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Paradigm Biopharmaceuticals (PAR)

Funding Secured For Patient Enrolment

Speculative
See key risks on Page 5 and Biotechnology Risk Warning on Page 9. Speculative securities may not be suitable for Retail Clients.

Recommendation
Buy (unchanged)
Price
$0.375
Valuation
$0.73 (previously $0.80)
Risk
Speculative

Sector

Pharmaceuticals & Biotechnology

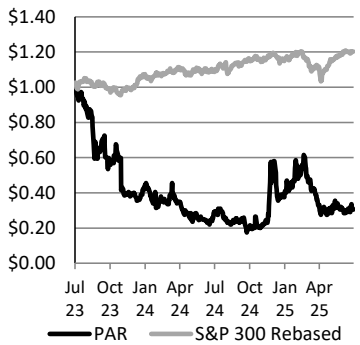
Expected Return	
Capital growth	**95%**
Dividend yield	**0%**
Total expected return	**95%**

Company Data & Ratios	
Enterprise value	**$121m**
Market cap	**$146m**
Issued capital	**389.4m**
Free float	**94%**
Avg. daily val. (52wk)	**$603,000**
12 month price range	**$0.17 - $0.66**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.31	0.39	0.24
Absolute (%)	0.00	-20.78	27.08
Rel market (%)	-1.73	-27.55	17.37

Absolute Price



SOURCE: IRESS

Favourable Terms For CN

PAR has secured a US$27m (A$41.2m) convertible note with specialist US investor Obsidian Global Partners. The funds will be used to execute on enrolments for the first of the global phase 3 clinical trials of iPPS in the treatment of knee osteoarthritis.

We consider the attraction of the CN is the validation of the scientific data provided by PAR in order to secure the investment by this 375highly regarded and astute investor. Obsidian conducted extensive due diligence on their investment over many months.

Secondly, the terms were highly attractive with no coupon over the life of the notes and conversion of the first tranche at A$0.75 – well ahead of the current share price. The funding allows PAR to complete enrolment of all 466 trial participants and deliver the interim analysis on the first patient group. The interim analysis will consider effect size between the two patient randomised cohorts and is a considered a meaningful indicator of likely future outcome.

Investment View: Retain Buy (Spec) Valuation $0.73

Our previous valuation was $0.80. Since our last research the company has restricted cash burn and we now expect it will finish FY25 with cash of approximately $21m (before the CN). We expect the funding announced today extends the cash runway to May/June 2026 following which additional capital is likely to be required.

The interim data announcement due in 1H26 is now the major catalyst for the stock with a positive readout likely to attract interest from pharma partners seeking to de-risk a potential investment into what we believe may be one of the largest pharma markets on offer. The search for a safe, well tolerated and effective non opioid pain relief for osteo arthritis represents one of the Holy Grails for modern medicine along with a cure for cancer and a treatment dementia.

We retain our Speculative Buy rating. Changes to earnings are significant in FY25, however, largely unchanged in FY26/27.

Earnings Forecast

June Year End	FY24	FY25e	FY26e	FY27e
Revenues	0.0	3.0	0.0	0.0
EBITDA $m	-58.6	-11.7	-56.0	-76.0
NPAT (underlying) $m	-58.6	-11.2	-55.5	-75.5
NPAT (reported) $m	-58.6	-11.2	-55.5	-75.5
EPS underlying (cps)	-16.3	-2.8	-12.4	-12.6
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

New Funding Package

PAR has secured a US$27m (A$41.2m) convertible note with specialist US investor Obsidian Global Partners. The funds will be used to execute on enrolments for the first of the global phase 3 clinical trials of iPPS in the treatment of knee osteoarthritis.

- The funding allows PAR to complete enrolment of all 466 trial participants and deliver the interim analysis on the first 50%. The interim analysis is expected in mid CY2026 and will represent a pivotal moment.
- The interim analysis is conducted at day 112 and will include an assessment of 'effect size' on pain reduction, rather than a full statistical analysis.

Beyond CY26, the terms of the CN appear highly flexible with multiple other avenues remaining available for the company to secure further funding.

Obsidian conducted extensive due diligence on their investment over many months which we regard as a validation of the scientific rigor of the data provided by PAR.

UPDATE FROM THE CLINIC

PAR_OA_012 is the first of two phase 3 trials expected to support approval of Zilosul (iPPS) for the treatment of moderate to severe osteoarthritis of the knee. The trial is a randomised (1:1), double blind, placebo controlled phase 3 enrolling ~466 patients.

