BELL POTTER

4 October 2022

Speculative
See key risks on Pages 6 and 7 and Biotechnology Risk Warning on Page 10. Speculative securities may not be suitable for Retail Clients.

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Paradigm Biopharmaceuticals (PAR)

One Giant Step for DMOAD

Recommendation
Buy (unchanged)
Price
$1.51
Valuation
$2.20 (previously $1.90)
Risk
Speculative

GICS Sector
Pharmaceuticals & Biotechnology

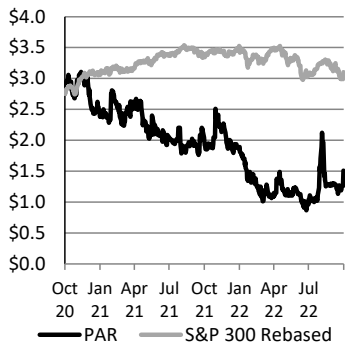
Expected Return	
Capital growth	45.7%
Dividend yield	0.0%
Total expected return	45.7%

Company Data & Ratios	
Enterprise value	$318.2m
Market cap	$422.2m
Issued capital	279.6m
Free float	92%
Avg. daily val. (52wk)	$942,000
12 month price range	$0.85 - $2.67

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	1.29	0.87	2.15
Absolute (%)	17.51	73.82	-29.91
Rel market (%)	21.76	73.77	-22.65

Absolute Price



SOURCE: IRESS

Disease Modify Osteoarthritis Drug (DMOAD)

The aim of OA-008 (the trial) was to provide novel scientific evidence to test the hypothesis that iPPS acts locally in the knee joint of osteoarthritis (OA) subjects as well as provide data on whether biomarker changes correlate with clinical outcomes (WOMAC pain and function assessments). Further evaluation on serum and urine biomarker correlations, and further longer-term clinical outcomes are in progress and are expected to report in CY23.

Changes in biomarkers support mechanism of action

This blinded, randomised, controlled trial included 3 dose cohorts. The headline data was generated from the twice weekly cohort relative to the control group. The trial achieved the primary endpoint of changes in numerous synovial fluid biomarkers which the investigators believe are consistent with controlling inflammation and cartilage preservation in the affected knee joint. In all cases the synovial biomarker changes in iPPS treated subjects at day 56 were favourable compared to placebo.

In relation to secondary endpoints, of the subjects in the twice weekly cohort, 60% of patients achieved ≥50% improvement in WOMAC pain scores with a mean percentage change in pain of 50% compared to 30% in the control group (p=0.05). The result achieved statistical significance despite the trial not being adequately powered (n=61) which in our view is a very significant outcome.

Next steps include 6 and 12 months follow up data with full analysis to follow in a peer reviewed published scientific journal.

Investment View: Retain Buy (Speculative) Valuation $2.20

The headline data from OA-008 is consistent with previous efficacy data in the use of iPPS for the treatment of knee osteoarthritis. We maintain our Buy (Speculative) rating. Valuation is upgraded from $1.90 to $2.20 following reviews to key assumptions regarding success in a phase 3 trial. Changes to earnings include dilution from the recent capital raise.

Earnings Forecast

June Year End	FY22	FY23e	FY24e	FY25e
Revenues	0.1	0.0	64.5	62.2
EBITDA $m	-39.4	-59.0	12.2	40.0
NPAT (underlying) $m	-39.4	-58.5	12.7	40.5
NPAT (reported) $m	-39.4	-58.5	12.7	40.5
EPS underlying (cps)	-16.9	-20.0	4.4	13.9
EPS growth %	na	na	na	2.2
PER (x)	nm	nm	34.7	10.9
FCF yield (%)	nm	nm	3.0	945%
EV/EBITDA (x)	nm	nm	26.0	8.0
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	na	na	20.4%	39.8%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Headline data from OA-008

PAR OA-008 Overview

In this report we use the terms iPPS (injectable pentosan polysulfate) and Zilosul interchangeably. Both terms refer to the drug under development by PAR.

The aim of OA-008 was to provide novel scientific evidence to test the hypothesis that iPPS acts locally in the knee joint of OA subjects as well as provide data on whether biomarker changes correlate with clinical outcome (WOMAC pain and function assessments). Further evaluation on serum and urine biomarker correlations, and further longer-term clinical outcomes are in progress.

The key elements of this phase 2 randomised, controlled trial design were:

Randomised, double blind study across 3 patient cohorts:

- Cohort 1 – PPS twice weekly at 2mg/kg for 6 weeks (19 patients);
- Cohort 2 – PPS once weekly at 2mg/kg for 6 weeks with a second injection being placebo (20 patients); and
- Cohort 3 – placebo twice weekly (22 patients).

