Paradigm Biopharmaceutical

A win already priced in

REDUCE

Current price:	A$1.27
Target price:	A$0.89
Previous target:	n.a.
Up/downside:	-29.9%
Reuters:	PAR.AX
Bloomberg:	PAR AU
Market cap:	US$121.6m
	A$168.1m
Average daily turnover:	US$0.10m
	A$0.10m
Current shares o/s	132.4m
Free float:	80%

Price performance	1M	3M	12M
Absolute (%)	41.1	28.3	309
Relative (%)	41.1	37.4	314

Iain WILKIE
AR 000468543
E iain.wilkie@morgans.com.au

Scott POWER
AR 000255971
E scott.power@morgans.com.au

Derek JELLINEK
AR 001001367
E derek.jellinek@morgans.com.au

- PAR is a clinical stage biopharmaceutical company focused on the treatment of orthopaedic and viral arthritis through its repurposed drug pentosane polysulfate sodium (iPPS).
- The outcome of the OA trial before EOCY18 is expected to generate significant interest as a non-opioid and non-steroid based treatment.
- Strong SAS results to date have spurred a rally in the share price over the last 12 months, and we believe high levels of trial success are already priced in.
- We initiate coverage on PAR with a Reduce recommendation and valuation range of A$0.16 to A$2.10 and price target of A$0.89. We note an investment in PAR is appropriate for investors with a higher risk profile.

A shortened pathway to approval

Paradigm (PAR) is an Australian biopharmaceutical company focused on repurposing the drug pentosan polysulfate sodium (PPS) in its injectable form (iPPS) primarily in the orthopaedic treatment of osteoarthritis (OA) and bone marrow edema lesions (BMEL). By repurposing existing drugs, PAR is able to utilise a shortened development pathway through the various drug approval agencies. The company has a number of clinical trial results due in the following 12 months, including its major Ph2b OA trial due by end CY18. PAR has also been running pre-clinical studies for its OA/BMEL indication via the TGA's special access scheme (SAS) with significant success to date including endorsements from a number of high-profile athletes who have received treatment under the scheme.

Read-through for pivotal trial – major catalyst

PAR has been proactively running an un-blinded treatment using ZILOSUL® via the TGA's SAS, using a similar dosing regimen to its pivotal Ph2b trial counterpart. To date, 145 patients with osteoarthritis have been treated and reported on with an 86.8% response rate for a reduction in joint pain and improvement in knee function. Pain level severity has been reduced by 51.2% on average across the group (compared to 15% pain reduction from opioid treatment for chronic pain in OA of the knee and hip – Seghal et al, 2013) and 91% improvement in knee function. We believe the SAS cases act as a confidence barometer for trial success due in 4QCY18 (of which to date has been extremely successful). We view a positive trial result as transformative for the company and will trigger high levels of interest from large pharmaceutical companies, looking to partner through Ph3 trials and the regulatory pathway.

Valuation range reflects binary nature

We have run a number of scenarios assuming different outcomes including: low (trial failure), current state (Ph2 pending), current state (Ph2 success), and a high case (unrisked) scenario. The valuation range between scenarios reflects the binary nature of the asset and consequently the large risk/reward profile it presents. Based on the successes of the SAS program to date and subsequent rally in the share price, we believe the market is already factoring in a high chance of success of the OA trial.

Investment view – taking profits ahead of binary event

We initiate coverage on PAR with a risked valuation range of A$0.16 (Ph2 failure) to A$2.10 (unrisked commercialised). While it isn't often investors get a significant read-through into the potential efficacy of a drug going through a double-blind trial, the rally over the last 12 months has increased potential risks to the downside if success is not achieved. We ultimately view trial success as the most likely scenario based on the strong SAS outcomes to date, although set our price target on a risk-weighted basis of 38% high case and 62% low case of which the high case weight representing the average success rate of success in Phase 2 trials. With significant value resting on many unknowns including size and scale of potential partnership and milestone details, we advocate investors to take profits into the recent rally and await further clarity post top-line results before reviewing and de-risking further. Risks to the upside relate to higher than forecast partnership deal terms. Due to the risks associated with regulatory clearance of pharmaceutical drugs, we initiate with a Reduce recommendation and A$0.89 target price. We note this investment is appropriate for investors with a higher risk-profile.

IMPORTANT DISCLOSURES REGARDING COMPANIES THAT ARE THE SUBJECT OF THIS REPORT AND AN EXPLANATION OF RECOMMENDATIONS CAN BE FOUND AT THE END OF THIS DOCUMENT. MORGANS FINANCIAL LIMITED (ABN 49 010 669 726) AFSL 235410 - A PARTICIPANT OF ASX GROUP

Powered by EFA

Figure 1: Financial summary

REVENUES	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Phase	Start	Phase 2	Phase 3	Phase 3	Phase 3	Approved	Approved	Commer	Commer	Commer	Commer	Commer	Commer
Risk	77%	38.0%	78.0%	78.0%	78.0%	89.0%	89.0%	70.0%	70.0%	70.0%	70.0%	70.0%	70.0%
Progressive Prob	77%	29.3%	22.8%	22.8%	22.8%	20.3%	20.3%	20.3%	20.3%	20.3%	20.3%	20.3%	20.3%
Year of commer	-	-	-	-	-	-	-	1	2	3	4	5	6
% of peak	0%	0%	0%	0%	0%	0%	0%	17%	33%	50%	67%	83%	100%
% market	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.7%	3.3%	5.0%	6.7%	8.3%	10.0%
Total market (m)	4.729	4.762	4.796	4.829	4.863	4.897	4.931	4.966	5.001	5.036	5.071	5.106	5.142
Price ($)	1,750	1,750	1,750	1,750	1,750	1,750	1,750	1,750	1,750	1,750	1,750	1,750	1,750
US potential	8,276.0	8,334.0	8,392.3	8,451.1	8,510.2	8,569.8	8,629.8	8,690.2	8,751.0	8,812.3	8,874.0	8,936.1	8,998.6
Unrisked													
Zilosul sales	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**144.8**	**291.7**	**440.6**	**591.6**	**744.7**	**899.9**
PAR royalties	-	-	-	-	-	-	-	14.5	29.2	44.1	59.2	74.5	90.0
Risked PAR royalties	-	-	-	-	-	-	-	2.9	5.9	8.9	12.0	15.1	18.3
MILESTONE													
Milestone	-	27.5	34.4	-	-	34.4	-	-	-	-	-	-	132.8
rMilestone	-	10.4	26.8	-	-	30.6	-	-	-	-	-	-	93.0
Total income (unrisked)	**-**	**27.5**	**34.4**	**-**	**-**	**34.4**	**-**	**14.5**	**29.2**	**44.1**	**59.2**	**74.5**	**222.8**
Total Income (risked)	**-**	**10.4**	**26.8**	**-**	**-**	**30.6**	**-**	**2.9**	**5.9**	**8.9**	**12.0**	**15.1**	**111.3**