65 sites (10 Australia, 55 USA) have been selected for recruitment with the company cherry picking the highest performing trial sites amongst those involved in earlier studies (specifically PAR_OA_002). The company expects to have all 466 patients enrolled by end 1H26 with reporting of interim analysis on the first 233 patients in mid CY26.

ENROLMENT TIMETABLE AND REPORTING

Australia - First patients have signed consents and are expected to be dosed in the coming days.

United States - Screening of patients has now commenced at multiple US sites, with first randomisation and dosing anticipated in the coming weeks.

There are 65 sites enrolling:

- At the rate of just 1 participant per month per site, the trial has the potential to recruit rapidly.
- Even at this modest rate, the first 230 patients should be enrolled in 4 months (say 31 October) with the last of these receiving a final dose at day 39 (say December 10, 2025) with interim analysis at day 112 – perhaps late Feb 2026.
- Based on this, there is significant slippage time built into the company's estimate for a mid year (2026) read out for the interim analysis on the first 233 patients.

The enrolment rate suggested here implies all 466 patients could be enrolled in ~8 months which is in line with the company's expectation to complete enrolment by end of 1H26.

Headline data on the day 112 primary endpoint of the trial could reasonably be ready in 2H CY26, however, the company is yet to announce its strategy around the release of that data.

The primary end point is day 112 with end of study at day 404. At this time we expect the trial would conclude in 2Q CY27. The confirmatory study is also expected to commence following interim data in mid CY26, hence plenty to consider.

EFFECT SIZE

The interim analysis is expected to include an estimate of effect size only. Interim analysis is normally limited to futility with no reporting of efficacy so as to avoid bias amongst future trial participants. Effect size is not the same as statistical significance, however, a large effect size is a marker for a successful trial outcome.

In clinical trials, effect size refers to a quantitative measure of the magnitude of the difference or relationship between the active group and the placebo group. It helps determine how meaningful or practically significant the results are, beyond just whether they are statistically significant.

The larger the effect size, the smaller the sample size required to achieve statistical significance. A highly meaningful effect size (measured in cohen's d) of >0.50 would be a good sign.

Clinical trial enrolment numbers are determined by an expected effect size which is assessed based on data from previous studies. When reporting the effect size the company is likely to state whether the effect size is in line or above/below the parameters included in the trial design.

Effect size is also important for commercial purposes. In practical terms, the greater the pain relief and function improvement, the more the developer can charge for the drug. In the US where drug prices are typically determined based on a detailed health economics (shorter hospital stays, reduced admissions, productivity at work etc) a drug that is safe and also highly effective is a highly valuable commodity.

Key Terms on US$27m Convertible Note

Face Value: $1.09 per note;

Coupon: – nil, no interest payable;

Maturity: – 24 months from purchase date;

Conversion Terms

Fixed Conversion Price:

- Fixed conversion on first tranche at A$0.75 and 150% of 5 day VWAP for later tranches

Variable Conversion Price

- Lesser of 94% of lowest 5 VWAPs (20 day period) or fixed conversion price

Default Conversion Price

- Lesser of 85% of lowest 10 day VWAP or fixed conversion price.

Other the first tranche where the conversion price is fixed, the conversion price is linked to the share price on the day.

The first conversion is July 2027 – well and truly after the interim readout in mid 2026 and also comfortably after the expected time frame for a headline data readout from PAR_OA_012.

Figure 1 - Summary of changes to earnings

	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	-11.7	-48.5	315%	-56.0	-66.0	18%	-76.0	-85.5	13%
NPAT	-11.2	-48.0	329%	-55.5	-65.5	18%	-75.5	-85.5	13%
EPS	-2.8	-7.1	152%	-12.4	-9.7	-22%	-12.6	-10.3	-18%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Our previous valuation was $0.80. Since our last research note the company has restricted its cash burn and we now expect it will finish the year with cash of approximately $21m.

We expect the funding announced today extends the cash runway to May/June 2026 following which additional capital is likely to be required.

Following expected dilution from the conversion of the CN announced today, the valuation is amended to $0.73. First commercial revenues not expected before at least CY28, noting that two phase trials are generally required for approval. Accelerated Approval based on the results from a single phase 3 trial followed by a confirmatory study are also a possibility, however, the data from the first trial would need to be overwhelmingly in favour of approval both from a safety and efficacy perspective – i.e. highly statistically significant.

