BELL POTTER

16 April 2020

Speculative

See key risks on Page 9 and Biotechnology Risk Warning on Page 12. Speculative securities may not be suitable for Retail Clients.

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Paradigm Biopharmaceuticals (PAR)

iPPS Takes Another Step Forward

Recommendation
Buy (unchanged)
Price
$1.77
Valuation
$2.79 (previously $2.96)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

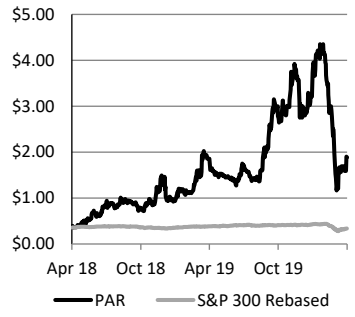
Expected Return	
Capital growth	**57.7%**
Dividend yield	**0.0%**
Total expected return	**57.7%**

Company Data & Ratios	
Enterprise value	**$317.4m**
Market cap	**$425.4m**
Issued capital	**224.8m**
Free float	**95%**
Avg. daily val. (52wk)	**$2.6m**
12 month price range	**$1.08 - $4.50**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	2.12	3.10	1.86
Absolute (%)	-11.1	-39.2	1.6
Rel market (%)	-13.9	-18.4	13.6

Absolute Price



SOURCE: IRESS

Regulatory Pathway Clearing

The recent market announcements and capital raise by PAR have provided significant clarity to numerous aspects of the company's development pathway for Zilusol.

In our view the most important aspect of the announcement was the FDA's views on the unique characteristics of the iPPS molecule produced by BenePharma. Their product is the only product which may be used in the phase 3 clinical trials, notwithstanding that PPS is off patent and that iPPS is seeking to be repurposed. The agency recognises the unique moieties of the BenePharma molecule and as such, any competitor contemplating a future generic is highly unlikely to be successful in the United States.

Paradigm will now proceed with the submission of the IND later this calendar year followed by two phase 3 studies commencing in 2021. The pivotal study will be conducted in the US and include 750 subjects while the confirmatory study of 400 subjects is likely to run in Europe and possibly Australia. The two studies will run concurrently, costing ~$80m.

The primary and secondary endpoints of the phase 3 studies will largely mimic the end points from the earlier phase IIb study. The inclusion criteria for the phase 3 study has been simplified to include knee osteoarthritis subjects with Kellgren Lawrence scores of 2, 3 or 4. The previous reference to numerical rating score has been dropped, hence simplify the outcomes.

Maintain Buy Rating

PAR has completed a $35m capital raise to fully fund the clinical program over the next 30 months. Headline results from the phase 3 are due to readout in 2H CY2022. Our price target is reduced by 6% reflecting the dilution. Changes to earnings reflect the higher than expected cost of the clinical program.

Earnings Forecast

June Year End	FY19	FY20e	FY21e	FY22e
Revenues	3.2	3.0	3.0	3.0
EBITDA $m	-8.7	-8.8	-42.0	-43.3
NPAT (underlying) $m	-15.6	-8.3	-41.5	-42.8
NPAT (reported) $m	-15.6	-8.3	-41.5	-42.8
EPS underlying (cps)	-10.5	-3.8	-18.9	-19.5
EPS growth %	na	na	na	na
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 %	-18.9%	-8.0%	-61.8%	-171.9%

SOURCE: BELL POTTER SECURITIES ESTIMATES

On Track For IND in 4Q2020

The key points from the update are as follows (in order of importance for shareholder value):

Intellectual Property

Subjects on the study must be dosed with iPPS manufactured by Bene Pharmaceuticals. We believe this substantially strengthens the standing of the intellectual property position of the company. As we understand the minutes of the pre-IND meeting recognise the unique chemical signature of the bene product as compared to any other compound of similar description. The BenePharma product is a semi synthetic with considerable trade secrets surrounding the manufacturing process, so while the patents on the chemical entity (i.e. PPS) may have expired, it is still the case that the BenePharma product has unique moieties which differentiate it from other manufacturer's version of the same drug.

It is not unreasonable to conclude that there is significant intellectual property in the manufacturing IP owned by BenePharma.

It is the company's view that the FDA has recognised these unique characteristics in the minutes of the pre IND meeting which leads PAR to represent that there is little chance of generic competition.

