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Paradigm Biopharmaceuticals (PAR)

Enrolments in Phase 3 Close

Speculative
See key risks on Page 3 and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.

Recommendation
Buy (unchanged)
Price
$0.555
Valuation
$0.80 (unchanged)
Risk
Speculative

Sector

Pharmaceuticals & Biotechnology

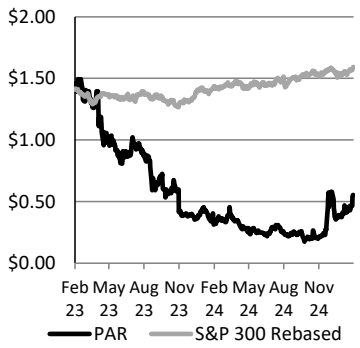
Expected Return	
Capital growth	**44.1%**
Dividend yield	**0.0%**
Total expected return	**44.1%**

Company Data & Ratios	
Enterprise value	**$191.1m**
Market cap	**$216.1m**
Issued capital	**389.4m**
Free float	**94%**
Avg. daily val. (52wk)	**$472K**
12 month price range	**$0.17 - $0.61**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.38	0.21	0.41
Absolute (%)	46.05	170.73	37.04
Rel market (%)	42.58	167.12	24.55

Absolute Price



SOURCE: IRESS

CRO selected, pushing ahead with site activations

The key points from the December quarter 4C are as follows. PAR's revised IND for Zilosul was opened in November 2024 allowing it to commence recruitment of its two phase 3 studies required for approval. The company expects to commence recruitment of the first patients at up to 10 sites in Australia in the current quarter with first patient dosed in the June quarter. In addition, "The company is actively engaging with stakeholders, including potential partners, to support the trial and future commercialisation". This engagement includes selection of a Clinical Research Organisation (CRO). To this end, earlier today Advanced Clinical – being a Chicago based firm was announced as the CRO to manage the global phase 3 trials.

Understandably PAR remains tight lipped regarding the progress of negotiations with potential development partners, however, it does appear the company will have a partner to share the clinical trial risk and funding requirement in at least some capacity.

Balance sheet and funding considerations

Closing cash at period end was $24.8m inclusive of funds from the recent $16m capital raise. Notional cash increases to ~$30m inclusive of a $6m R&D tax credit received after the end of the period. 2Q25 cash burn $3.6m with guidance for 3Q25 at $12m inclusive of trial set up cost incl site activation and ongoing operational expenses.

PAR will proceed with a 1 for 4 loyalty option program for existing shareholders with a $0.65c exercise price. The option program is one of the funding measures the company has pursued in addition to partnerships or a license agreement.

Investment view – Buy (Spec) Valuation $0.80

We believe there remains multiple pharma groups engaged with the company for a partnering deal on the Zilosul phase 3 program. The catalysts to consummate a deal include appointment of the CRO, site activations and first patients enrolled. There are no significant changes to the financial model. Valuation remains $0.80 and we maintain our Buy rating.

Earnings Forecast

June Year End	FY24	FY25e	FY26e	FY27e
Revenues	0.0	3.0	0.0	0.0
EBITDA $m	-58.6	-48.5	-66.0	-86.0
NPAT (underlying) $m	-58.6	-48.0	-65.5	-85.5
NPAT (reported) $m	-58.6	-48.0	-65.5	-85.5
EPS underlying (cps)	-16.3	-7.1	-9.7	-10.3
EPS growth %	na	nm	nm	nm
PER (x)	nm	nm	nm	nm
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	nm	nm	nm	nm
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	na	na	na	na

SOURCE: BELL POTTER SECURITIES ESTIMATES

Key stakeholder engagement ongoing

TGA says no to provisional approval

The TGA in Australia has denied the company's application for provisional approval of iPPS for knee osteoarthritis. The TGA acknowledged that preliminary clinical results for PPS demonstrated clinically meaningful benefits for patients suffering from moderate to severe OA of the knee, however, such benefits are not considered significant for patients with minor or mild OA, as these conditions are not deemed seriously debilitating. Accordingly, the company is required to pursue a traditional registration pathway.

From our perspective, TGA provisional approval in the absence of data from a large randomised multicentre trial was unlikely. While the TGA appears to have rejected the company's application on the basis of modest benefit to patients with minor or mild OA, it has conveniently ignored the very considerable benefit to patients with moderate to severe disease. The FDA and EMA are the two bodies whose opinion really matters for drug approvals and PAR is quite rightly pursing its clinical program.