Of the 61 patients, 48 had Kellgen Lawrence grades of 3-4, indicating moderate to severe osteoarthritis. With small patient numbers, the study was not powered to achieve statistical significance.

PRIMARY ENDPOINT

The trial is seeking to collect data to support the hypothesis that certain molecules are a reliable biomarker of OA. The Primary Endpoint for OA-008 was the change (reduction) from baseline at day 56 in one or more synovial fluid biomarkers. These biomarkers and the outcome achieved are summarised below:

Table 1 - Synovial fluid biomarkers

Measure	Outcome
Nerve Growth Factor (NGF)	Reduced
Tumour Necrosis Factor Alpha (TNFα)	Reduced
Interleukin (IL-6)	Reduced
Cartiage oliomeric matrix protein (COMP)	Reduced
Aggrecan (ARGS) fragment	Reduced
Tissue inhibitor matrix metalloproteinase 1 (TIMP-1)	Increased

SOURCE: COMPANY DATA

This endpoint was selected as the data will be key to supporting the proposed mechanism of action of Zilosul with regulators. The direction of movement (Increased/Reduced) were in line with expectation. In all cases, the changes in synovial fluid biomarkers at day 56 were favourable compared to placebo controls.

The headline data does not quantify these changes. The detailed data has been held back in anticipation of a future peer reviewed journal.

Secondary Endpoints

Secondary endpoints include:

- Correlation between synovial fluid biomarker changes and clinical outcomes.
- Changes in baseline to days 56, 168 (nearly 6 months) and 12 months in one or more synovial fluid biomarkers;
- Change in WOMAC scores for pain, function, stiffness and quality of life; and

- Radiographic changes in the bone and joint.

The headline data does not include the detailed analysis of secondary endpoints. The headline data included the following key points:

In respect of the cohort for twice weekly iPPS:

- mean percentage change from baseline WOMAC pain was 50% compared to 30% on placebo (p=0.05). The proportions achieving ≥30% and ≥ 50% improvements in pain were 73% and 60% respectively; and
- mean percentage change from baseline WOMAC function is 50% compared to 25% for placebo (p=0.017).

We note this headline data is consistent with previous studies, notably the earlier phase 2 in 112 patients in which 46% of subjects receiving iPPS showed a greater than 50% reduction in pain from baseline KOOS[1].

Discussion

Dosing - Today's release does not discuss the outcome of the single weekly dose of iPPS. The absence of any analysis of outcomes from this cohort leads us to believe the results were inferior or inconsistent to the twice weekly dose group.

OA-008 is likely instructive to investigators as to the outcomes from the ongoing dose escalation study currently under way in the US. The twice weekly dosing at 2mg/kg is more likely to be confirmed as the final dose in the pivotal study and confirmatory study due to commence enrolment in CY23.

As far as we are aware the entire data set reported since 2018 has been generated from patients dosed twice weekly for 6 weeks including the data reported here. While we do not have the data from the single weekly dose regimen, it is almost inconceivable that the company or regulators would consider a phase 3 trial under any other dosing regime.

Pain Reduction - We note the p value on reduction in pain scores at p=0.05. In our view this is a remarkable outcome given the very small sample size. The trial was not powered to achieve statistical significance, yet it has managed to meet this hurdle. It is not unreasonable to assume that with larger patients numbers of the same patient group with same clinical outcomes, a corresponding p value could be more statistically significant (i.e. < p value).

The p value on WOMAC function score of p=0.017 is highly significant.

Mechanism of action - The changes in synovial fluid biomarkers are indicative of a multi modal mechanism of action resulting in reduced pain and increased joint function. In particular we note the reduction of key inflammatory cytokine biomarkers TNFα, IL-6 and Nerve Growth Factor. The reduction of these and other molecules in the synovial fluid represents a rational mechanism of action which address the underlying pain condition.

The company had previously reported changes in some synovial fluid biomarkers from the earlier OA-005 trial (which reported in 2018). The historical trial measured changes in COMP and ADAMTS-5. The direction of the change in COMP between OA-005 and OA-008 is consistent (reductions). ADAMTS-5 was not reported in OA-008.

Safety – iPPS was well tolerated. There were no serious adverse events and no adverse events of special interest amongst participants receiving iPPS or placebo.

The headline data did not include radiographic analysis.

[1] The earlier trial measure pain score using the alternative KOOS rating score – Knee injury and osteoarthritis outcome score. Investigators subsequently changed to the WOMAC rating system which is more universally accepted in the United States and Europe.