EXPENSES	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Growth:	2%												
Expenses	2.3	2.4	2.4	2.4	2.5	2.5	2.5	2.6	2.6	2.7	2.7	2.7	2.8
R&D	6.6	6.7	6.8	-	-	-	-	-	-	-	-	-	-
Rebate Add-back (42.5%) from previous year	(2.7)	(2.8)	(2.8)	(2.9)	-	-	-	-	-	-	-	-	-
Marketing	0	-	-	-	-	-	-	-	-	-	-	-	-
Other	0	-	-	-	-	-	-	-	-	-	-	-	-
Total Expenses	**6.2**	**6.3**	**6.4**	**(0.4)**	**2.5**	**2.5**	**2.5**	**2.6**	**2.6**	**2.7**	**2.7**	**2.7**	**2.8**
Op cashflow unrisked	(6.2)	21.2	28.0	0.4	(2.5)	31.8	(2.5)	11.9	26.5	41.4	56.5	71.7	220.0
Op cashflow risked	(6.2)	4.2	20.4	0.4	(2.5)	28.1	(2.5)	0.4	3.3	6.3	9.3	12.4	108.5
Unrisked tax & free cashflows													
Accum gains/losses	-15.1	6.1	34.1	34.6	32.1	63.9	61.4	73.3	99.8	141.2	197.7	269.4	489.4
Tax	-	(6.4)	(8.4)	(0.1)	0.7	(9.6)	0.8	(3.6)	(8.0)	(12.4)	(16.9)	(21.5)	(66.0)
Free cashflow	(6.2)	14.9	19.6	0.3	(1.7)	22.3	(1.8)	8.3	18.6	29.0	39.5	50.2	154.0
Risked tax & free cashflows													
Accum gains/losses	(15.1)	(10.9)	9.5	10.0	7.5	35.6	33.0	33.4	36.7	42.9	52.3	64.6	173.1
Tax	-	-	(6.1)	(0.1)	0.7	(8.4)	0.8	(0.1)	(1.0)	(1.9)	(2.8)	(3.7)	(32.5)
Free cashflow	(6.2)	4.2	14.3	0.3	(1.7)	19.6	(1.8)	0.2	2.3	4.4	6.5	8.7	75.9

Figure 2: Market data

MARKET DATA	#
Population of target market	325.70
Prevalence of disease	12.1%
Post-traumatic portion	12.0%
Number of Cases Forecast for Year 1	4.7
Annual Population Growth	0.70%
Peak Market Penetration	10.0%
Revenue Per Unit ($US)	$ 1,750
Market Ramp Time to Peak Penetration (Years	5
Hold peak	5
Life cycle of drug	20
Royalty Rate	10.0%
WACC	12.5%
Tax rate	30%

Figure 3: Milestone assumptions

Trial/Phase data

Phase	Progression risk	M'stone	MS $	rMS $
Start	100.0%	**229**		
Pre-clinical	69.0%	0%	-	
Phase 1	77.0%	0%	-	
Phase 2	38.0%	12%	$ 27.5	$ 10.4
Phase 3	78.0%	15%	$ 34.4	$ 26.8
Approved	89.0%	15%	$ 34.4	$ 30.6
Commer	70.0%	58%	$ 132.8	$ 93.0

Figure 4: Valuation

	Unrisked NPV	Trial failure
Royalties	$203.73	$0.00
Milestones	$102.95	$0.00
Expenses	-$24.43	$0.00
Taxes	-$84.68	$0.00
Net position ($USm)	$16.17	$16.17
Total ($Usm)	$213.75	$16.17
Total ($Am)	$295.48	$22.36
Per share	**$2.10**	**$0.16**
Weighting	38%	62%
Valuation	$0.80	$0.10
Weighted valuation	**$0.89**	

SOURCE: MORGANS RESEARCH, COMPANY

Paradigm Biopharmaceuticals

Investment highlights

Large addressable market – >4m post-traumatic BMEL injuries p.a. leading to US$8.3bn market for ZILOSUL® (*CDC, Cleveland Clinic*).

- **Non-opioid or steroidal** treatment for > 33m OA sufferers in the USA with a commercial potential over US$1bn p.a. Significant tailwinds with a large push by US health authorities to combat highly addictive opioid based medicines for the treatment of pain.
- **Reduction in costs** – utilising the FDA 505(b)(2) pathway for the repurposing of a pre-approved drug.
- **Reduction in risk** – due to the repurposed status of PPS and its long term safety profile, there is a 2.5x higher probability of commercialisation compared to a new drug formulation.
- **Multiple indications** – due to the anti-inflammatory characteristics of PPS, PAR is able to utilise the same drug for numerous indications, ranging from orthopaedic bone bruising, viral arthritis (Ross River Virus, Chikungunya), and inflammatory bowel disease.
- **Near term share price catalysts** with several major trial results and study read-outs over the next 12 months. Positive trial results would likely, in our view, be met by partnership deals with major global pharmaceutical companies.
- **Special Access Scheme** permits pre-approval treatment of ZILOSUL® and allows real-world evidence data on a number of primary endpoints including pain reduction and improvement in disease symptoms which have been highly positive to date.