Figure 1 - Summary of earnings changes

	2025			2026			2027		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	3.0	3.0	na	0.0	0.0	na	0.0	0.0	na
EBITDA	-48.5	-58.5	21%	-66.0	-66.0	na	-86.0	-86.0	na
NPAT	-48.0	-58.0	21%	-65.5	-65.5	na	-85.5	-85.5	na
EPS	-7.1	-8.5	20%	-9.7	-9.6	na	-10.3	-10.3	na

SOURCE: BELL POTTER SECURITIES ESTIMATES

The key change to earnings relates to the deferral of $10m in R&D expense from FY25 into subsequent years. The model continues to assume PAR raises additional shareholder funds, however, the company's funding requirement remains fluid at this time pending the outcome of partnering discussions and other key stakeholder engagement.

We retain our Buy (Speculative) recommendation and valuation of $0.80.

Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals is an Australia biotechnology company focused on repurposing Pentosan Polysulfate Sodium (PPS) for the treatment of Osteoarthritis (OA) in the knee. If approved the drug will have the brand name Zilosul.

The global market for a safe, effective treatment that provides superior patient outcomes compared to the standard of care is a multiple blockbuster. The recently completed phase II study produced some highly encouraging results that are worthy of further clinical trials.

In the US along the incidence of moderate to severe osteoarthritis is estimated at 30m persons. The pricing of the drug will ultimately be determined by the economic benefit associated with its use as well as the cost of other therapies. The conservative estimate is US$2,500 per year which places the addressable market in the tens of billions of US$.

Within the FDA's Centre for Drug Evaluation and Research (CDER), it is the office of Neuroscience – Division of Anesthesiology, Addiction Medicine, and Pain Medicine that is (DAAP) that is responsible the review of iPPS.

PATHWAY TO APPROVAL

The IND for Zilosul was opened in November 2024. PAR will enrol 2 phase 3 trial involving ~1,000 patients in total with a primary endpoint of pain reduction at day 112.

ADJACENT INDICATIONS

The second indication for PPS is mucopolysaccharidoses (MPS), a group of inherited lysosomal storage disorders. A key unmet medical need in this class of inherited disease is the lack of treatment of joint pain and dysfunction akin to osteoarthritis, hence the applicability of iPPS in treating these rare joint diseases. MPS is classified as an Orphan Indication/Designation in the US/EU and provides Paradigm the opportunity to serve a US$1.4bn p.a. market that is in desperate need of new cost-effective treatments.

KEY RISK AREAS

Regulatory Pathway - PAR is seeking registration for iPPS under the 505(b)2 regulatory pathway. The pathway is designed specifically for repurposed drugs including changes in dose form, strength, route of administration, formulation, dosing regimen or indication. This proposed repurposing of PPS has some rare characteristics.

While the drug has been approved for years as an oral format and there is ample safety data, the proposed format, the dose and the indication (being OA) are all new.

There is also the issue of the opioid crisis. PPS is a non steroid, non opioid, non addictive substance that has been shown to have a significant impact of pain levels associated with OA. It may help to reduce the accidental deaths from opioid overdose.

PAR will present a comprehensive set of safety data from the recent Phase II trial together with data from subjects treated in the compassionate use program and two phase 3 trials, thus representing a safety set of ~1,000 subjects. The evidence of treatment will be established from two adequate and well controlled studies and further supported by the phases 2 data set.

Intellectual Property

The company has several patents over the formulation and dosing on iPPS for the treatment of OA. The validity of these patents is highly likely to be challenged at some point, especially if the drug is a commercial success.

The company has an exclusive supply contract with Bene Pharmaceuticals (Bene). We understand the exclusivity applies to human use only (excludes veterinary use). Bene holds the only drug Masterfile with the FDA to manufacture PPS. This supply contract

represents a crucial piece of the company's value as it effectively prevents or delays the creation of generics.

We are not aware of the contractual conditions that may lead to a termination of this contract (if any).

We understand there are some other manufacturers of PPS, however, these products are not registered for human use and may not be referenced in any application for registration for human use. We understand the primary use of these products is veterinary.

Clinical Risk

The efficacy of iPPS has not been validated in a large, multicentre, randomised, controlled clinical trial. There is no guarantee that the results from earlier studies will be repeated in a larger phase III study.

Commercial Validation

Our valuation makes assumptions regarding selling price and volume in relation to future revenues from the sale of iPPS. In order for physicians to prescribe the drug and for payers to offer reimbursement, the clinical trials will need to demonstrate clinically significant improvement over the standard of care i.e. meaningful improvement in patient quality of life for pain reduction, side effect management and mobility amongst others. Early indicators based on the data from the phase II study are encouraging.