Next Steps

1Q23 – 6 month follow up data on WOMAC pain, function stiffness and patient global impression of change;

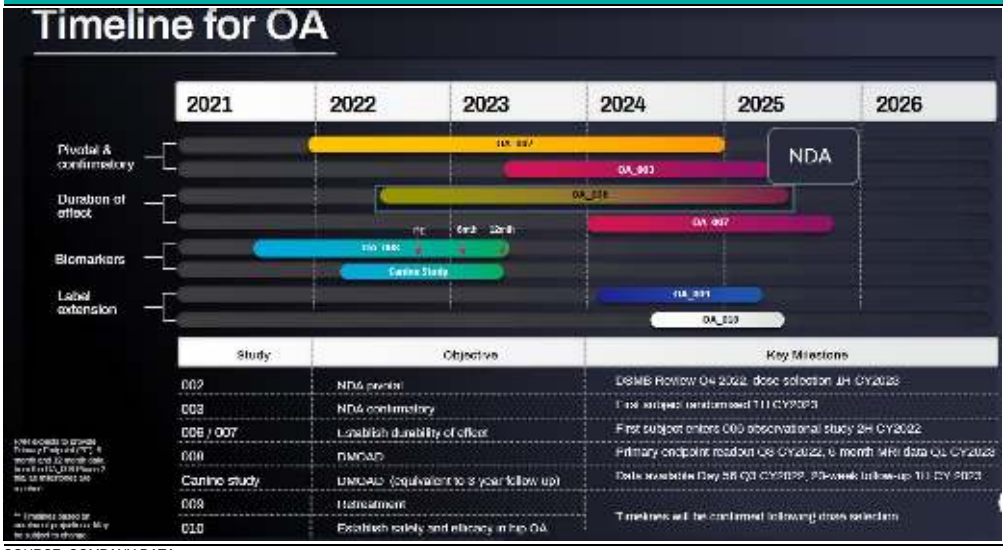
Changes in correlation between synovial fluid, serum and urine biomarkers and correlation with changes in clinical outcomes;

MRI changes in the bone and joint; and

MPS data presentation.

2Q23 – final dosing for pivotal studies announced and commencement of recruitment in the pivotal and confirmatory studies.

Figure 1 - Clinical Trial Summary



SOURCE: COMPANY DATA

Early Data In Canine Study

Interim observations in 9 osteoarthritic dogs each receiving 3mg/kg iPPS weekly for 6 weeks demonstrated key outcomes:

- 7 of 9 had meaningful function improvements in the affected limb at week 8 compared to baseline; and
- Dogs demonstrated a response to iPPS treatment with changes in cartilage degradation biomarkers in the synovial fluid.

The characteristics of OA are similar in both humans and dogs. It is expected that the canine model of OA will provide insights that may parallel the human experience. In particular, all stages of development in dogs are represented over a shorter time frame including disease onset (as compared to humans). The investigators believe the model is advantageous for the evaluation of the disease modifying capability of iPPS that would otherwise take longer in a human model.

The experiment carries no weight with regulators, nevertheless it is an inexpensive exercise with potential large benefits for the design of future studies, in particular for re-dosing.

Valuation

We had previously allowed for dilution from a capital raise. In August 2022 the company raised $66m in new capital at $1.30 via the issue of 50.8m new shares representing dilution of 21.7%.

Table 2 - Summary of earnings changes

	2023			2024			2025		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	0.0	0.0	na	64.5	59.1	9%	62.2	62.2	0%
EBITDA	-59.0	-66.0	12%	12.2	2.0	-511%	40.0	40.0	0%
NPAT	-58.5	-65.5	12%	12.7	2.5	-409%	40.5	40.5	0%
EPS	-20.0	-22.7	13%	4.4	0.8	-445%	13.9	13.9	0%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Following the headline data reported today we increase the likelihood of success in a phase 3 trial in OA from 55% to 60% in our risk adjusted model. The discounted cash flow model utilises a WACC of 17% (unchanged).

Changes to earnings are relatively small in value but larger in percentage terms. The key change in FY23 EBITDA is to increase the expected R&D credit from the Australian Government. FY24 includes an assumption for milestone income on an assumed deal in MPS. In the absence of any deal the company is funded into 1Q CY24[2]. Valuation is raised from $1.90 to $2.20 representing a 16% increase.

[2] Refer capital raise presentation August 2022, page 14.

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$2,500 per year which places the addressable market in the tens of billions of US$.

PROGRESS IN THE CLINIC

December 2018 - PAR announced headline results from its phase 2b randomised, double blind, placebo controlled multicentre trial, investigating subjects with Osteoarthritis and concurrent Bone Marrow Edema (BME) lesions (n=112). The trial met the clinical endpoint of change in Knee Injury and Osteoarthritis Outcome Score (KOOS) pain achieving both clinically meaningful and statistically significant results between placebo and PPS.

The headline results were followed up with strong signals of efficacy in the secondary endpoints (including KOOS function). This phase II trial was conducted at 6 sites in Australia.