PPS is certainly not a readily available small molecule drug where generic copies are likely. We know with certainty that BenePharma has the only Drug Masterfile (DMF) for iPPS with the FDA, therefore, no other pharma group may reference that DMF in any future submission without BenePharma's specific permission. Such permission is highly unlikely as PAR has the exclusivity rights. The exclusivity deal with BenePharma runs until 2040 with a further 10 year option. (i.e. PAR's option).

Based on the minutes from the FDA (which the company has para-phrased in its market release) it would appear that Paradigm will be the sole provider of Zilusol to the US market for many years.

COMPETITORS

Despite the significantly strengthened IP position, it remains the case that osteoarthritis is a very large and potentially profitable market. If Zilusol does obtain a registration others are almost certain to follow in Paradigm's footsteps.

As the generic pathway is now blocked, a competitor pathway may involve the development of what the FDA calls a Therapeutic Protein Biosimilar, not unlike the biosimilars for blockbuster drugs such as Abbvie's Humira (adalimumab – a monoclonal antibody) indicated for the treatment of rheumatoid arthritis and other inflammation. There are now 8 FDA approved copies on this multi-billion dollar blockbuster drug. None of these are yet launched in the US as they infringe the US patents. Humira was first approved in the US in December 2002 and the first biosimilar was not approved until 2016, 14 years after the reference drug.

The development of biosimilars is an exhausting process and only modestly less exhausting than development of a new chemical entity. As such biosimilar competition or competition from a new chemical entity is not contemplated at this time.

Paradigm also has several dosing and regime patents over iPPS for the treatment of knee osteoarthritis. These represent additional obstacles to competitors.

We conclude that the Paradigm's IP position is substantially strengthened by virtue of the FDA's position on the exclusive use of the BenePharma molecule of PPS.

Development Pathway

In our view it is apparent that the FDA is receptive to the conduct of a phase 3 trial in the United States. The FDA has now had ample opportunity to review the summarised safety and efficacy data of the Paradigm experiences to date. If there was going to be a problem then we believe it would have emerged in this release.

CERTAINTY ON SIZE OF PHASE 3

The pre IND meeting minutes with the FDA have confirmed the company will be required to conduct two phase 3 trials. The first of these will be conducted in the US. The second study will run concurrently in Europe. The US trial will enrol 750 subjects with and follow them for 18 months, while the European trial will enrol 400 with a follow up period of 12 months.

Subjects will be dosed twice weekly for 6 weeks and observed for duration of effect. This is the identical protocol as was used in the phase IIb.

The estimated cost of the phase III program is A$80m or US$43,000 per patient. We had previously estimated the cost per patient at US$30,000.

Subjects on the trial will be followed for either 12 or 18 months, however, the primary endpoint is likely to be the mean pain reduction at day 53 (as outlined below). Secondary endpoints are likely to include pain reduction at 12 months. The latter secondary endpoint is likely to be for information purposes only and specifically to provide data on when subjects can be retreated.

Duration of effect at 12 months has been reported in most SAS subjects, however, this is data has not been released.

The company will seek a meeting with the European Medicines Authority for later this year to ensure the osteoarthritis trial will meet EU regulatory requirements for approval.

Comfort On Clinical Endpoints

The phase 3 trials are expected to use similar primary and secondary endpoints of pain and functionality as were used in the phase IIb trial. Also relevant, the control group in these studies will be dosed with saline (being a non-active placebo).

The primary endpoint for the Phase IIb was a reduction in the KOOS pain score from baseline at day 53. The endpoint was met across the entire population and the difference between the control group and the active arm of the study was statistically significant.

Across the total population in the phase IIb trial, 46.2% of subjects showed a greater than 50% reduction in pain scores (at day 53) as compared to ~22.5% of the placebo group. A reduction in pain scores was sustained through day 165 and remained statistically significant at the conclusion of the study.

The phase 3 trials will use the WOMAC rating scale rather than KOOS (as was used in phase 2b trial)[1]. WOMAC is the preferred rating scale of the FDA and is more popular in North America[2]. A 25% reduction in WOMAC pain score from baseline in usually regarded as clinically meaningful.