Understanding PAR's drug

What is PPS: PPS is a semi-synthetic compound made from European Beech trees and has been in use over the last 60 years in Europe for the treatment and prevention of blood clots. PPS is generally characterised as anti-inflammatory, anti-histamine, anti-clotting, prevents premature cell death (necrosis), and also prevents cartilage degeneration. PAR's primary use for the drug is the treatment of BMEL through slowing the breakdown of cartilage in the joint as well as significantly reducing joint pain and function without the use of opioid or non-steroidal anti-inflammatory drugs (NSAIDs). Successful preclinical studies and treatments via the TGA's special access scheme (SAS) have helped to drive recent confidence in the efficacy of the drug in these indications.

Targeting multiple indications

- **OA/BMEL:** PAR's lead treatment indication. Acts as an anti-inflammatory to reduce swelling and improve blood flow to the region. The drug works by inhibiting enzymes released post-acute injuries which degrade cartilage tissue whilst also acting as an anti-inflammatory to reduce joint pain. PPS has also been established as the leading treatment for OA disorders in dogs and horses. Significant market potential with >4m BMEL injuries p.a. in the US. PAR is currently conducting Phase 2b trial with results anticipated at the end of CY18.
- **Viral Arthritis:** Treatment of Ross River Virus (RRV) and Chikungunya (CHIKV) which are athritogenic alpha viruses typically transmitted through mosquito bites. Infection typically results in joint and muscular pain, fever and joint inflammation. Results from Phase 2a trial anticipated 4QCY18.
- **Heart Failure:** PPS acts as an inhibitor to a key enzyme involved in the degenerative process in heart failure. Investigation is in pre-clinical phase.
- **Respiratory/Hay Fever:** Existing program which failed to meet its end-points of total nasal symptom score and peak nasal respiratory flow in its Phase 2a trial in 2017. PAR continues to analyse trial data and looking to reformulate and partner.

PAR's portfolio also consists of the IL-1RA Peptide which is a potential treatment for IBD, cancer-related cachexia, colitis, and Crohn's disease. Safety profile and efficacy already confirmed in Phase 1/2 trial.

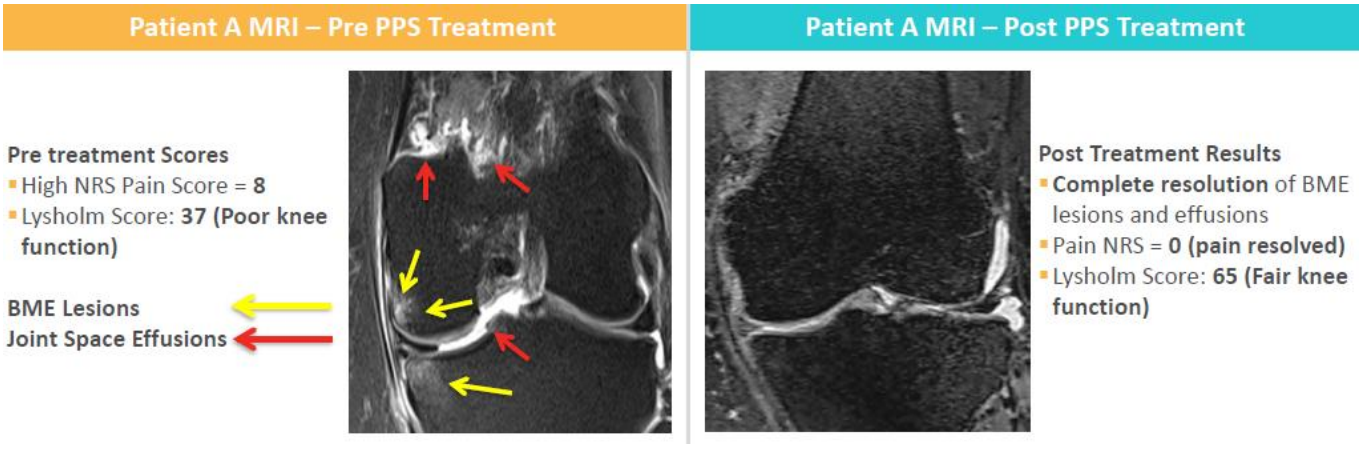
Figure 5: PAR indication pipeline

Drug candidate	Indication(s)	Preclinical	SAS Pilot/Phase 1	Phase 2	Milestones (next 12 months)
Orthopaedic - Bone Marrow Edema/Lesions (Bone Bruising)					
PPS	BME with acute injuries (ACL etc)			~10 ACL Patients	ACL-BME Phase 2a results read out
	BME with Osteoarthritis (OA) - placebo controlled			100 OA patients	Commenced Phase 2b BME/OA Trial
	BME with Osteoarthritis (OA) - RWE Open Label		100 OA patients open label / RWE		25 patient groups reported quarterly
Viral Arthritis - Alphavirus					
PPS	Ross River Virus (RRv)		30 SAS RRv Patients	24 RRv Patients	Complete Phase 2
	Chikungunya virus (CHIKV)				Enter Phase 2 + other pilot studies
Respiratory					
PPS	Allergic rhinitis (hay fever)		20 Phase 1 safety	40 x 2 patient crossover	Analyse trial data and reformulate
	Chronic Obstructive Pulmonary Disease (COPD)				Develop formulation & partner
	Allergic asthma				Develop formulation & partner
Cardiovasuclar					
PPS	Heart failure				Conduct 24 person placebo controlled Phase 1/2
Inflammation & autoimmune					
Novel Anti IL-1 RA inhibitor peptide	auto-immune disorders (IBD, Crohn's disease, GVHD), oncology, complications from cytotoxic drugs (mucositis) and cancer cachexia		26 patients phase 1/2		Reformulate into oral compound. Finalise data pack & partner or progress human clinical trials

