Paradigm Biopharmaceuticals

PAR.AX

MST Access

A research platform of MST Financial

25 July 2023

Stage 1 PAR-002 trial recruited

NEED TO KNOW

- Stage 1 PAR-002 trial recruitment completed
- Strong supporting clinical data to date
- MST notes change in dosing regimen

Completion of Stage 1 recruitment: Data from Stage 1 will determine the safest and most effective dose for ongoing Phase 3 trials.

Data to date supportive: Phase 2b and PAR-008 study reported statistically significant results at Day 53/56 cohorts respectively at 2mg/kg X 2 weekly dosage. Canine studies are also supportive of longer-term efficacy.

FDA change to Phase 3 dosing: MST notes that the Stage 1 PAR-002 doses, from which the Phase 3 dose will be selected, do not include the most 'effective' dose from Phase 2b and PAR-008 trials.

Investment Thesis

Zilosul® carries lower development risk: Zilosul® is a repurposed injectable form of Pentosan Polysulphate Sodium (PPS). PPS offers safety data from its market launch in the 1950s for cystitis. In addition, efficacy and safety data from PAR's clinical trials and its use in Australia's Special Access Scheme (SAS) for Knee Osteoarthritis (KOA) patients are also supportive.

Higher-than-average probability of approval with caveat: The similarity of the Phase 2b, PAR-008 and Phase 3 trials endpoints supports a higher than average probability that the Phase 3 trial will also deliver a statistically significant result – noting a different dosing regimen. Approval of PPS for OA in horses in December 2022 and PAR's canine study data are supportive.

Unmet need within in a large market: While the current OA markets are large, the approved therapies do not meet the clinical need. Many offer short-term relief only with significant side effects limiting their uptake. In MST's view, approval of Zilosul® as a safe, effective, disease modifying therapy would see significant market uptake and expand the existing market.

Valuation

The safety profile of Zilosul® and clinical data presented to date coupled with the unmet need of OA support MST's DCF valuation of $2.06ps. In MST's view, its share price of $0.96 reflects the general sector trends and market uncertainty around PAR's commercialisation pathway. The DCF valuation may only be realised on confirmation a licensing agreement or other commercial arrangement has been successfully concluded.

Risks

The valuation is subject to the usual drug development risks; regulatory approval, commercial uptake – market entry, market size, market share, pricing, drug supply, competitor products, timing and potential licensing metrics – all may differ to MST assumptions, presenting upside/downside risk. Further funding will be required to complete the planned clinical trial programs.

Equities Research Australia

Biotechnology

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PARADIGM BIOPHARMA

ASX-listed biotechnology company, Paradigm Biopharma's (PAR.AX) strategy is to take already approved medicines that have shown safety and efficacy in one condition and repurpose them for new indications. The aim is to reduce time, cost and risk. Its first candidate is injectable pentosan polysulphate sodium (iPPS), Zilosul®, for use in osteoarthritis of the knee (KOA) and hip (HOA) and mucopolysaccharidosis (MPS), a genetic enzyme disease. Zilosul®'s mechanism of action offers potential application use in a number of other diseases. Clinical data to date have demonstrated benefit with minimal adverse effects.

https://paradigmbiopharma.com

Valuation	**A$2.06ps**
Share Price	**A$0.96ps**
Market cap	**A$272m**
Cash on hand	**A$73.2m (as at Q3FY23)**

Upcoming Catalysts and Newsflow

Period		
H2CY23	Dose for ongoing Phase 3 program determined	12-mont
H2CY23	12-month DMOA data	Topline d
H2CY23	MPS VI & I trial data	

Share Price (A$)

