BELL POTTER

4 April 2023

Speculative

See key risks on Page 6 and Biotechnology Risk Warning on Page 11. Speculative securities may not be suitable for Retail Clients.

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Paradigm Biopharmaceuticals (PAR)

Mercury Rising

Recommendation
Buy (unchanged)
Price
$1.345
Target (12 months)
$2.20 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

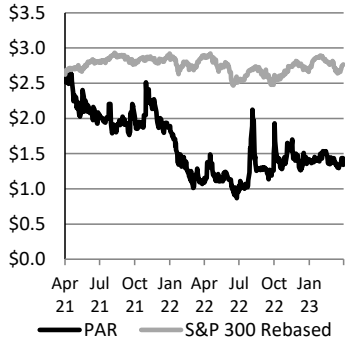
Expected Return	
Capital growth	**63.6%**
Dividend yield	**0.0%**
Total expected return	**63.6%**

Company Data & Ratios	
Enterprise value	**$293.0m**
Market cap	**$376.0m**
Issued capital	**279.5m**
Free float	**92%**
Avg. daily val. (52wk)	**$1.3m**
12 month price range	**$0.85 - $2.15**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	1.40	1.37	1.07
Absolute (%)	-4.29	-2.19	25.56
Rel market (%)	-3.97	-4.21	29.84

Absolute Price



SOURCE: IRESS

Biomarker Data Remains Highly Supportive

PAR continues to make every post a winner with the latest data from the company's phase 2 randomised clinical trial providing further evidence of efficacy and safety for iPPS. PARA_OA_008 was designed to generate data to test the hypothesis that changes in the biomarkers correlate with knee pain reduction and improved knee function. The key data released today concerned the secondary endpoints of radiographic changes in bone/ joint together with further data on biomarkers.

Imaging showed a material improvement in cartilage degradation for participants on drug vs control. Both the once weekly and twice weekly dose groups showed trends of improvement in cartilage preservation compared to control with the once weekly dose cohort achieving statistical significance despite small participant numbers.

A broad panel of potential biomarkers in blood, urine and synovial fluid were assessed. Participants on treatment showed persistent beneficial effects of iPPS compared to placebo. In the company's view the biomarkers indicate cartilage sparing changes in iPPS subjects compared to placebo.

Where to now

PAR will use the data to request a Type D meeting with the FDA in order to seek guidance regarding the adequacy of its proposed endpoints in the upcoming phase 3 trials to support a future label claim for a disease modifying osteoarthritis drug (DMOAD). If successful iPPS would be the first ever drug to attain this status. If the label claim ultimately includes DMOAD, this may have significant implications for revenues and valuation. Enrolment of the phase 3 program is continuing as planned.

Investment View: Buy (Speculative), Valuation $2.20

We retain our Buy (Speculative) rating and valuation of $2.20. The next major catalyst will include the 12-month data from PARA_OA_008 later this year.

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	30.9	9.7
FCF yield (%)	nm	nm	3.3	1061%
EV/EBITDA (x)	nm	nm	24.0	7.3
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

Encouraging Progress

Overview

PAR reported day 168 data from OA-008 being its randomised phase 2 study to generate data 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).

PAR had previously reported on the headline data at day 56 of the trial and this had been strongly supportive. The Primary Endpoint for OA-008 is the change (reduction) from baseline at day 56 in one or more synovial fluid biomarkers.

New data which emerged today concerns the numerous secondary endpoints.

Following the results announced today, the company intends to seek a Type D meeting with the FDA in the coming months in order to progress a discussion regarding a potential future label claim which may include for Disease Modifying Osteo-arthritis Drug (DMOAD). If successful, iPPS would be the first drug to include such a label in this indication. Future discussions regarding any label claim are dependent upon successful completion of phase 3 studies, however, the safety and efficacy data to this point are highly encouraging. PAR will be requesting guidance from the FDA regarding the adequacy of the planned phase 3 endpoints to support the DMOAD status.

If the label includes DMOAD status, this is likely to have material consequences for downstream pricing and the company's valuation.

Secondary Endpoints

The secondary endpoints are:

- Correlation between synovial fluid biomarker changes and clinical outcomes.
- Changes in baseline to days 56, 168 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.

We summarise the new data as follows, noting that key elements have been held back in lieu of future conference presentations and peer reviewed publications.