SOURCE: COMPANY

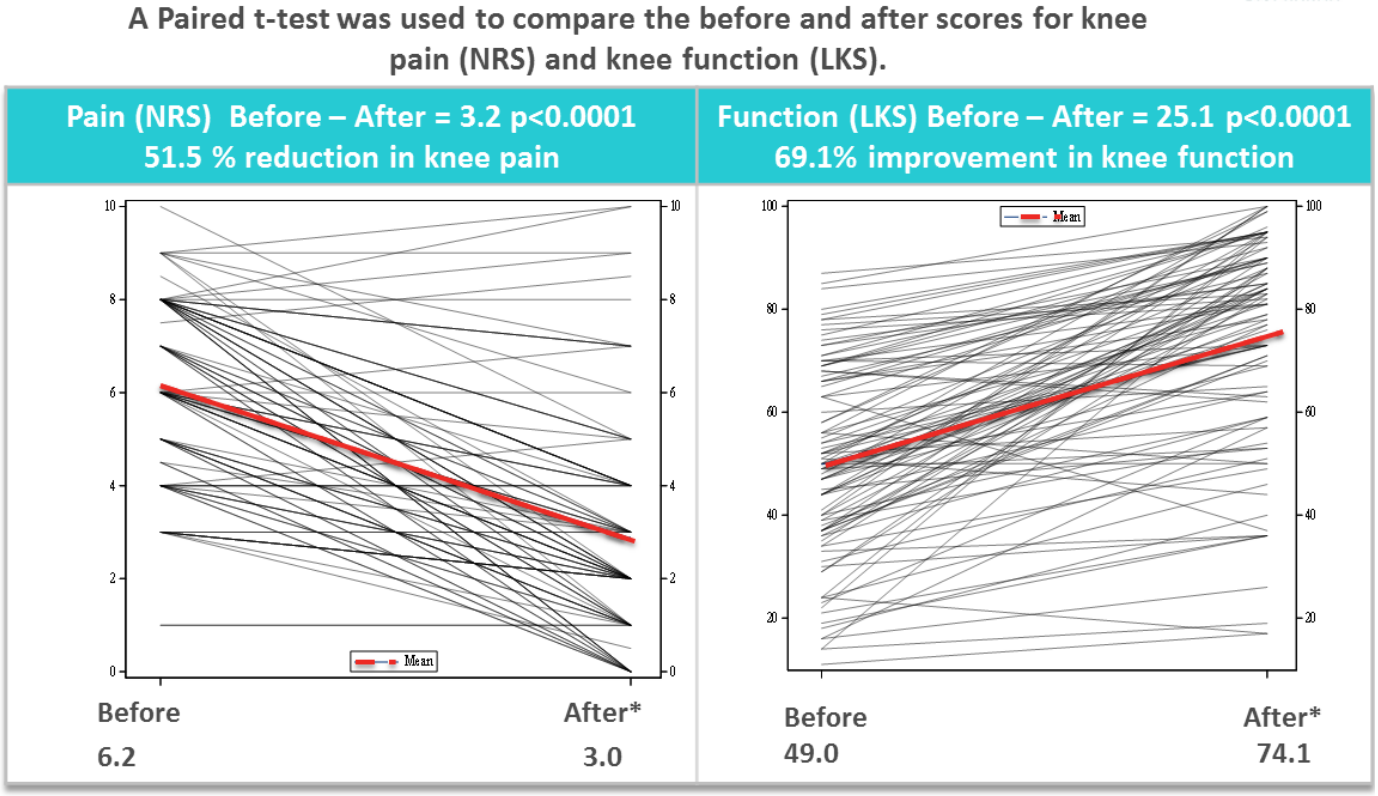
Readthrough via Special Access Scheme: In parallel to the Phase 2b OA/BMEL clinical trial (n=110), PAR has been proactively running an un-blinded treatment using ZILOSUL® via the TGA's special access scheme. To date, 145 patients with osteoarthritis have been treated and reported on with an 86.8% response rate for a reduction in joint pain and improvement in knee function. PAR has also reported that of the 145 patients, pain has been reduced by >51.2% on average across the group. There have been a number of high-profile athletes who as a result of their careers have developed severe knee pathologies which have been resolved by using the treatment. PAR is targeting ~500 real-world examples under the SAS and we view this data as a positive read-through on the efficacy and success of the pivotal phase 2b results due at the end of CY18.

Figure 6: PPS treatment on BML patient through SAS



SOURCE: COMPANY

Figure 7: OA/BML – First 125 patients treated via SAS. Good responses for both pain and function so far



*After = Results taken from patients six weeks post final treatment, i.e. twelve weeks from first dose, therefore it is anticipated that any placebo response will be somewhat reduced. Injections are Subcutaneous, NOT intra-articular.

SOURCE: COMPANY

PAR recently announced that it has entered into an agreement with the NFL Pro Players' Elite Network (PPEN) to commence recruitment and treatment on US-based players. The treatments will be made under the FDA Expanded Access program (SAS equivalent). We see this as a significant boost to PAR's U.S. profile, with highly visible participants and a large ready-made market should iPPS prove to be successful in its regulatory approvals.

Biotech market in Australia

There are a number of reasons to be cautious. Recent results on success and failures in the space.

There have been a number of significant events across ASX listed biotechnology stocks within the last 12 months which we think useful to highlight - and how the market has reacted on news of achievement or failure of clinical trial results.

Trial successes:

Biotron (BIT): Phase 2 trial for BIT225, targeting the HIV-1 Vpu viroporin protein. The trial was double-blinded, placebo-controlled, randomised and mutli-centre study. Results showed that on its 12 week, once daily, oral treatment in combination with ART (antiretroviral treatment) – the BIT225 drug showed statistically significant immune response (clearance of virus from Macrophage reservoirs) in patients treated with the active drug. Market cap A$10.3m prior to result release (28-Sep-18) up to A$170m by 17-Oct-18 (+1500% gain). The share price has since settled back to A$95m.

Trial failures:

Bionomics (BNO): Phase 2 trial for BNC210, a negative allosteric modulator of the alpha-7 nicotinic acetylcholine receptor, in patients with PTSD. Results showed the treatment was tolerable and safe, although found no broad benefits. Primary endpoint failure. Share price declined by 66% on the day (2-Oct-18),

and has drifted progressively lower since. BNO retains a number of other assets and indications within its portfolio.

Factor Therapeutics (FTT): Phase 2 trial for VF001 in the treatment of venous leg ulcers. Analysis demonstrated no clinically meaningful difference in measures of wound healing compared to placebo. All ongoing development of treatment has ceased and staffing reduced to skeleton levels. Share price reduced by 96% on the day (14-Nov-18) to around cash backing of A$2.5m.