Source: FactSet, MST Access

Figure 1: Financial Summary

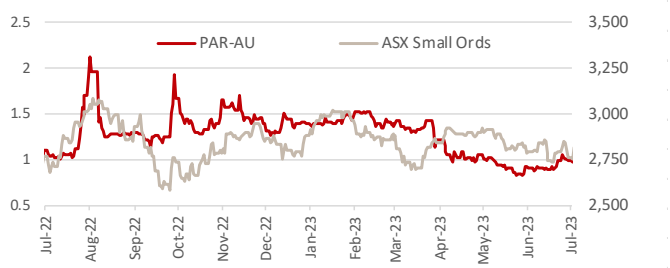
Paradigm Biopharmaceuticals — PAR-AU

Year end 30 June

MARKET DATA

Share Price	**A$/share**	**0.96**
52 week high / low	A$	2.15 - 0.82
Valuation (12 month forward)	**A$**	**2.06**
Market capitalisation	**A$m**	**272**
Shares on issue	m	285
Options	m	4
Other equity	m	70
Potential shares on issue (dilute	m	359

12 month performance



INVESTMENT FUNDAMENTALS		FY21	FY22	FY23E	FY24E	FY25E
EPS Reported (undiluted)	¢	(16.7)	(16.8)	(18.9)	(10.5)	(10.1)
EPS Underlying (undiluted)	**¢**	**(16.7)**	**(16.8)**	**(18.9)**	**(10.5)**	**(10.1)**
Underlying EPS growth	%	n/m	n/m	n/m	n/m	n/m
P/E Reported (undiluted)	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
P/E at Valuation	x	n/m	n/m	n/m	n/m	n/m
Dividend	**¢**	**-**	**-**	**-**	**-**	**-**
Payout ratio	%	0%	0%	0%	0%	0%
Yield	**%**	**-**	**-**	**-**	**-**	**-**

PROFIT AND LOSS (A$)		FY21	FY22	FY23E	FY24E	FY25E
Revenue & Other Income	A$m	8.7	8.7	9.0	31.4	26.1
Expenses	A$m	(43.2)	(48.0)	(63.4)	(70.0)	(63.3)
EBITDA	**A$m**	**(34.5)**	**(39.3)**	**(54.4)**	**(38.6)**	**(37.2)**
D&A	A$m	-	-	-	-	-
EBIT	**A$m**	**(34.5)**	**(39.3)**	**(54.4)**	**(38.6)**	**(37.2)**
Interest	A$m	0.2	0.0	1.1	1.8	1.7
Tax	A$m	-	-	-	-	-
Underlying NPAT	**A$m**	**(34.3)**	**(39.2)**	**(53.2)**	**(36.9)**	**(35.5)**

KEY RATIOS (A$)		FY21	FY22	FY23E	FY24E	FY25E
Forecast year end shares	m	230	233	282	352	352
Market cap (Y/E / Spot)	**$m**	**483**	**225**	**271**	**338**	**338**
Net debt /(cash)	$m	(71)	(40)	(63)	(96)	(60)
Enterprise value	**$m**	**412**	**185**	**208**	**242**	**278**
EV/Sales	x	47.2	21.2	23.2	7.7	10.6
EV/EBITDA	**x**	n/m	n/m	n/m	n/m	n/m
EV/EBIT	x	n/m	n/m	n/m	n/m	n/m
Net debt / Enterpprise Value	x	n/m	n/m	n/m	n/m	n/m
Gearing (net debt / EBITDA)	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Operating cash flow per share	$	(0.2)	(0.1)	(0.1)	(0.1)	(0.1)
Price to operating cash flow	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Free cash flow	**$m**	**(34.3)**	**(32.2)**	**(39.1)**	**(36.9)**	**(35.5)**
Free cash flow per share	$	(0.15)	(0.14)	(0.14)	(0.10)	(0.10)
Price to free cash flow	**x**	**n/m**	**n/m**	**n/m**	**n/m**	**n/m**
Free cash flow yield	**%**	n/m	n/m	n/m	n/m	n/m
Book value / share	$	0.34	0.18	0.22	0.28	0.18
Price to book (NAV)	**x**	**2.8**	**5.3**	**4.4**	**3.4**	**5.3**
NTA / share	$	0.33	0.17	0.21	0.27	0.17
Price to NTA	**x**	**2.9**	**5.7**	**4.6**	**3.5**	**5.5**
EBITDA margin	%	n/m	n/m	n/m	n/m	n/m
ROE (Average Equity)	%	n/m	n/m	n/m	n/m	n/m
ROA (EBIT)	%	n/m	n/m	n/m	n/m	n/m
Interest cover (EBIT / net interes	x	n/m	n/m	n/m	n/m	n/m

