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%

Source: Bloomberg

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

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Analyst(s) own shares in the following stock(s) mentioned in this report:

– N/A

- 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 risked 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.

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

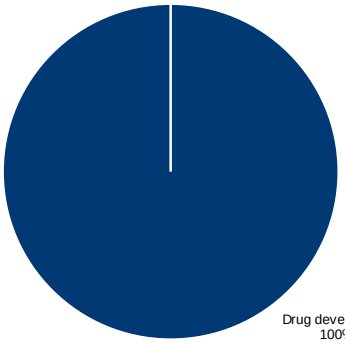
as at April 7, 2020

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:	https://paradigmbiopharma.com/	Upside/downside to target price (%):	2.7

Company description

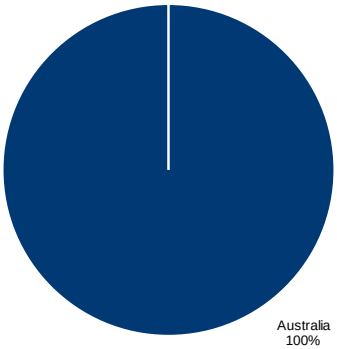
Paradigm Biopharmaceuticals Limited (PAR) is an Australian biopharmaceutical company focused on repurposing the drug 'pentosan polysulphate sodium' (PPS) for the treatment of bone marrow edema. Paradigm is targeting addressable markets with the aim to use the shortened development pathway utilising repurposed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

Business segmentation by revenue FY20



SOURCE: MORGANS

Geographical segmentation by revenue FY20



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: • Commence Phase 3 Clinical Trial in USA
Phase 2/3 MPS Clinical Trial: • Commence Phase 2/3 Clinical Trial in USA and EU
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

Licencing 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
Milestone payments	0.0	0.0	0.0	0.0	70.2
Royalty	0.0	0.0	0.0	0.0	0.0
R&D rebate	2.7	3.0	2.3	5.7	0.0
Total revenue	**2.7**	**3.0**	**2.3**	**5.7**	**70.2**
EBITDA	**-6.2**	**-15.9**	**-22.1**	**-49.0**	**15.2**
Associate income	0.0	0.0	0.0	0.0	0.0
Depreciation	0.0	0.0	0.0	0.0	0.0
EBITA	-6.2	-15.9	-22.1	-49.0	15.2
Amortisation/impairment	0.0	0.0	0.0	0.0	0.0
EBIT	**-6.2**	**-15.9**	**-22.1**	**-49.0**	**15.2**
EBIT(incl associate profit)	-6.2	-15.9	-22.1	-49.0	15.2
Net interest expense/FX	0.0	0.0	0.3	1.6	1.8
Pre-tax profit	**-6.3**	**-15.6**	**-20.5**	**-47.2**	**16.1**
Income tax expense	0.0	0.0	0.0	0.0	4.8
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
NPAT	**-6.3**	**-15.6**	**-20.5**	**-47.2**	**11.2**
Significant items	0.0	0.0	0.0	0.0	0.0
NPAT post abnormals	-6.3	-15.6	-20.5	-47.2	11.2

Cash flow statement	2018A	2019A	2020F	2021F	2022F
EBITDA	-6.2	-15.9	-22.1	-49.0	15.2
Other cash items	0.0	0.0	0.0	0.0	0.0
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
Cash flow from ops (1)	**-6.1**	**-6.4**	**-20.2**	**-48.0**	**-1.1**
Capex (2)	0.0	0.0	0.0	0.0	0.0
Disposals/(acquisitions)	0.0	0.0	0.0	0.0	0.0
Other investing cash flow	0.0	-6.5	0.0	0.0	0.0
Cash flow from invest (3)	**0.0**	**-6.5**	**0.0**	**0.0**	**0.0**
Incr/(decr) in equity	5.9	82.8	33.5	0.0	0.0
Incr/(decr) in debt	0.0	0.0	0.0	0.0	0.0
Ordinary dividend paid	0.0	0.0	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
Cash flow from fin (5)	**5.9**	**82.8**	**33.5**	**0.0**	**0.0**
Forex and disc ops (6)	0.0	0.0	0.0	0.0	0.0
Inc/(decr) cash (1+3+5+6)	-0.3	69.9	13.3	-48.0	-1.1
Equity FCF (1+2+4)	-6.2	-6.4	-20.2	-48.0	-1.1