Ellex Medical Lasers (ELX): LEAD trial for the treatment of late Age-related Macular Degeneration (AMD) using ELX's 2RT® treatment. Trial showed 13.6% of participants developed late AMD after the 36 month treatment versus 17.2% in the sham group. While top-line results failed to meet the primary endpoints, the results still resulted in a 77% reduction in rate of progression from intermediate AMD to late AMD. The share price dropped 13.3% on the day. The trial was a small part of the company that still develops and manufactures lasers and diagnostic equipment for eye disease.

Paradigm (PAR): Phase 2a allergic rhinitis (hay fever) clinical trial using PPS on post-challenge nasal symptoms using the allergen challenge model in subjects with seasonal hay fever. Primary endpoints of total nasal symptom score and peak nasal respiratory flow were found not to be statistically significant versus placebo. Share price declined 50.7% on the day (16-Jun-17). PAR has a number of other indications to be trialled (see Figure 5).

Commentary:

It has become clear, especially over the last 12 months, that investors in this space are becoming increasingly binary in their reactions on the release of critical trial results. Successes can be met with large returns (in the case of BIT), and equally met with large losses in the event of endpoint failure (BNO, FTT) – especially when the price has run into an announcement. What we've seen over the last year is single asset/indication companies which fail to reach their endpoints typically revert to cash backing / shell status while companies with a number of assets or indications are sold off in line with market value prescribed to the failed indication.

While PAR is a multi-indication company, it is still single asset (being PPS) which has previously seen disappointment through the failed Hay Fever trial (share price down 50% on the day). We believe the market is prescribing the majority of PAR's value to the OA/BMEL indication which may lead to a fairly binary outcome for its OA/BMEL results in late CY18.

Due to the rally in the share price over the last 12 months, we see most of the immediate term upside already priced in and prefer to wait for the OA/BMEL results and then focus on the structure and scale of potential partnership deals stemming from a successful result.

Intellectual Property / Patent profile

PAR has a multi-faceted IP protection with minimum life of patents out to 2030 – 2035 as well as securing an exclusive 20 year supply agreement with PPS producer bene PharmaChem who remains the only FDA approved supplier of PPS. Production of PPS is complex and bene PharmaChem's manufacturing process is a protected trade secret. PAR's most significant patents include the use of injectable PPS for the treatment of OA/BMEL in USA, Europe, Australia, China, Japan, and New Zealand.

Current treatment options for OA

There are numerous treatment routes in OA, ranging from mild painkillers to surgical repair. The proposed route of treatment varies significantly depending on level of pain, as well as level of available movement, with surgical report often being the last resort.

The typical treatments are as follows:

- **Non-steroidal anti-inflammatory drugs (NSAIDs)** ie ibuprofen – provides pain and inflammatory relief but does not treat underlying pathology and common side-effects include nausea, heartburn, drowsiness, and constipation.
- **COX-2 inhibitors** (high strength NSAID) – typically prescribed to more severe OA patients. Has higher pain relief and anti-inflammatory properties to the above although comes with an increased risk of heart problems.
- **Opioids** i.e. oxycodone – provides temporary relief from high levels of pain but does not treat the underlying issues or provide any anti-inflammatory response. Significant side effects including nausea, vomiting, chest pain, difficulty breathing, seizures, kidney and liver failure, etc. Opioids are highly addictive and are subject to significant negative attention.
- **Corticosteroids** – provide pain relief and anti-inflammatory response although again do not treat underlying pathology. Typical side-effects include acne, insomnia, headaches, dizziness, nausea, liver disease etc.
- **Hyaluronic acid** – naturally occurring and acts as a joint lubricant and shock absorber. Treatment provides temporary pain relief and has anti-inflammatory properties although recent studies suggest the injections have no clinically relevant effect *(American Academy of Orthopaedic Surgeons).*

PAR's target market: moderate to severe pain

- **Joint replacement** – surgical option and often the last resort. While treating the underlying pathology, the surgery is often expensive and comes with the typical operating and post-operating risks and side effects.

While there are a number of treatment options, there remains significant side-effects to most therapies. While PPS is not immune to side effects of its own (which include nausea, stomach pain, diarrhoea, and dizziness), on balance we view the safety profile as superior to what we view as its most direct competition being COX-2 inhibitors, opioids, corticosteroids, and hyaluronic acid. Within this grouping, treatment has predominately pain and anti-inflammatory properties although no treatment to the underlying pathology readily measureable.

Catalysts

PAR has a number of critical share price catalysts over the next 12 months which predominately revolve around recruitment numbers, clinical results, and potential partnership deals upon trial success.

- Recruitment numbers in Phase 2b OA/BMEL trial. (Positive, completed)
- Ongoing release of SAS patient outcomes. PAR plans to release these outcomes every 20-25 patients completed (n ~ 500). (Positive, read-through for OA/BMEL results)
- Phase 2a viral arthritis trial results 4QCY18. (Positive)
- Phase 2b OA/BMEL clinical trial results (n = 110) – Q4CY18. (Major, becomes an attractive partnership/takeover target)
- Potential partnership agreements with major pharmaceutical companies in treatments for BMEL with OA. (Major, Milestone revenue)

Segments and outlook

Outlook/guidance: Due to the pre-approval (and pre-revenue) nature of PAR's major projects, timing and achievement of primary and secondary end-points are the key aspects for the company. Post the recent placement in October 2018 where PAR raised A$10m, the company has sufficient cash (pending sufficient and timely recruitment) to fund its two major Phase 2 trials at which point the viability of PAR's major investment thesis will be known.

Model assumptions

Due to the early-stage nature of PAR and the risks surrounding clinical trials, we have valued the company on failure and success, as well as variations to the risk profile upon successful outcomes.

We have run a risk-adjusted model based on each case, anticipated partnership agreements and milestone payments to bring the product through to commercialisation, and subsequent royalty generation from the lead ZILOSUL® product. While we note PAR has a number of possible indications, we remain focused on the lead OA/BMEL product which we believe has the highest value and which the market is tracking and prescribing value to.