BALANCE SHEET (A$)		FY21	FY22	FY23E	FY24E	FY25E
Cash	A$m	71.0	39.7	62.6	95.7	60.2
Receivables	A$m	8.5	6.7	0.7	1.3	1.1
Inventory	A$m	-	-	0.4	0.8	0.7
PPE	A$m	0.1	0.1	0.1	0.1	0.1
Intangibles	A$m	2.9	2.9	2.9	2.9	2.9
Other	A$m	2.2	1.3	1.3	1.3	1.3
Total Assets	**A$m**	**84.8**	**50.7**	**67.9**	**102.1**	**66.2**
Accounts Payable	A$m	5.0	7.1	5.0	1.3	1.1
Borrowings	A$m	-	-	-	-	-
Leases	A$m	0.8	0.6	0.4	0.4	0.4
Provisions	A$m	0.8	0.7	0.8	0.8	0.8
Other	A$m	-	-	-	-	-
Total Liabilities	**A$m**	**6.5**	**8.4**	**6.2**	**2.5**	**2.2**
Shareholder's equity	**A$m**	**78.3**	**42.3**	**61.8**	**99.6**	**64.0**

CASH FLOW (A$)		FY21	FY22	FY23E	FY24E	FY25E
Receipts from customers	A$m	-	0.1	8.1	22.0	26.1
Payments to suppliers and employe	A$m	(38.6)	(41.8)	(55.7)	(70.0)	(63.3)
Milestones, R&D Rebates, Grants	A$m	3.4	9.5	7.4	9.3	-
Interest	A$m	0.3	0.0	1.0	1.8	1.7
Tax	A$m	-	-	-	-	-
Operating cash flow	**A$m**	**(34.9)**	**(32.2)**	**(39.1)**	**(36.9)**	**(35.5)**
Capex	A$m	(0.0)	-	-	-	-
Acquisitions	A$m	-	-	-	-	-
Other	A$m	0.7	-	0.0	-	-
Investing cash flow	**A$m**	**0.7**	**-**	**0.0**	**-**	**-**
Borrowings	A$m	(0.0)	0.1	0.1	-	-
Equity	A$m	1.0	-	62.2	70.0	-
Dividend	A$m	-	-	-	-	-
Financing cash flow	**A$m**	**1.0**	**0.1**	**62.3**	**70.0**	**-**
Change in Cash / FX	A$m	(33.3)	(32.1)	23.2	33.1	(35.5)
Year end cash	**A$m**	**71.1**	**39.7**	**62.6**	**95.7**	**60.2**

Source: MST, Company Reports

Phase 3 dosing considerations

Dose confirmation studies

PAR's Phase 3 program of its Knee Osteoarthritis (KOA) drug Zilosul® progresses with news that it has completed recruitment of the patients for Stage 1 of the PAR-002 clinical trial. At the FDA's request, PAR is undertaking the additional study to confirm the dosing for the pivotal Phase 3 trial trials, PAR-002 and PAR-003. The aim of the Stage 1 study is to determine the 'lowest effective' dose, aiming to maximise the clinical benefit with lowest risk of adverse effects. The FDA will consider factors such as safety, clinical effects and patient convenience in determining the dosing regimen.