The interim data announcement is now the major catalyst for the stock with a positive readout likely to attract interest from pharma partners seeking to de-risk a potential investment into what we believe may be one of the largest pharma markets on offer.

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 Anaesthesiology, 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 1 July 2025

Recommendation	Buy, Speculative
Price	$0.375
Target (12 months)	$0.73

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	6.3	10.0	-
Other expenses including R&D	-60.3	-65.1	-21.0	-66.0	-76.0
EBITDA	-53.3	-58.6	-11.7	-56.0	-76.0
Depreciation	-	-	-	-	-
Amortisation	-	-	-	-	-
EBIT	-53.3	-58.6	-11.7	-56.0	-76.0
Finance income	1.4	-	0.5	0.5	0.5
Pre tax profit	**-51.9**	**-58.6**	**-11.2**	**-55.5**	**-75.5**
Tax expense	-	-	-	-	-
NPAT- reported	-51.9	-58.6	-11.2	-55.5	-75.5

Cashflow (A$m)	FY23	FY24	FY25e	FY26e	FY27e
Gross cashflow	-46.1	-66.9	-11.7	-50.9	-76.0
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	-11.2	-50.4	-75.5
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	-11.2	-50.4	-75.5
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	62.2	28.3	15.0	20.0	60.0
Movement in debt	0.0	-0.1	0.0	41.0	0.0
Dividends paid	0.3	0.0	0.0	0.0	0.0
Change in cash held	17.3	(37.7)	3.8	10.6	(15.5)
Cash at beginning of period	39.7	56.3	17.8	21.6	32.2
Cash at year end	56.3	17.8	21.6	32.2	16.7

Balance Sheet (A$m)	FY23	FY24	FY25e	FY26e	FY27e
Cash	56.3	17.8	21.6	32.2	16.7
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	31.1	36.6	21.1
Trade payables	12.2	2.8	2.8	2.8	2.8
Debt (leases)	0.3	0.2	0.2	41.2	41.2
Other provisions	0.9	0.6	0.6	0.6	0.6
Total Liabilities	13.4	3.6	3.6	44.6	44.6
Net Assets	53.7	23.7	27.5	-8.0	-23.5
Share capital	209.9	238.1	253.1	273.1	333.1
Retained earnings	(163.6)	(220.8)	(232.0)	(287.5)	(363.0)
Reserves	7.4	6.4	6.4	6.4	6.4
Shareholders Equity	53.7	23.7	27.5	-8.0	-23.5

Last sale 01/07/2025	0.375
Recommendation	Buy (Spec)
Issued Capital	389.4
Market Cap	146.0

Valuation Ratios (A$m)	FY23	FY24	FY25e	FY26e	FY27e
Reported EPS (cps)	-18.4	-16.3	-2.8	-12.4	-12.6
Normalised EPS (cps)	-18.4	-16.3	-2.8	-12.4	-12.6
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	-1.6
NTA (cps)	18.0	5.9	6.3	-2.5	-4.5
P/NTA (x)	0.0	0.1	0.1	-0.2	-0.1
Book Value (cps)	19.1	6.8	7.1	-1.8	-4.0
Price/Book (x)	0.0	0.1	0.1	-0.2	-0.1
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%	-113%	-104%
Net debt/Assets	0%	0%	0%	25%	116%
Gearing	net cash	net cash	net cash	877%	2378%
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

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The fact that the intellectual property base of a typical biotechnology company lies in science not generally regarded as accessible to the layman adds further to the riskiness with which biotechnology investments ought to be regarded. Clinical and regulatory risks are inherent in biotechnology stocks. Biotechnology developers usually seek U.S. FDA approval for their technology which is a long and arduous three phase process to prove the safety, effectiveness and appropriate application or use of the developed drug and even after approval a drug can be the subject of an FDA investigation of subsequently discovered possible links between the drug and other diseases not previously diagnosed. Furthermore, the Australian exchange listed biotechnology sector is subject to influence by the global biotechnology sector, particularly that in the USA. Consequently, Australian exchange listed biotechnology stocks can experience sharp movements, both upwards and downwards, in both valuations and share prices, as a result of a re-rating of the sector both globally and in the USA, in particular. Investors are advised to be cognisant of these risks before buying such a stock.

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