As part of its presentation to support the capital raising, the company presented data on mean WOMAC pain score reduction from 34 subjects involved in the Special Access Scheme (SAS) in Australia. In these subjects the mean pain score reduction from baseline was 45%. In the phase IIb trial subjects treated with iPPS achieved a mean pain score

[1] WOMAC Wester Ontario and McMaster Universities Osteo Arthritis Index

[2] The consensus opinion among the trial investigators at the 6 Australian sites in the phase IIb was to use KOOS rather than WOMAC. Both KOOS and WOMAC are validated and accepted by the FDA, however, WOMAC does appear to be more popular for commercial purposes (i.e. for reimbursement).

reduction from baseline of 50.1%. The mean reduction in pain scores is comparable under both measures.

Both KOOS and WOMAC are self-assessment questionnaires. Figure 6 in Appendix 1 contains a helpful comparison of the two sets of questions. The summarised data from the 34 SAS subjects is presented in figure 2.

Figure 1 - WOMAC scores for 34 SAS subjects

n=34	Mean baseline value (95% confidence limits)	Mean post treatment value	Average reduction in pain %
Pain walking on a flat suface	5.94 (5.23, 6.65)	3.18 (2.46, 3.90)	44.8%
Pain going up/down stairs	7.24 (6.56, 7.92)	4.3 (3.38, 5.22)	37.9%
Pain at night while in bed	4.97 (3.96, 5.97)	1.68 (0.96,2.4)	75.1%
Pain sitting or lying	4.15 (3.36, 4.94)	1.59 (1.87, 2.30)	61.4%
Pain standing upright	5.29 (4.61, 5.97)	2.53 (1.78, 3.28)	48.5%
WOMAC pain subscale	**27.4 (2.39, 30.81)**	**13.4 (9.97, 16.78)**	**44.9%**

SOURCE: COMPANY DATA

Note that if the primary endpoint of the phase 3 trial is pain reduction, the drug will either meet or not meet the end point of statistical difference on this measure alone. Both KOOS and WOMAC address other measures including joint stiffness and physical function. The data on these other measures will be collected, however, it will not be relevant to the primary endpoint of the study.

Additional WOMAC pain scores on 100 subjects from the SAS program will be released in 3Q CY2020.

SECONDARY ENDPOINTS

There were several secondary endpoints in the phase IIb trial:

- Reduction in volume, size and grade of bone marrow edema lesions (BML) as determined by MRI;
- Mean change in KOOS pain score at day 165;
- Number of subjects that had greater than 50% reduction in KOOS pain score from baseline to day 165;
- Patient Global Impression of Change (PGIC); and
- Mean % change in baseline – KOOS activities of daily living.

Each of these secondary endpoints was achieved with the key takeout that iPPS potentially has a claim at being the first drug with disease modification claims in the osteoarthritis indication. **The consistency and strength of the trend in these secondary endpoints from the phase IIb should provide investors with a considerable degree of confidence that the upcoming large RCT stands a very good chance of meeting these endpoints.**

As fare as the FDA is concerned the important secondary endpoints are pain and functionality (i.e. change in pain scores and PGIC).

PAR will also include the BML and biomarkers (ADAMTS-5, COMP) as secondary endpoints in the Phase 3 clinical trial in order to facilitate reimbursement discussions with insurers based on disease modification.

In regard to the Phase 3, the references to KOOS will be substituted for WOMAC.

In regard to PGIC, PAR published further data regarding PGIC for the 34 subjects in the SAS program in Australia. 87% of subjects reported a minimum of a moderately better. This includes 65% who reported either, 'better and definite improvement or 'a great deal better'. This data was not part of a clinical trial program, therefore there is no result regarding statistical significance.

Figure 2 - WOMAC SCORES – SAS PATIENTS

PGIC Score (Subjects with WOMAC scores)

Visit PGIC Scores	WOMAC Subjects (N = 34)
Post-Baseline	
No Change (or condition has got worse)	0
Almost the same, hardly any change at all	2 (5.7%)
A little better, but no noticeable change	2 (5.7%)
Somewhat better, but the change has not made any real difference	0
Moderately better, and a slight but noticeable change	8 (22.9%)
Better and a definite improvement that has made a real and worthwhile difference	13 (37.1%)
A great deal better and a considerable improvement that has made all the difference	9 (25.7%)
Missing	1 (2.9%)
Note: PGIC scores are summarised for subjects with WOMAC scores.Abbreviations: PGIC = Patient Global Impression of Change ; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index Program Name: t-14-2-3-pgic; Source data: PGIC, WOMAC	

85.7% (30 out of 34) of SAS patients had reported Patient global impression of Change (PGIC) of moderately to definite and considerable improvement in their OA condition with iPPS (Zilosul®) treatment.