PAR's Phase 2b and PAR-008 trials explored two treatment doses - 2mg X2 weekly and 2mg X1 weekly. The FDA has requested a change to the dosing protocols. Stage 1 PAR-002 includes three treatment cohorts;

- 1.5mg/kg of body weight 2X weekly
- 2mg/kg of body weight 1X weekly + placebo 1X weekly
- Fixed doses including 100mg (≤65 kg), 150mg (>65 to ≤90 kg) or 180mg (>90 kg) + placebo 1X weekly
- Placebo 2X weekly

In keeping with the PAR-008 and the Phase 2b trials, patients will receive the treatment for six weeks. The FDA will consider safety and efficacy data from the Stage 1 cohorts as well as data from other clinical studies of PPS to determine the dosing regimen for the ongoing Phase 3 trial program. Patient screening and randomisation to trial dosing arms are expected to be completed during Q3CY23. Confirmation of the dose will allow for the start of Stage 2 PAR-002 and PAR-003 Phase 3 trials. Data from patients in Stage 1 of PAR-002 who have received either the 'confirmed' or placebo dose will be included in the ongoing trial program.

The results of PAR-002 and PAR-003 are planned for late CY24/H1CY25. The primary endpoint for the US Food and Drug Administration (FDA) in the pivotal study is change from baseline at Day 56 in the standardised Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)® pain questionnaire, while the EU's European Medicines Agency (EMA) requires both pain and function as primary endpoints. Secondary endpoints 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. Positive trial results are expected to support approval in the key global markets.

Proof to date

MST reviews the clinical data from PAR's earlier trials to assess the likely outcomes in terms of probability of approval and potential market uptake. In terms of supporting data, MST also notes that Zycosan®, a prescription animal drug containing 250 mg pentosan polysulphate sodium/mL, was approved by the FDA in December 2022 for Osteoarthritis (OA) in horses. It is approved at a dosage of 3.0 mg/kg of body weight (1.4 mg/lb) administered once per week for four weeks. PAR's canine studies have been supportive of both a therapeutic effect and longer-term benefit.

i) Phase 2b trial

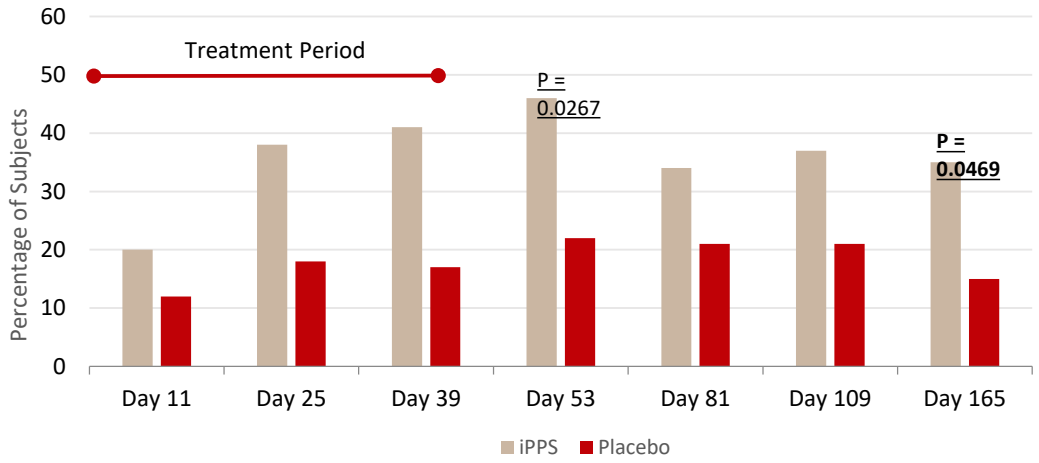
Day 53 data

Dosing for PAR's Phase 2b clinical trial of 112 patients was 2mg/kg body weight twice weekly. It assessed patients by the Knee Injury and Osteoarthritis Outcome Score (KOOS) measurement system. KOOS is an extension of the WOMAC, which is being used in PAR's Phase 3 program. The Phase 2b primary endpoint, pain reduction at Day 53 from the start of the six week (42 day) dosing regimen, was met in the subgroup of the trial cohort, patients within the Numerical Rating Scale (NRS) stratum of 4-6 or moderate pain (~70% of the trial patients). The primary endpoint PGIC was statistically significant at 0.0062 compared to placebo. Patients in the NRS 7-8 (more severe pain) (~30% of the cohort) did not report a statistically significant change. The data were also supportive of secondary endpoints including function, quality of life, volume of bone marrow oedema lesions (BMEL). BMEL, signs of 'swelling' in the bone marrow, are associated with OA pain.