Correlation between synovial fluid biomarkers and clinical outcomes – no further analysis at this time, however, some additional data (but not all) regarding pains scores, function and stiffness were included in the headline data. The most promising results were from the group being dosed twice weekly. The key data released today included:

- For the twice weekly dose cohort at day 168, a 50% improvement in function was reported by 53% of participants vs 22% of placebo (p=0.067).

PAR did not release data for the day 168 pain scores, however, other anecdotal data was suggestive of a sustained improvement in pain. Specifically, the use of rescue pain medication in the twice weekly group was significantly lower (5 days) in the twice weekly cohort vs placebo (23 days).

Further in regard to pain, the crucial data related to day 56 pain scores (being the primary endpoint for the upcoming phase 3 approval studies) as was reported in October 2022.

Changes in baseline synovial fluid biomarkers

Key biomarkers of cartilage matrix degradation and risk of osteoarthritis progression (COMP, C2C and urinary CTXII) indicate cartilage sparing changes in iPPS subjects when measured by serum, urine, or synovial fluid at days 56 and 168. The company concluded that molecular biomarkers of cartilage degradation in iPPS-treated subjects were favourable compared to placebo control. The key bio-markers reported today are listed in figure 1.

Figure 1 - Changes in molecular biomarkers

Bio-marker	Day 168 vs placebo
C2C (serum)	Reduced (p=0.024)
CTX II (urine)	Reduced
COMP (Synovial fluid)	Reduced
COMP (serum)	Reduced
ARGS (synovial fluid)	Reduced (p=0.024)
ARGS (serum)	Reduced

SOURCE: COMPANY DATA

The biomarkers reported here are specific to cartilage degradation compared to the range of biomarker measures in the day 56 reporting. All biomarker data was recorded, however, the advice of KOL's has been to emphasise this group (of biomarkers) with the FDA as they are well known in research for their association with cartilage degradation.

Change in WOMAC scores for pain, function, stiffness and quality of life.

At day 56 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. There is no further data on pain scores at day 168 at this time.

Radiographic changes in bone and joint

Trial participants were subject to MRI exams at baseline and day 168 with changes evaluated using a standard scoring system by blinded radiologists. The scores are then used to calculate a total score or index, which provides a quantitative measure of disease activity or severity.

Despite small participant numbers and a short follow-up interval compared to the generally slow structural progression in OA, changes consistent with DMOAD efficacy were observed in a number of disease features. These changes were most notably related to cartilage loss, bone marrow lesions, and osteophyte formation, as early as 6 months after initiating treatment with iPPS. Collectively, the majority of the statistically significant changes observed were consistent with a positive disease modifying effect of treatment with iPPS on OA.

Subjects receiving once-weekly iPPS demonstrated an average 21% improvement in mean cartilage loss score in the medial femur, whereas the placebo arm showed a slight (4%) worsening of cartilage loss (p=0.065). The twice-weekly iPPS group, showed trends of improvement (though not statistical) or stabilisation of cartilage preservation compared to the placebo group.

In relation to bone marrow lesions, lesions in the lateral femur decreased by an average 38% in the once-weekly iPPS arm, whereas in the placebo arm it increased by 47% (p=0.056). Bone marrow edema lesions in the entire lateral tibiofemoral compartment decreased by an average 17% in the once-weekly iPPS arm, but increased by 56% in the placebo arm (p=0.028). The results are subject to ongoing analysis.

CONCLUSION

Based on our first review of the data it does not appear unreasonable to assume a link between the favourable changes in radiographic evidence, favourable changes in biomarkers and the clinical outcomes achieved by participants in the trial. The clinical data continues to be highly supportive of the company's ongoing efforts in the clinic as well as potential development partners.

Recap of PAR OA-008

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.

OA-008 is a phase 2 randomised, double blinded controlled study in 61 patients covering three dose 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).

The headline data from day 56 was reported in October 2022. All the primary and secondary endpoints were met. Of the 61 patients, 48 had Kellgren Lawrence grades of 3-4, indicating moderate to severe osteoarthritis. The study was not powered to achieve statistical significance.