Focus on US sales for OA indication: We focus on the US market only (~50% of global market) due to bene PharmaChem being the sole FDA approved manufacturer of PPS. Due to the generic nature of the asset, we expect competition to eventually arrive but this would require drug manufacturers to run through the FDA approval process which is both expensive (R&D, equipment, processing, FDA costs) and can take years (compliance to current GMP, stability batches, environmental impact, quality checks, FDA submissions) until a suppliable product is marketable.

PAR has locked up supply through a 20 year agreement as well as its own patents surrounding the use of the injectable form for the treatment of OA/BMEL. We would expect it could take a number of years before any significant competition arrives with a similar product/pathway.

While we would expect sales outside of the US upon commercialisation, we consider this upside to our numbers.

Within our model, we have assumed:

- PAR to partner with large pharmaceutical company after a Ph2b trial success in order to complete Ph3 trial and commercialise;
- Addressable market for ZILOSUL® of ~4.7m injuries p.a;
    - Based on US population of 325.7m *(Source: United States Census Bureau)*

      Multiplied by:
    - 12.1% prevalence of OA *(Source: Centre for Disease Control and Prevention).*

      Multiplied by:
    - 12% of OA is associated with some form of post-traumatic injury *(Source: The Cleveland Clinic)*
- US$1,750 price per treatment (Source: PAR non-deal roadshow presentation – May 2017) of which PAR to receive an ongoing 10% royalty from sales (Morgans estimates –single digit royalties); and
- Forecast ZILOSUL® to incrementally grow up to 10% of post-traumatic addressable market in the US.

Figure 8: PAR market assumptions

MARKET DATA	#	Comments
Population of target market	325.70	U.S population 2018
Prevalence of disease	12.1%	Centre for Disease Control (CDC)
Post-traumatic portion	12.0%	Cleveland Clinic - Post Traumatic Arthritis
Number of Cases Forecast for Year 1	4.7	
Annual Population Growth	0.70%	Worldbank, 2016
Peak Market Penetration	10.0%	
Revenue Per Unit ($US)	$ 1,750	PAR - Non deal roadshow presentation - Mar-2017
Market Ramp Time to Peak Penetration (Years)	5	Study of peak penetration rates. Blockbuster drugs

SOURCE: MORGANS RESEARCH, COMPANY

We have applied a discount to our forecasted cashflows to reflect historical success rates of drugs at various stages of FDA approval and the likelihood of ZILOSUL® achieving commercial success. Achievement of clinical stage success would result in risk mitigation in line with the following phase level (i.e. royalty risk mitigation discounts reduce from 62% to 22%).

Figure 9: Success rates by therapeutic area: Benchmarks

Therapeutic Area	Phase 1	Phase 2	Phase 3	Approval
Arthritis & Pain	77%	38%	78%	89%
Central Nervous System	66%	46%	62%	78%
Cardiovascular	63%	43%	76%	84%
Gastrointestinal	67%	49%	71%	86%
Immunology	65%	45%	65%	82%
Infectious Diseases	71%	51%	80%	97%
Metabolism	48%	52%	79%	93%
Oncology	77%	44%	62%	85%
Respiratory Diseases	63%	41%	60%	77%

SOURCE: Tufts University, 2010; Villiger, 2012

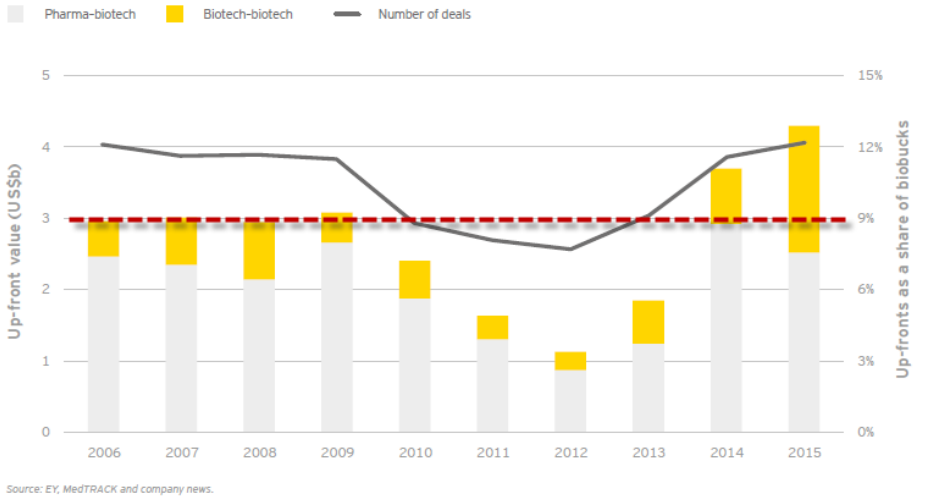
We have assumed A$6.0m p.a. in trial costs and product development activities in FY19 and A$3.0m in FY20 at which point a larger partner would fund the Phase 3 trial and regulatory costs through to commercialisation in FY25.

We forecast office and admin costs to increase 5% over the last reported period p.a.

Milestone payment: The size and structure of a potential milestone payment is a large driver to PAR's short/medium term value. The up-front amount, timing and deal terms of the subsequent milestone payments vary materially from deal to deal.

We assume PAR will partner with a large biopharmaceutical to fund the costs of a Phase 3 trial (typically cost ~US$150m). We have forecast a potential total deal value worth US$229m (10 year average of potential deal value in the US – *EY, MedTRACK 2016*). We forecast a higher back-end loading on the milestone payments due to the increased partner risk. We forecast 12% upfront, 15% on Phase 3 start, 15% on completion, and 58% on remaining approval and commercialisation milestones.

Figure 10: US and European strategic alliances based on up-front payments, 2006-15



SOURCE: *EY, MedTRACK 2016.*

We have applied a progressive probability model based on studies on historical success rates and are set out in Figure 11 below.