Day 165

Longer term data at Day 165 showed that ~35% of patients reported a greater than 50% reduction in KOOS pain score versus the placebo cohort with ~15% reporting a 50% reduction in pain. The result was clinically meaningful and statistically significant. Positive trends in BMEL changes were also reported.

Figure 2: Phase 2b (NRS 4-6) trial subjects with >50% reduction in KOOS Pain from Baseline



Source: PAR

ii) PAR-008 Biomarker DMOA trial

OA is a multi-modal disease, involving many biological pathways. Biomarkers are objective, quantifiable characteristics of biological processes. Changes in a biomarker can be measured to indicate changes in normal biological and pathogenic processes or responses to a treatment or other intervention. As examples, the Cancer Antigen 125 (CA125) is commonly expressed in ovarian cancer and high cholesterol levels are associated with cardiac disease. From a clinical perspective, changes in these markers can be very helpful in deciding when to prescribe a drug for the patient and/or monitor the effect of a treatment. In the clinical trial setting, biomarkers can be surrogate markers of a treatment effect whereby lower cholesterol levels may support the drug's ability to reduce the risk of a heart attack or a reduction in CA125 a sign of disease regression.

The PAR-008 trial includes 61 subjects with moderate to severe KOA. Subjects received either 2 mg/kg Zilosul® (iPPS) twice weekly, once weekly or placebo injections for six weeks. In keeping with Phase 3 trial, participants are assessed by the WOMAC osteoarthritis index to establish clinical measurements.

The primary endpoints for PAR-008 Phase 2 trial are changes in biomarkers that potentially support a Disease Modifying Osteoarthritis (DMOA) effect - the ability to change the course of the disease rather than address symptoms only. Pain and function are also assessed and therefore provide further data of the probability of approval.

Follow up assessments post treatment at the pre-determined endpoints of Day 56 and 168 days, have been completed. A final clinical review is planned at 12 months post treatment.

Day 56 data

The primary endpoint for PAR-008 Phase 2 clinical trial, was a change in the selected synovial fluid biomarkers at Day 56 following Zilosul® treatment for six weeks. PAR reported that the endpoint was met in the 2 mg/kg Zilosul® (iPPS) twice weekly dosing cohort. Changes including inflammatory cytokines (TNF-α, IL-1β, and IL-6), pain mediator (NGF), and cartilage markers such as COMP, ARGS, and TIMP-1 biomarkers supported reduced pain and inflammation and cartilage preservation. The data are supportive of potential disease modification effect.

PAR also reported that participants receiving 2mg 2X weekly Zilosul® demonstrated a statistically significant improvement at Day 56 in pain, function, stiffness, and overall WOMAC scores compared to the placebo arm. The mean percentage change from baseline in WOMAC pain was 50% lower in Zilosul® treated patients versus 30% lower in the placebo arm. Similarly, WOMAC function showed a 50%

improvement in 2X weekly treatment cohort which compared to 25% in the placebo cohort (p=0.017). The results were in keeping with the Phase 2b trial results. There were no new safety signals.

Day 168 data

PAR reported that data at Day 168 did not show a statistically significant change in pain in either the 2X or 1X weekly treatment cohorts. PAR reported 'persistent responses' out to Day 168 in WOMAC index scores for pain, function, stiffness for 2mg X twice-weekly Zilosul® compared to placebo control. PGIC showed a positive trend for Zilosul® compared to placebo at Day 168 (p=0.061). PAR-008 12-month pain and function data are planned to be released during Q3CY23. In MST's view, duration of effect is important given the treatment burden.