SOURCE: COMPANY DATA

Based on this data we observe that there is a continuation of the trend towards pain relief for the majority of the subjects, further, that the effect size appears to be material i.e. 65% of subjects reported at least the better and definite improvement in patient global impression of change

In the phase IIb trial, PGIC was measured at day 53 and the difference between the treatment group and placebo was statistically significant (p=0.0062)[3].

Target population

Inclusion critera for the Phase IIb was:

Clinical diagnosis of osteoarthritis (OA) in one or both knees and a radiographic diagnosis showing a Kellgren-Lawrence score of 2, 3, or 4 (i.e. moderate to severe knee OA) and baseline pain scores of NRS 4 – 8 (stratified 4 – 6, 7 – 8).

For the phase 3 studies the target population will include subjects with clinically diagnosed OA of the knee with Kellgren Lawrence score of 2, 3 or 4.

The Kellgren Lawrence scale ranges from 0 (being no radiographic features of OA present) through to 5 (severe sclerosis and bone deformity).

The inclusion criteria for the phase 3 is straight forward and removes any confusion regarding results across different subgroups that may have been created by the NRS pain scores.

Other Matters

The dossier for the Investigational New Drug (IND) in osteoarthritis of the knee remains on track to be lodged with the FDA in 4Q2020 as per previous expectation.

[3] For the purposes of this analysis, the WOMAC scoring system for SAS subjects was scored from 0 – 10 and not 0 – 4.

Negotiations with the TGA in Australia for a provisional approval are continuing. The timing regarding future announcements remains uncertain, however, we note the company comment that it could be generating revenue in Q1 CY2021. Unlike in the US, the TGA does not have firm deadlines for action, hence it is not possible to provide further clarity on the requirements for approval. That said, the company now has safety and efficacy data from 450 subjects with knee OA treated with Zilusol, most of which were treated in Australia. This is a considerable body of data. It remains to be seen whether the TGA will await evidence from the large randomised trials before granting an approval. Inclusion on the PBS is not a consideration at this time (without the efficacy data from a RCT).

PAR will seek a joint submission to the EMA and FDA for a new IND in MPS later this year. This item had been previously announced and remains on course.

100 subjects a month is not unreasonable as a target recruitment rate

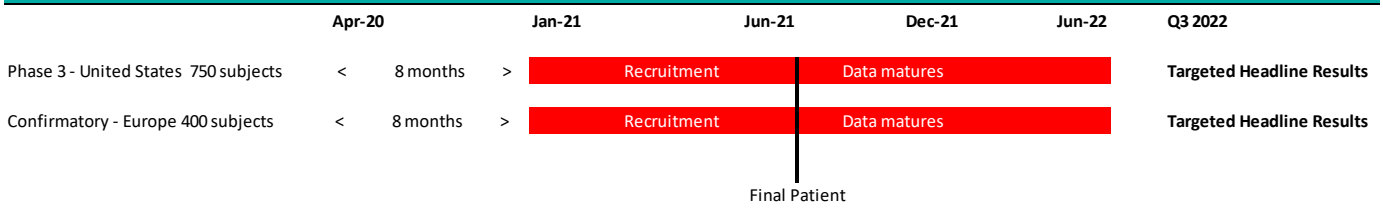
CLINICAL TRIAL RECRUITMENT

PAR anticipates commencing recruitment of the Phase 3 trials in January 2021 with mid 2022 completion and headline readout in Q3 2022.

The US trial has a minimum follow up of 12 months, therefore the meet this timeline, the last patient would have to be recruited in June 2021 – only 6 months after recruitment commences.

In our view the timing is aggressive by a few months.

Figure 3 - Overview of phase 3 timing



SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

In the 8 months between now and the target commencement of enrolment there is an immense volume of work to complete including the submission of the IND dossier, selection of a CRO, site recruitment and ethics approval at each site to mention a few. This would be a challenge under favourable conditions, let alone in the current COVID19 environment.

Capital Raising

The company has now raised $35m at $1.30 via the issue of ~27m new shares. The dilution to existing shareholders is 10% with the theoretical ex placement price of $1.64/shr.

