.0	0.0	0.0	0.0	0.0	<b>Per share data</b>	<b>2018A</b>	<b>2019A</b>	<b>2020F</b>
Disposals/(acquisitions)	0.0	0.0	0.0	0.0	0.0	No. shares	141.5	192.2	224.7
Other investing cash flow	0.0	-6.5	0.0	0.0	0.0	EPS (cps)	-4.3	-8.1	-9.1
<b>Cash flow from invest (3)</b>	<b>0.0</b>	<b>-6.5</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	EPS (normalised) (c)	-4.3	-8.1	-9.1
Incr/(decr) in equity	5.9	82.8	33.5	0.0	0.0	Dividend per share (c)	0.0	0.0	0.0
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0	Dividend payout ratio (%)	0.0%	0.0%	0.0%
Ordinary dividend paid	0.0	0.0	0.0	0.0	0.0	Dividend yield (%)	0.0%	0.0%	0.0%
Preferred dividends (4)	0.0	0.0	0.0	0.0	0.0				
Other financing cash flow	0.0	0.0	0.0	0.0	0.0	<b>Growth ratios</b>	<b>2018A</b>	<b>2019A</b>	<b>2020F</b>
<b>Cash flow from fin (5)</b>	<b>5.9</b>	<b>82.8</b>	<b>33.5</b>	<b>0.0</b>	<b>0.0</b>	Sales growth	n.a.	n.a.	n.a.
Forex and disc ops (6)	0.0	0.0	0.0	0.0	0.0	Operating cost growth	n.a.	156.7%	39.1%
Incr/(decr) cash (1+3+5+6)	-0.3	69.9	13.3	-48.0	-1.1	EBITDA growth	n.a.	-156.6%	-39.1%
Equity FCF (1+2+4)	-6.2	-6.4	-20.2	-48.0	-1.1	EBITA growth	n.a.	n.a.	-121.6%
						EBIT growth	n.a.	n.a.	131.0%
						NPAT growth	n.a.	n.a.	n.a.
						Pre-goodwill NPAT growth	n.a.	n.a.	n.a.
						Pre-goodwill EPS growth	n.a.	n.a.	n.a.
						Normalised EPS growth	n.a.	n.a.	n.a.
<b>Balance sheet</b>	<b>2018A</b>	<b>2019A</b>	<b>2020F</b>	<b>2021F</b>	<b>2022F</b>	<b>Operating performance</b>	<b>2018A</b>	<b>2019A</b>	<b>2020F</b>
Cash & deposits	2.4	72.3	88.8	44.6	45.4	Asset turnover (%)	0.0	0.0	0.0
Trade debtors	2.7	3.5	0.4	0.9	11.5	EBITDA margin (%)	n.a.	n.a.	n.a.
Inventory	0.0	0.0	0.0	0.0	0.0	EBIT margin (%)	n.a.	n.a.	n.a.
Investments	0.0	0.0	0.0	0.0	0.0	Net profit margin (%)	n.a.	n.a.	n.a.
Goodwill	0.0	0.0	0.0	0.0	0.0	Return on net assets (%)	-45.7	-19.2	-23.1
Other intangible assets	9.9	3.0	3.0	3.0	3.0	Net debt (A\$m)	-2.4	-72.3	-88.8
Fixed assets	0.0	0.0	0.0	0.0	0.0	Net debt/equity (%)	-18.0	-87.4	-92.7
Other assets	0.0	0.0	0.0	0.0	0.0	Net interest/EBIT cover (x)	n.a.	389.4	84.5
<b>Total assets</b>	<b>15.2</b>	<b>85.5</b>	<b>98.9</b>	<b>55.2</b>	<b>66.6</b>				
Short-term borrowings	0.0	0.0	0.0	0.0	0.0	<b>Internal liquidity</b>	<b>2018A</b>	<b>2019A</b>	<b>2020F</b>
Trade payables	1.1	2.3	2.7	6.0	6.0	Current ratio (x)	1.5	26.7	29.1
Long-term borrowings	0.0	0.0	0.0	0.0	0.0	Receivables turnover (x)	0.0	0.0	0.0
Provisions	0.3	0.4	0.4	0.4	0.4	Payables turnover (x)	6.6	9.4	8.9
Other liabilities	0.3	0.0	0.0	0.0	0.0				
<b>Total liabilities</b>	<b>1.6</b>	<b>2.7</b>	<b>3.1</b>	<b>6.4</b>	<b>6.4</b>				
Share capital	26.6	109.5	143.0	143.0	143.0				
Other reserves	2.0	4.1	4.1	4.1	4.1				
Retained earnings	-15.1	-30.7	-51.2	-98.4	-87.2				
Other equity	0.0	0.0	0.0	0.0	0.0				
<b>Total equity</b>	<b>13.6</b>	<b>82.8</b>	<b>95.8</b>	<b>48.6</b>	<b>59.8</b>				
Minority interest	0.0	0.0	0.0	0.0	0.0				
Total shareholders' equity	13.6	82.8	95.8	48.6	59.8				
Total liabilities & SE	15.2	85.5	98.9	55.0	66.3				

SOURCE: MORGANS RESEARCH, COMPANY

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