PATHWAY TO APPROVAL

The company is pursuing a 505(b)2 registration pathway in the US. PAR is now enrolling patients in the first arm of a clinical trial.

ADJACENT INDICATIONS

Paradigm recently executed an Exclusive In-License Agreement for the use of iPPS in the treatment of 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 intends to conduct two phase 3 studies, one pivotal study of 900 subjects and a confirmatory phase 3 study of ~700 subjects.
- 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 nearly 1,700 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.

Paradigm Biopharmaceuticals

as at 4 October 2022

Recommendation	Buy, Speculative
Price	$1.51
Valuation	$2.20

Table 2 - Financial summary

Profit & Loss (A$m)	FY21	FY22	FY23e	FY24e	FY25e
Year Ending June					
Risk adjusted revenues	**-**	**-**	**-**	**64.5**	**62.2**
COGS (Bene Royalty expense)	-	-	-	(2.2)	(2.1)
Gross profit	0.0	-0.1	0.0	63.2	61.0
GP margin	na	0%	na	0%	98%
R&D incentive	8.9	8.7	12.0	10.0	-
Other expenses	-43.2	-48.0	-71.0	-61.0	-21.0
EBITDA	-34.3	-39.4	-59.0	12.2	40.0
Depreciation	-	-	-	-	-
Amortisation	-	-	-	-	-
EBIT	-34.3	-39.4	-59.0	12.2	40.0
Finance income	-	-	0.5	0.5	0.5
Pre tax profit	**-34.3**	**-39.4**	**-58.5**	**12.7**	**40.5**
Tax expense	-	-	-	-	-
NPAT- reported	-34.3	-39.4	-58.5	12.7	40.5

Cashflow (A$m)	FY21	FY22	FY23e	FY24e	FY25e
Gross cashflow	-35.1	-32.2	-62.4	12.2	40.0
Net interest	0.2	0.0	0.5	0.5	0.5
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-34.9	-32.2	-61.9	12.7	40.5
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	-34.9	-32.2	-61.9	12.7	40.5
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	1.0	0.1	63.4	0.0	0.0
Movement in debt	0.0	0.1	-0.2	-0.2	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Change in cash held	(33.9)	(32.0)	1.3	12.5	40.5
Cash at beginning of period	104.0	71.0	39.7	41.0	53.5
Cash at year end	71.0	39.7	41.0	53.5	94.0

Balance Sheet (A$m)	FY21	FY22	FY23e	FY24e	FY25e
Cash	71.0	39.7	41.0	53.5	94.0
Receivables	8.5	6.7	8.0	8.0	8.0
Other current assets	1.4	0.8	0.8	0.8	0.8
Intangibles	3.0	3.0	3.0	3.0	3.0
Other	1.0	0.5	0.5	0.5	0.5
Total assets	84.8	50.7	53.3	65.8	106.3
Trade payables	5.0	7.1	5.0	5.0	5.0
Debt (leases)	0.8	0.6	0.4	0.2	0.2
Other provisions	0.7	0.7	0.7	0.7	0.7
Total Liabilities	6.5	8.4	6.1	5.9	5.9
Net Assets	78.3	42.3	47.2	60.0	100.4
Share capital	147.0	147.1	210.5	210.5	210.5
Retained earnings	(75.2)	(114.1)	(172.6)	(159.9)	(119.4)
Reserves	6.5	9.3	9.3	9.3	9.3
Shareholders Equity	78.3	42.3	47.2	60.0	100.4

Last sale 04/10/2022	1.51
Recommendation	Buy (Spec)
Issued Capital	279.6
Market Cap	422.2

Valuation Ratios (A$m)	FY21	FY22	FY23e	FY24e	FY25e
Reported EPS (cps)	-14.9	-16.9	-20.0	4.4	13.9
Normalised EPS (cps)	-14.9	-16.9	-20.0	4.4	13.9
EPS growth (%)	na	na	na	na	218%
PE(x)	**nm**	**nm**	**nm**	**34.7**	**10.9**
EV/EBITDA (x)	nm	nm	nm	26.0	8.0
EV/EBIT (x)	nm	nm	nm	26.0	8.0
NTA (cps)	32.8	16.9	15.6	20.1	34.4
P/NTA (x)	0.0	0.1	0.1	0.1	0.0
Book Value (cps)	34.1	18.2	16.7	21.1	35.4
Price/Book (x)	0.0	0.1	0.1	0.1	0.0
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	297%	945%
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

Interim Results (A$m)	1H22	2H22	1H23e	2H23e
Revenues from product sales	-	-	-	-
R&D Rebate	-	8.7	-	12.0
Operating expenses	(27.0)	(21.0)	(30.5)	(40.5)
EBIT	(27.0)	(12.3)	-	-

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

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