Figure 4 - Cash position following $35m raise

Reconciliation of Pro-Forma cash and trial costs	
March 2020 cash at bank	A$74.5m
+ Proceeds from capital raising	A$33.5m
= Pro-Forma cash at bank March 2020 post raising	A$108.0m
- Estimated Cost of Phase 3 OA trial	A$80.0m
- Estimated Cost of Pivotal MPS trial	A$9.0m
= Cash remaining for operational costs of the business, further R&D and working capital for at least 2 years	A$19.0m

SOURCE: COMPANY DATA

The company had ample capital to commence the US pivotal study, however, at some point it would have required further capital to complete the program. This could have come through one of several means:

- A capital raise now – not ideal given collapse in global markets due to coronavirus, but at 10% dilution, this is a modest price given the certainty the funding provides;
- A capital raise at a later time – also not unreasonable, however, this strategy would have created fertile ground for shorting activity as the market would have a high degree of confidence that the company was likely to raise capital. This would have represented an overhang on the stock and the potential for shorting activity is likely to have represented an unacceptable risk for the Board.
- Non dilutive capital (i.e. a partnering deal) prior to the completion of the trial. Ideally the PAR Board will desire a global partnering deal in a few years time. Partnering prior to completion of the pivotal trial potentially leaves billions of dollars in shareholder value on the table.

  While the upfront component of a deal may have been used to complete the trial, PAR would have been negotiating from a position of weakness. A weak balance (i.e. lacking the cash to complete the clinical program) would have considerably reduced its negotiating position. In addition the volatility in global markets and the knock effect this has for any transaction represents a significant risk that any deal may have been forthcoming.

The purpose of the capital raise was to provide sufficient funds to complete the clinical program in its entirety. In doing so the company creates the following benefits for shareholders:

- It eliminates any potential for an overhang on the stock related to a future capital raise. As the clinical program is fully funded there is no need for PAR to seek further capital;
- It provides the company's partners (clinical research organisations, BenePharma, hospitals participating in the trial and trial participants) and regulators with the certainty that the company has the financial capability to complete the program; and
- Allows the Board to negotiate future partnering negotiations from a position of strength and to ignore low ball bids.

Following the raise PAR has $108m in cash.

CHANGES TO EARNINGS AND VALUATION

We have update the costs associated with the R&D program and have adjusted the balance sheet to reflect the capital raise. Valuation is reduced from $2.96 to $2.79 reflecting the dilution from the capital raise.

Figure 5 - Summary of earnings changes

	2020			2021			2022		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	3.0	3.0	0%	3.0	3	0%	3.0	3	0%
EBITDA	-8.8	-8.8	0%	-42.0	-27.5	-53%	-43.3	-28.3	-53%
NPAT	-8.3	-8.3	0%	-41.5	-27.0	-54%	-42.8	-27.8	-54%
EPS	-3.8	-4.3	13%	-18.9	-14.0	-35%	-19.5	-14.5	-35%

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

We maintain our Buy rating.

Appendix 1 WOMAC v KOOS

Figure 6 - Comparison of WOMAC v KOOS

KOOS Pain Questionnaire	Rating Scale	WOMAC pain Questionnaire	Rating Scale
P1 How often do you experience knee pain	0 – 4, where 0= never, 4 = always	-	-
P2 Pain twisting/pivoting on your knee	0 – 4, where 0= never, 4 = extreme pain	-	-
P3 pain straightening knee fully	0 – 4, where 0= never, 4 = extreme pain	-	-
P4 Pain bending knee fully	0 – 4, where 0= never, 4 = extreme pain	-	-
P5 Pain walking on flat surface	0 – 4, where 0= never, 4 = extreme pain	1. Pain walking on flat surface	0 – 4, where 0= never, 4 = extreme pain
P6 Pain going up and down stairs	0 – 4, where 0= never, 4 = extreme pain	2. Pain going up/down stairs	0 – 4, where 0= never, 4 = extreme pain
P7 Pain at night while in bed	0 – 4, where 0= never, 4 = extreme pain	3. Pain at night	0 – 4, where 0= never, 4 = extreme pain
P8 Pain sitting or lying	0 – 4, where 0= never, 4 = extreme pain	4. Pain sitting/lying	0 – 4, where 0= never, 4 = extreme pain
P9 Pain standing upright	0 – 4, where 0= never, 4 = extreme pain	5. Pain standing upright	0 – 4, where 0= never, 4 = extreme pain
KOOS Pain Score	**0 – 100 where 100 = no pain and 0 = extreme pain**		**0 – 20 where 0 = no pain, 20 = extreme pain**

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. This report refers extensively to the injectable format of the drug "iPPS".