Going Concern Risk

The company is not funded to complete the phase 3 clinical program. While PAR has several funding options available including partnerships with large pharma partners and raising further capital from shareholders, there are no guarantees that either of these will provide the capital required in order to obtain an approval for iPPS and begin generating revenues. Accordingly there is considerable risk that the company will remain a going concern.

Paradigm Biopharmaceuticals

as at 31 January 2025

Recommendation	Buy, Speculative
Price	$0.555
Valuation	$0.80

Table 1 - Financial summary

Profit & Loss (A$m)	FY23	FY24	FY25e	FY26e	FY27e
Year Ending June					
Risk adjusted revenues	-	-	3.0	-	-
COGS (Bene Royalty expense)	-	-	-	-	-
Gross profit	0.0	0.0	3.0	0.0	0.0
GP margin	na	0%	0%	0%	0%
R&D incentive	7.0	6.5	10.0	10.0	-
Other expenses including R&D	-60.3	-65.1	-61.5	-76.0	-86.0
EBITDA	-53.3	-58.6	-48.5	-66.0	-86.0
Depreciation	-	-	-	-	-
Amortisation	-	-	-	-	-
EBIT	-53.3	-58.6	-48.5	-66.0	-86.0
Finance income	1.4	-	0.5	0.5	0.5
Pre tax profit	**-51.9**	**-58.6**	**-48.0**	**-65.5**	**-85.5**
Tax expense	-	-	-	-	-
NPAT- reported	-51.9	-58.6	-48.0	-65.5	-85.5

Cashflow (A$m)	FY23	FY24	FY25e	FY26e	FY27e
Gross cashflow	-46.1	-66.9	-48.5	-60.9	-86.0
Net interest	0.9	1.0	0.5	0.5	0.5
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-45.2	-65.9	-48.0	-60.4	-85.5
Maintenance capex	0.0	0.0	0.0	0.0	0.0
Capitalised clinical trial spend	0.0	0.0	0.0	0.0	0.0
Free cash flow	-45.2	-65.9	-48.0	-60.4	-85.5
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	62.2	28.3	128.0	0.0	60.0
Movement in debt	0.0	-0.1	0.0	0.0	0.0
Dividends paid	0.3	0.0	0.0	0.0	0.0
Change in cash held	17.3	(37.7)	80.0	(60.4)	(25.5)
Cash at beginning of period	39.7	56.3	17.8	97.8	37.4
Cash at year end	56.3	17.8	97.8	37.4	11.9

Balance Sheet (A$m)	FY23	FY24	FY25e	FY26e	FY27e
Cash	56.3	17.8	97.8	37.4	11.9
Receivables	6.8	5.1	5.1	-	-
Other current assets	0.7	1.3	1.3	1.3	1.3
Intangibles	3.0	3.0	3.0	3.0	3.0
Other	0.3	0.2	0.2	0.2	0.2
Total assets	67.1	27.3	107.3	41.8	16.3
Trade payables	12.2	2.8	2.8	2.8	2.8
Debt (leases)	0.3	0.2	0.2	0.2	0.2
Other provisions	0.9	0.6	0.6	0.6	0.6
Total Liabilities	13.4	3.6	3.6	3.6	3.6
Net Assets	53.7	23.7	103.7	38.2	12.7
Share capital	209.9	238.1	366.1	366.1	426.1
Retained earnings	(163.6)	(220.8)	(268.8)	(334.3)	(419.8)
Reserves	7.4	6.4	6.4	6.4	6.4
Shareholders Equity	53.7	23.7	103.7	38.2	12.7

Last sale 31/01/2025	0.555
Recommendation	Buy (Spec)
Issued Capital	389.4
Market Cap	216.1

Valuation Ratios (A$m)	FY23	FY24	FY25e	FY26e	FY27e
Reported EPS (cps)	-18.4	-16.3	-7.1	-9.7	-10.3
Normalised EPS (cps)	-18.4	-16.3	-7.1	-9.7	-10.3
EPS growth (%)	na	na	nm	nm	nm
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBITDA (x)	nm	nm	nm	nm	nm
EV/EBIT (x)	nm	nm	nm	nm	-2.2
NTA (cps)	18.0	5.9	15.0	5.3	1.2
P/NTA (x)	0.0	0.1	0.0	0.1	0.5
Book Value (cps)	19.1	6.8	15.5	5.7	1.5
Price/Book (x)	0.0	0.1	0.0	0.1	0.4
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	0%	0%	0%	0%	0%
FCF yield %	nm	nm	nm	nm nm	
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	0%	0%	0%	0%	0%
Gearing	net cash	net cash	net cash	net cash	net cash
Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Interest cover (x)	n/a	n/a	n/a	n/a	n/a

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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