Balance sheet	2018A	2019A	2020F	2021F	2022F
Cash & deposits	2.4	72.3	88.8	44.6	45.4
Trade debtors	2.7	3.5	0.4	0.9	11.5
Inventory	0.0	0.0	0.0	0.0	0.0
Investments	0.0	0.0	0.0	0.0	0.0
Goodwill	0.0	0.0	0.0	0.0	0.0
Other intangible assets	9.9	3.0	3.0	3.0	3.0
Fixed assets	0.0	0.0	0.0	0.0	0.0
Other assets	0.0	0.0	0.0	0.0	0.0
Total assets	**15.2**	**85.5**	**98.9**	**55.2**	**66.6**
Short-term borrowings	0.0	0.0	0.0	0.0	0.0
Trade payables	1.1	2.3	2.7	6.0	6.0
Long-term borrowings	0.0	0.0	0.0	0.0	0.0
Provisions	0.3	0.4	0.4	0.4	0.4
Other liabilities	0.3	0.0	0.0	0.0	0.0
Total liabilities	**1.6**	**2.7**	**3.1**	**6.4**	**6.4**
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
Total equity	**13.6**	**82.8**	**95.8**	**48.6**	**59.8**
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

Closing price (A$)	1.69	Price target (A$)	1.74
Valuation metrics			
Methodology -DCF-PER Comp		Target Price	$1.74
DCF valuation inputs			
Rf	3.00%	10-year rate	5.25%
Rm-Rf	5.50%	Margin	2.0%
Beta	1.80	Kd	5.00%
CAPM (Rf+Beta(Rm-Rf))	12.9%	Ke	14.9%
E/EV*Ke+D/EV*Kd(1-t)		NPV cash flow (A$m)	386.4
Equity (E/EV)	96.5%	Minority interest (A$m)	0.0
Debt (D/EV)	3.5%	Net debt (A$m)	0.0
Interest rate	5.00%	Investments (A$m)	0.0
Tax rate (t)	30.0%	Equity market value (A$m)	386.4
WACC	12.9%	Diluted no. of shares (m)	224.7
		DCF valuation	$1.72

Multiples	2018A	2019A	2020F	2021F	2022F
Enterprise value (A$m)	377.4	307.5	291.0	335.2	334.4
EV/Sales (x)	n.a.	n.a.	n.a.	n.a.	n.a.
EV/EBITDA (x)	-61.0	-19.4	-13.2	-6.8	22.0
EV/EBIT (x)	-60.9	-19.3	-13.2	-6.8	22.0
PE (pre-goodwill) (x)	-38.9	-20.8	-18.5	-8.0	33.8
PEG (pre-goodwill) (x)	-0.2	0.0	0.1	0.3	-0.3

At target price	2018A	2019A	2020F	2021F	2022F
EV/EBITDA (x)	-60.9	-19.3	-13.2	-6.8	22.0
PE (pre-goodwill) (x)	-39.9	-21.4	-19.0	-8.3	34.7

Per share data	2018A	2019A	2020F	2021F	2022F
No. shares	141.5	192.2	224.7	224.7	224.7
EPS (cps)	-4.3	-8.1	-9.1	-21.0	5.0
EPS (normalised) (c)	-4.3	-8.1	-9.1	-21.0	5.0
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
Dividend payout ratio (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Dividend yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%

Growth ratios	2018A	2019A	2020F	2021F	2022F
Sales growth	n.a.	n.a.	n.a.	n.a.	n.a.
Operating cost growth	n.a.	156.7%	39.1%	121.6%	-131.0%
EBITDA growth	n.a.	-156.6%	-39.1%	-121.6%	131.0%
EBITA growth	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT growth	n.a.	n.a.	n.a.	n.a.	n.a.
NPAT growth	n.a.	n.a.	n.a.	n.a.	n.a.
Pre-goodwill NPAT growth	n.a.	n.a.	n.a.	n.a.	n.a.
Pre-goodwill EPS growth	n.a.	n.a.	n.a.	n.a.	n.a.
Normalised EPS growth	n.a.	n.a.	n.a.	n.a.	n.a.

Operating performance	2018A	2019A	2020F	2021F	2022F
Asset turnover (%)	0.0	0.0	0.0	0.0	0.0
EBITDA margin (%)	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT margin (%)	n.a.	n.a.	n.a.	n.a.	n.a.
Net profit margin (%)	n.a.	n.a.	n.a.	n.a.	n.a.
Return on net assets (%)	-45.7	-19.2	-23.1	-100.8	25.4
Net debt (A$m)	-2.4	-72.3	-88.8	-44.6	-45.4
Net debt/equity (%)	-18.0	-87.4	-92.7	-91.7	-75.9
Net interest/EBIT cover (x)	n.a.	389.4	84.5	30.7	-8.5

Internal liquidity	2018A	2019A	2020F	2021F	2022F
Current ratio (x)	1.5	26.7	29.1	7.0	7.1
Receivables turnover (x)	0.0	0.0	0.0	0.0	0.0
Payables turnover (x)	6.6	9.4	8.9	11.3	-2.5

SOURCE: MORGANS RESEARCH, COMPANY

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