BELL POTTER

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Speculative

See key risks on Page 4 and Biotechnology Risk Warning on Page 8. Speculative securities may not be suitable for Retail Clients.

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Paradigm Biopharmaceuticals (PAR)

FDA Opens the IND for Zilosul

Recommendation
Buy (unchanged)
Price
$0.455
Valuation
$0.80 (previously $0.47)
Risk
Speculative

Sector

Pharmaceuticals & Biotechnology

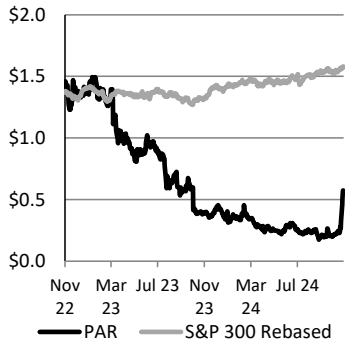
Expected Return	
Capital growth	**75.8%**
Dividend yield	**0.0%**
Total expected return	**75.8%**

Company Data & Ratios	
Enterprise value	**$141.9m**
Market cap	**$158.9m**
Issued capital	**350m**
Free float	**94%**
Avg. daily val. (52wk)	**$322,000**
12 month price range	**$0.17 - $0.61**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.21	0.24	0.38
Absolute (%)	173.81	144.68	51.32
Rel market (%)	171.09	139.44	31.52

Absolute Price



SOURCE: IRESS

Phase 3 Studies May Commence In CY25

Following conclusion of the 28 day waiting period, the revised Investigative New Drug application for iPPS (Zilosul) in the treatment of knee osteoarthritis (OA) is now cleared in the United States. Consequently the company may commence recruitment of the phase 3 trials. This event is pivotal for the company which is now officially in late stage clinical development.

PAR is not currently funded to run the two phase 3 trials required for regulatory approval. Consequently the Board will take a period to consider all available options commencing with an assessment of the likely funding requirement for the company from the present to a potential approval in approximately 3 years from now. All options remain open for consideration including partnering discussions along with raising further equity.

Safety and Efficacy Data Strongly Supportive

The safety and efficacy data for Zilosul have consistently shown the drug to be highly effective and safe for patient use at the phase 3 dose. In addition, there are up to 120 sites already through ethics approval and likely able to commence patient recruitment rapidly. The size of the prize for approval the Osteoarthritis market is highly lucrative to say the least. The US market is at least $3bn annually on conservative estimates and likely multiple times larger.

Investment View: Retain Buy (Spec) Valuation $0.80

The opening of the IND in the US is significant step forward. The risk of clinical trial failure is substantially reduced and the recent move in share price is a reasonable representation of this change. Valuation is amended to $0.80 following changes to funding assumptions in the financial model which assumes further equity issuance and a partnering deal ahead of approval in ~3 years time.

Earnings Forecast

June Year End	FY24	FY25e	FY26e	FY27e
Revenues	0.0	3.0	0.0	0.0
EBITDA $m	-58.6	-58.5	-66.0	-86.0
NPAT (underlying) $m	-58.6	-58.0	-65.5	-85.5
NPAT (reported) $m	-58.6	-58.0	-65.5	-85.5
EPS underlying (cps)	-16.3	-8.5	-9.6	-10.3
EPS growth %	na	nm	0.1	0.1
PER (x)	nm	nm	nm	-4.4
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	nm	nm	nm	-1.7
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

All Options On The Table

Following conclusion of the 28 day waiting period, the revised Investigative New Drug application for iPPS (Zilosul) in the treatment of knee osteoarthritis is now cleared in the United States. Consequently the company may commence recruitment of the phase 3 trials. This event is pivotal for the company which is now officially in late stage clinical development.

It has been an arduous process to this point with the determination of the final dose subject to intense scrutiny at the FDA. This additional scrutiny has caused many months of delay and investment in clinical trials which ultimately proved little value add (we refer here to the dosing study of 2023). Thankfully regulators in both the US and Europe have now allowed the approval studies (the two phase 3 trials) to commence.

Development Options

All options remain on the table for the Phase 3 including partnering discussion and PAR running the trials itself in conjunction with a clinical research organisation.

The company's position in any future funding discussion (either with shareholders or pharma partners) is substantially enhanced by the following factors:

- Regulators in both the US and Europe have cleared the phase 3 protocol;
- Extensive pre-clinical and clinical data packages are now available for due diligence by prospective partners;
- We believe up to 120 sites that participated in the previous PAR_OA_002 remain available to participate in subsequent trials. Each of these have cleared ethics and is likely to require only minimal time to commence dosing; and
- There are almost no competing trials in OA. It is reasonable to expect the trials would recruit rapidly, particularly from the 10 sites in Australia.

About the Phase 3

Primary endpoint is a change from baseline in pain at day 112.

Key secondary endpoints include:

- Pain and functional assessments at multiple timepoints up to Day 404;
- Patient Global Impression of Change (PGIC); and
- Structural changes as measured by MRI and X-ray.

Investigators will conduct a futility analysis when enrolment reaches 50% (n=466). Placebo will be saline injection.

There has been no discussion of a potential commencement date for a confirmatory trial, however, it is reasonable to expect this second trial may not commence until after the futility analysis is complete.