PRIMARY ENDPOINT

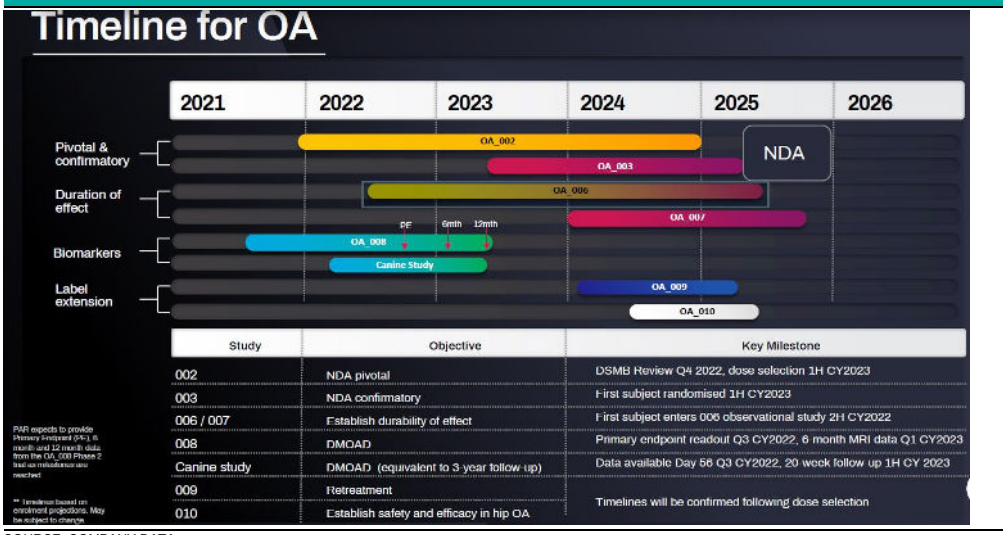
The Primary Endpoint for OA-008 was the change (reduction) from baseline at day 56 in one or more synovial fluid biomarkers. These biomarkers and the outcome achieved are summarised below: The direction of movement (Increased/Reduced) were in line with expectation. In all cases, the changes in synovial fluid biomarkers at day 56 were favourable compared to placebo controls. The detailed data was held back in anticipation of a future peer reviewed journal.

Figure 2 - 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

Figure 2 - Clinical Trial Summary



SOURCE: COMPANY DATA

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

Para_OA-002 is the first of the company's two phase 3 trials. Stage 1 is a dose selection whereby participants are randomised to receive one of three PPS dose regimens or placebo for 6 weeks. The primary objective of stage 1 will be to select the dose for use in stage 2 and Paradigm's subsequent confirmatory trial (PARA_OA_003).

In stage 2, participants will be randomised 1:1 to receive the selected PPS dose regimen or placebo for 6 weeks. The primary endpoints in the pivotal study are change from baseline at Day 56 in the standardised WOMAC® pain questionnaire with secondary outcomes to include change from baseline at multiple time points out to day 168 in WOMAC® pain and function, Patient Global Impression of Change (PGIC), and Quality of Life (QoL) assessments.

The global PARA_OA_002 phase 3 clinical trial is currently screening and enrolling participants in Australia, the US, and now the UK with sites in Europe and Canada to be activated in the 2H CY22. PAR_OA_002 is expected to enrol 700 participants. PARA_OA_003 is expected to enrol 900 patients.

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 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.

Revenue Forecast and Funding

Our financial forecast includes an assumption that the company completes an out license deal for iPPS in FY24. The nature of this transaction includes a large 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.

Based on the operating cash burn for the 6 month period ended 31 December 2022 (net $17.7m) and cash balance of $83.9m, it is likely the company will require additional funding in order to complete the two phase 3 clinical trials required for registration of iPPS for the treatment of knee osteoarthritis.

An out license transaction may provide all or some of the funding required to complete these trials. The company may also require all or part of the funding required to complete these trials from shareholders.

Paradigm Biopharmaceuticals

as at 4 April 2023

Recommendation	Buy, Speculative
Price	$1.345
Valuation	$2.20

Table 1 - Financial summary

Profit & Loss (A$m)	FY21	FY22	FY23e	FY24e	FY25e
Year Ending June					
Risk adjusted revenues	**-**	**0.1**	**-**	**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 04/04/2023	1.35
Recommendation	Buy (Spec)
Issued Capital	279.5
Market Cap	376.0

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**	**30.9**	**9.7**
EV/EBITDA (x)	nm	nm	nm	24.0	7.3
EV/EBIT (x)	nm	nm	nm	24.0	7.3
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	334%	1061%
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	1H23	2H23e
Revenues from product sales	-	-	-	-
R&D Rebate	-	8.7	1.2	10.8
Operating expenses	(27.0)	(21.0)	(33.0)	(38.0)
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

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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Disclosure: Bell Potter Securities acted as Lead manager of the company's August 2022 capital raised for $66m and received fees for that service.

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