Figure 11: Forecast milestone payments and payment risks

Phase	Progression risk	M'stone	MS $	rMS $
Start	100.0%	**229**		
Pre-clinical	69.0%	0%	-	
Phase 1	77.0%	0%	-	
Phase 2	38.0%	9%	$ 20.6	$ 7.8
Phase 3	78.0%	15%	$ 34.4	$ 26.8
Approved	89.0%	15%	$ 34.4	$ 30.6
Commer	70.0%	61%	$ 139.7	$ 97.8

MS = Milestone value
rMS = Milestone value post progression risk applied

SOURCE: *EY, MedTRACK 2016*

Sensitivity analysis

We have conducted a sensitivity analysis across our model assumptions. We have highlighted three forecast assumptions which we believe are most sensitive to changes and would result in the greatest variance to our forecasts. It should be noted that this sensitivity analysis treats each assumption in isolation. Furthermore, the changes in the key variables are not intended to be indicative of the complete range of variables that may be experienced. In practice, changes in variables may offset each other or be additive and it is likely the PAR management would proactively respond to any adverse changes.

Due to the nature of the pre-approved pharmaceutical assets and reliance on regulatory approval to be able to generate material cashflows, the value of the business is predominately based on future revenues. For this reason, rather than place emphasis on the impact to NPAT within a particular financial year – we focus on the impact to our weighted valuation.

Figure 12: Sensitivity analysis

Assumption variable	Change in value	Change in valuation
Milestone total deal value	+/- 10%	$ 0.03
Royalty rate	+/- 1%	$ 0.06
Peak market penetration	+/- 1%	$ 0.06

SOURCE: MORGANS RESEARCH, COMPANY

Valuation and risks

High and low cases

We have valued PAR using a high and low case which considers the risks associated with clinical stage assets.

Low case: Sum of parts methodology. Based on unsuccessful trial. Valued on cash backing and net assets.

High case: DCF methodology. Commercial success. PAR to partner with global pharma to run Phase 3 trial. Multiple assumptions including addressable market, drug pricing, peak penetration rates, potential partnership deal and structures.

Blended valuation

There are two main variables which are ranged between our scenarios being a commercialisation success factor and historical milestone payout. Our low case reflects trial failure and value based on current net assets of A$16.2m or A$0.16 per share. Likewise, our high case reflects commercial success and results in an NPV of A$295.5m or A$2.10 per share.

The two scenarios provide our valuation range and we set our 12 month price target based on a 38% / 62% blend of the two valuations (high / low case). The weighting is based on a 38% historical Phase 2 progression risks associated with arthritis and pain assets. Given the current share price and the proximity to our price target, we initiate coverage with a Reduce recommendation.

Additional commentary – on successful result in December

While we initiate coverage on a Reduce following the recent rally, there still remains upside potential on a successful Phase 2 result, seeing potential value up to A$1.67 (assuming no change to our other variables) given our commercialisation success rate factor rises from 38% to 78%. We are encouraged by the SAS successes to date, but remain cautious noting PAR has had similar pre-clinical success in its hay fever indication (May-17) to announce shortly after that the trial had failed to meet its primary endpoints (Jun-17). On balance, we view PAR's share price has run too far given the risks and prefer to wait for a pull-back after the OA/BMEL top-line results. We view the receipt of positive top-line results as a significant liquidity event, and may present an opportunity to enter the stock at a reasonable price and volume without the binary risk.

Figure 13: Valuation - Blended low & high case scenario

	Unrisked NPV	Trial failure
Royalties	$203.73	$0.00
Milestones	$102.95	$0.00
Expenses	-$24.43	$0.00
Taxes	-$84.68	$0.00
Net position ($USm)	$16.17	$16.17
Total ($USm)	$213.75	$16.17
Total ($Am)	$295.48	$22.36
Per share	**$2.10**	**$0.16**
Weighting	38%	62%
Valuation	$0.80	$0.10
Weighted valuation	**$0.89**	

SOURCE: MORGANS RESEARCH, COMPANY

We note our high case assumes approval of the lead OA/BMEL indication. Failure of the Phase 2b OA/BMEL trial achieving its primary and secondary end-points may result in significant delays to potential milestone payments and royalty revenues.

Key risks

- **Clinical trial risk:** Despite favourable indications of PPS viability for the treatment of OA/BMEL through SAS treatments to date, there is no guarantee of trial success and subsequent commercialisation of the drug. Unsuccessful results will significantly impact the valuation and adversely affect our valuation and forecasts.
- **Partnership risks:** Due to significant costs associated with Phase 3 trials and bringing a new drug to market, PAR's model includes engaging in strategic partnering deals. Failure or a breakdown in favourable partnerships may be detrimental to the company and its ability to generate future cashflows.
- **Timing risks**: A delay in trial completion may not only push potential partnering deals, it may also affect ideal terms and resulting milestone payments / royalty payments. Due to PAR's cash constraints and trial costs, any significant delay to potential upfront/milestone payments may also adversely affect funding capabilities.
- **Competition risk:** The emergence of increased competition for the treatment of OA/BMEL may impact the market value of the drug through potential pricing pressures, or decreased market share.

Board and management

Figure 14: Board and management

Name	Position	Notes
Graeme Kaufman	Non-executive Chairman	Broad experience in development and commercialisation of pharmaceutical drugs, previously CFO at CSL, executive VP of Mesoblast and Chairman of Bionomics.
Paul Rennie	Managing Director	Extensive experience in drug development and commercialisation, previously COO & Executive VP, New Product Development of Mesoblast.
John Gaffney	Non-executive Director	30+ years experience as a lawyer, previously Director of Patrys.
Christopher Fullerton	Non-executive Director	Chartered Accounting and investment banking expertise, previously Non-executive Chairman of Bionomics and Cordlife (now Life Corporation).
Dr Ravi Krishnan	Chief Scientidic Officer	Significant experience in experimental pathology and investigating novel compounds with immune modulatory effects and anti-inflammatory properties.
Kevin Hollingsworth	CFO & Company Secretary	Previously CFO and Co-Sec of Mesoblast and Patrys.