Partnering considerations and trial cost estimates

Assuming US$75,000 per patient, the estimated cost of the two phase 3 studies (~1,000 patients in total) is ~US$75m (A$115m). Each patient will have 12 doses of drug plus multiple screening assessments and multiple follow ups for more than 1 year following completion of dosing. Fortunately the primary endpoint is a mere 3 months from initial dosing.

Rationalising this cost however, we estimate Zilosul has an addressable market of an estimated 31m OA sufferers in the US alone. At US$2,500 per patient with 5% market penetration, the market is estimated at US$3bn minimum and considerably larger once rest of world demand is realised. Patients may ultimately return for several courses of therapy over several years given the chronic nature of the disease.

Consequently we expect significant interest from potential pharma partners who each face major patent cliffs in core franchises and are on the lookout for in license opportunities.

Tempering the attitude of potential partners is the nature of the disease. Central Nervous System disease is a difficult indication where the placebo response is often the factor which leads to trials failing to achieve a statistically significant outcome or a highly statistically significant outcome. i.e. a drug with only a minor effect size is unlikely to gain support from payers. Highly effective pain relief is essential for commercial success.

PAR is pursuing a 505b2 registration in the United States. The composition of matter patent on Zilosul is long since expired, however, PAR has extensive patent protection with new dosage and use patents underpinned by the discovery work conducted over recent years.

Conclusions

The prize for success is enormous and with FDA having signed off on the IND, the path is open for a potential partner to run two large but relatively inexpensive trials (compared to oncology @+US$200k/patient) in a relatively short time frame.

Given these risk factors, a back ended deal with lower upfront and higher milestone payments for development and commercial success are likely negotiating points.

These are just some of the factors that may influence the outcomes which should become more clear in the ensuing months.

Our financial model has been adjusted to reflect further equity issuance allowing PAR to self fund the trial and provide working capital through to approval which we estimate may be in 2028. This is one of several scenarios which may emerge in the months ahead. Alternatively the company may seek to out license the drug to a development partner, which avoids the dilution of a major capital raise while handing the major spoils (and risk) to a partner.

Our valuation is based on a DCF model which assumes a WACC of 18.25%. Valuation is amended from $0.47 to $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.

Revenue Forecast and Funding

Our financial forecast includes an assumption that the company completes an out license deal for iPPS in FY25. The nature of this transaction includes a small upfront payment followed by a series of development milestones. Transactions of this nature are commonplace in the biotechnology industry, however, the execution of such a transaction is dependent upon numerous factors including but not limited to the results of clinical trials, the company's funding position and demand from potential partners.

There is no guarantee that such a transaction will be executed and the terms of any such transaction may be different to the assumptions in the model.

Paradigm Biopharmaceuticals

as at 29 November 2024

Recommendation	Buy, Speculative
Price	$0.455
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	-71.5	-76.0	-86.0
EBITDA	-53.3	-58.6	-58.5	-66.0	-86.0
Depreciation	-	-	-	-	-
Amortisation	-	-	-	-	-
EBIT	-53.3	-58.6	-58.5	-66.0	-86.0
Finance income	1.4	-	0.5	0.5	0.5
Pre tax profit	**-51.9**	**-58.6**	**-58.0**	**-65.5**	**-85.5**
Tax expense	-	-	-	-	-
NPAT- reported	-51.9	-58.6	-58.0	-65.5	-85.5

Cashflow (A$m)	FY23	FY24	FY25e	FY26e	FY27e
Gross cashflow	-46.1	-66.9	-58.5	-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	-58.0	-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	-58.0	-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)	70.0	(60.4)	(25.5)
Cash at beginning of period	39.7	56.3	17.8	87.8	27.4
Cash at year end	56.3	17.8	87.8	27.4	1.9

Balance Sheet (A$m)	FY23	FY24	FY25e	FY26e	FY27e
Cash	56.3	17.8	87.8	27.4	1.9
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	97.3	31.8	6.3
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	93.7	28.2	2.7
Share capital	209.9	238.1	366.1	366.1	426.1
Retained earnings	(163.6)	(220.8)	(278.8)	(344.3)	(429.8)
Reserves	7.4	6.4	6.4	6.4	6.4
Shareholders Equity	53.7	23.7	93.7	28.2	2.7

Last sale 29/11/2024	0.455
Recommendation	Buy (Spec)
Issued Capital	349.3
Market Cap	158.9

Valuation Ratios (A$m)	FY23	FY24	FY25e	FY26e	FY27e
Reported EPS (cps)	-18.4	-16.3	-8.5	-9.6	-10.3
Normalised EPS (cps)	-18.4	-16.3	-8.5	-9.6	-10.3
EPS growth (%)	na	na	nm	13%	7%
PE(x)	**nm**	**nm**	**nm**	**nm**	**-4.4**
EV/EBITDA (x)	nm	nm	nm	nm	-1.7
EV/EBIT (x)	nm	nm	nm	nm	-1.7
NTA (cps)	18.0	5.9	13.5	3.8	0.0
P/NTA (x)	0.0	0.1	0.0	0.1	-12.9
Book Value (cps)	19.1	6.8	14.0	4.2	0.3
Price/Book (x)	0.0	0.1	0.0	0.1	1.4
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

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