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. We expect the company to apply for the IND relating to the pivotal study in late calendar 2020. PAR aims to begin a phase III trial in the US in CY2021.

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 750 subjects and a confirmatory phase 3 study of ~400 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 1,400 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 16 April 2020

Recommendation	Buy, Speculative
Price	$1.77
Valuation	$2.79

Table 1 - Financial summary

Profit & Loss (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Year Ending June					
Gross royalties	-	-	-	-	-
Gross milestones	-	-	-	-	-
Gross revenues	-	-	-	-	-
Risk adjusted revenues	-	-	-	-	-
COGS (Bene Royalty expense)	-	-	-	-	-
Gross profit	-	-	-	-	-
GP margin	na	na	na	na	na
R&D incentive/Upfront receipts	2.7	3.2	3.0	3.0	3.0
Total revenues	**2.7**	**3.2**	**3.0**	**3.0**	**3.0**
Other expenses	**-8.9**	**-11.9**	**-11.8**	**-45.0**	**-46.3**
EBITDA	**-6.2**	**-8.7**	**-8.8**	**-42.0**	**-43.3**
Depreciation	-	-	-	-	-
Amortisation	- -	6.9	-	-	-
EBIT	-6.2	-15.6	-8.8	-42.0	-43.3
Sundry income	0.1	-	0.5	0.5	0.5
Pre tax profit	-6.1	-15.6	-8.3	-41.5	-42.8
Tax expense	-	-	-	-	-
NPAT- normalised	-6.1	-15.6	-8.3	-41.5	-42.8
Net abnormal items	-	-	-	-	-
Reported NPAT	-6.1	-15.6	-8.3	-41.5	-42.8

Cashflow (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Gross cashflow	-6.1	-6.5	-8.2	-42.0	-43.3
Net interest	0.1	0.1	0.5	0.5	0.5
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-6.0	-6.4	-7.7	-41.5	-42.8
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	-6.0	-6.4	-7.7	-41.5	-42.8
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	5.9	82.8	35.0	0.0	0.0
Movement in investments	0.0	0.0	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Change in cash held	(0.1)	76.4	27.2	(41.5)	(42.8)
Cash at beginning of period	2.6	2.5	72.4	99.6	58.1
Cash at year end	2.5	72.4	99.6	58.1	15.3

Balance Sheet (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Cash	2.4	72.4	99.6	58.1	15.3
Receivables	2.7	3.5	3.0	3.0	3.0
Other current assets	0.1	6.6	6.6	6.6	6.6
Intangibles	9.9	3.0	3.0	3.0	3.0
Total assets	15.2	85.5	112.2	70.7	27.9
Trade payables	1.1	2.3	2.3	2.3	2.3
Other provisions	0.3	0.4	0.4	0.4	0.4
Total Liabilities	1.3	2.7	2.7	2.7	2.8
Net Assets	13.9	82.8	109.5	68.0	25.2
Share capital	26.9	109.5	144.4	144.4	144.4
Retained earnings	(15.1)	(30.7)	(39.0)	(80.5)	(123.3)
Reserves	2.1	4.1	4.1	4.1	4.1
Shareholders Equity	13.9	82.8	109.5	68.0	25.2

Last sale 15/04/2020	1.77
Recommendation	Buy (Spec)
Issued Capital	197.8
Market Cap	396.3

Valuation Ratios (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Reported EPS (cps)	-5.4	-10.5	-3.8	-18.9	-19.5
Normalised EPS (cps)	-5.4	-10.5	-3.8	-18.9	-19.5
EPS growth (%)	na	na	na	na	na
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBITDA (x)	nm	nm	nm	nm	nm
EV/EBIT (x)	nm	nm	nm	nm	nm
NTA (cps)	3.3	41.5	48.6	29.7	10.1
P/NTA (x)	0.5	0.0	0.0	0.1	0.2
Book Value (cps)	11.2	43.1	50.0	31.0	11.5
Price/Book (x)	0.2	0.0	0.0	0.1	0.2
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 %	-274%	-187%	-200%	-1069%	-1103%
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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