SOURCE: MORGANS RESEARCH, COMPANY

Substantial shareholders

Figure 15: Substantial shareholders as at FY18 annual report

Name	Position	% of total shares
Paul Rennie and related companies	22,599,543	18.1%
MJGD Nominees Pty Ltd	6,242,286	5.0%
Irwin Biotech Nominees Pty Ltd	5,360,313	4.3%
Nancy Edith Wilson-Ghosh	3,910,935	3.1%
Brett Langan	3,750,000	3.0%

SOURCE: MORGANS RESEARCH, COMPANY

Queensland

Brisbane	+61 7 3334 4888
Stockbroking, Corporate Advice, Wealth Management	
Brisbane: Edward St	+61 7 3121 5677
Brisbane: Tynan Partners	+61 7 3152 0600
Brisbane: North Quay	+61 7 3245 5466
Bundaberg	+61 7 4153 1050
Cairns	+61 7 4222 0555
Caloundra	+61 7 5491 5422
Gladstone	+61 7 4972 8000
Gold Coast	+61 7 5581 5777
Ipswich/Springfield	+61 7 3202 3995
Kedron	+61 7 3350 9000
Mackay	+61 7 4957 3033
Milton	+61 7 3114 8600
Noosa	+61 7 5449 9511
Redcliffe	+61 7 3897 3999
Rockhampton	+61 7 4922 5855
Spring Hill	+61 7 3833 9333
Sunshine Coast	+61 7 5479 2757
Toowoomba	+61 7 4639 1277
Townsville	+61 7 4725 5787

New South Wales

Sydney	+61 2 9043 7900
Stockbroking, Corporate Advice, Wealth Management	
Sydney: Grosvenor Place	+61 2 8215 5000
Sydney: Reynolds Securities	+61 2 9373 4452
Sydney: Currency House	+61 2 8216 5111
Armidale	+61 2 6770 3300
Ballina	+61 2 6686 4144
Balmain	+61 2 8755 3333
Bowral	+61 2 4851 5555
Chatswood	+61 2 8116 1700
Coffs Harbour	+61 2 6651 5700
Gosford	+61 2 4325 0884
Hurstville	+61 2 8215 5079
Merimbula	+61 2 6495 2869
Mona Vale	+61 2 9998 4200
Neutral Bay	+61 2 8969 7500
Newcastle	+61 2 4926 4044
Orange	+61 2 6361 9166
Port Macquarie	+61 2 6583 1735
Scone	+61 2 6544 3144
Wollongong	+61 2 4227 3022

Victoria

Melbourne	+61 3 9947 4111
Stockbroking, Corporate Advice, Wealth Management	
Brighton	+61 3 9519 3555
Camberwell	+61 3 9813 2945
Domain	+61 3 9066 3200
Geelong	+61 3 5222 5128
Richmond	+61 3 9916 4000
South Yarra	+61 3 8762 1400
Southbank	+61 3 9037 9444
Traralgon	+61 3 5176 6055
Warrnambool	+61 3 5559 1500

Australian Capital Territory

Canberra	+61 2 6232 4999

Northern Territory

Darwin	+61 8 8981 9555

Tasmania

Hobart	+61 3 6236 9000

Western Australia

West Perth	+61 8 6160 8700
Stockbroking, Corporate Advice, Wealth Management	
Perth	+61 8 6462 1999

South Australia

Adelaide	+61 8 8464 5000
Norwood	+61 8 8461 2800
Unley	+61 8 8155 4300

Disclaimer
The information contained in this report is provided to you by Morgans Financial Limited as general advice only, and is made without consideration of an individual's relevant personal circumstances. Morgans Financial Limited ABN 49 010 669 726, its related bodies corporate, directors and officers, employees, authorised representatives and agents ("Morgans") do not accept any liability for any loss or damage arising from or in connection with any action taken or not taken on the basis of information contained in this report, or for any errors or omissions contained within. It is recommended that any persons who wish to act upon this report consult with their Morgans investment adviser before doing so. Those acting upon such information without advice do so entirely at their own risk.

This report was prepared as private communication to clients of Morgans and is not intended for public circulation, publication or for use by any third party. The contents of this report may not be reproduced in whole or in part without the prior written consent of Morgans. While this report is based on information from sources which Morgans believes are reliable, its accuracy and completeness cannot be guaranteed. Any opinions expressed reflect Morgans judgement at this date and are subject to change. Morgans is under no obligation to provide revised assessments in the event of changed circumstances. This report does not constitute an offer or invitation to purchase any securities and should not be relied upon in connection with any contract or commitment whatsoever.

Disclosure of interest
Morgans may from time to time hold an interest in any security referred to in this report and may, as principal or agent, sell such interests. Morgans may previously have acted as manager or co-manager of a public offering of any such securities. Morgans affiliates may provide or have provided banking services or corporate finance to the companies referred to in the report. The knowledge of affiliates concerning such services may not be reflected in this report. Morgans advises that it may earn brokerage, commissions, fees or other benefits and advantages, direct or indirect, in connection with the making of a recommendation or a dealing by a client in these securities. Some or all of Morgans Authorised Representatives may be remunerated wholly or partly by way of commission.

This report was prepared solely by Morgans Financial Limited. ASX did not prepare any part of the report and has not contributed in any way to its content. The role of ASX in relation to the preparation of the research reports is limited to funding their preparation, by Morgans Financial Limited, in accordance with the ASX Equity Research Scheme. ASX does not provide financial product advice. The views expressed in this research report may not necessarily reflect the views of ASX. To the maximum extent permitted by law, no representation, warranty or undertaking, express or implied, is made and no responsibility or liability is accepted by ASX as to the adequacy, accuracy, completeness or reasonableness of the research reports.

Regulatory disclosures
Analyst owns shares in the following mentioned company(ies):

Recommendation structure
For a full explanation of the recommendation structure, refer to our website at http://www.morgans.com.au/research_disclaimer

Research team
For analyst qualifications and experience, refer to our website at http://www.morgans.com.au/research-and-markets/our-research-team

Research coverage policy
For an overview on the stock selection process, refer to our website at https://www.morgans.com.au/research-and-markets/company-analysis/Research-Coverage-Policy

Research independence statement
https://www.morgans.com.au/Research-Independence-Statement

Stocks under coverage
For a full list of stocks under coverage, refer to our website at http://www.morgans.com.au/research-and-markets/company-analysis/ASX100-Companies-under-coverage and
http://www.morgans.com.au/research-and-markets/company-analysis/EX-100-Companies-under-coverage

www.morgans.com.au

If you no longer wish to receive Morgans publications please contact your local Morgans branch or write to GPO Box 202 Brisbane QLD 4001 and include your account details.

13.06.18