In terms of a DMOA role, trends in biomarkers have supported positive trends in pain reduction, inflammation and cartilage. Magnetic Radiologic Imaging (MRI) data have also showed positive trends in cartilage and bone changes with reduction in both BMELs and cartilage loss in the treatment arm. During the H2CY23, PAR aims to proffer the biomarker data to regulatory agencies (FDA and EMA) as support to discussions on pathways to a disease modification label for Zilosul®. To date, there are no approved DMOA therapies. Safety data through to Day 168 showed no new signals.

PAR-008 12-month clinical (pain and function) data are planned to be released during Q3CY23. In MST's view, safety is not a high risk given the long use of PPS which was first approved in the 1950s.

Stage 1 PAR-002

With the completion of recruitment of patients for Stage 1 of the PAR-002 trial, the next planned milestone is the results of an interim analysis of the patient data. The key purpose of the interim analysis is the selection of the dose regimen for Stage 2 of the PAR-002 and the PAR-003 trials by the trial's Data Monitoring Committee (DMC). The efficacy criteria for the interim analysis are based on endpoints for pain and WOMAC® Functional Index and PGIC score. The DMC will also examine the differences among the three Zilosul® dose and placebo groups. The efficacy and safety data will determine the selection ongoing dose for the Phase 3 trial program.

Approval and Market Uptake

Approval

The primary endpoint for the Phase 3 trial is the change from baseline in WOMAC pain at Day 56. PAR's Phase 2b demonstrated a statistically significant improvement at Day 53 in pain by the KOOS rating scale in participants receiving 2mg/kg body weight twice-weekly Zilosul®. Similarly, PAR reported that participants receiving 2mg/kg twice-weekly Zilosul® dose in its PAR-008 cohort demonstrated a statistically significant improvement at Day 56 in pain, function, stiffness by WOMAC scoring compared to the placebo arm.

MST notes that to date, PAR's clinical studies have only shown a statistically significant effect with a 2mg/kg twice weekly dosing schedule. This dose has not been included in the Stage 1 study. The FDA/EMA considerations were more widely based taking into consideration previous PPS clinical trials and factors such as patient convenience. As noted by MST in previous reports, the twice weekly six week injection regimen, necessitating 12 physician visits, is onerous.

In MST's view, the change in trial protocol brings risk to the assumption that 'success' to date in the Phase 2b and PAR-008 trials brings higher probability of approval in the Phase 3 trial program. Generally, Phase 3 trial aim to repeat /optimise a positive Phase 2 trial protocol in a larger cohort to further enhance the probability of success.

Figure 3: Patient dosing example

Patient Example		Variable Dose		Fixed Dose	PAR Ph 2b , 008 Trials
Phase 3 Dosing	Patient Weight	1.5mg 2X weekly	2mg X 1X weekly	X 1 weekly	2 mg X 2 weekly
≤ 65kg	60kg	180	120	100	240
>65kg ≤ 90kg	80kg	240	160	150	320
> 90kg	100kg	300	200	180	400

Source: PAR

Under the Phase 3 trial dosing options, patients look to receive a lower dosing regimen than those in the clinical trials to date.

Market Uptake

1. **Clinical need:** A strong driver of market uptake is clinical need. OA represents a debilitating disease with no effective, safe therapies. Current treatment is based on short term analgesia and anti-inflammatory medications – many carry significant adverse effects. Joint replacement, commonly the last option, brings high cost and its own complications. Confirmation of a safe, effective, long- lasting treatment is likely to see significant uptake. PAR's data to date support safety and efficacy to Day 53/56.

2. **Prevalence:** From a market size perspective, there is a large potential treatment population. OA is estimated to affect >100m people in the developed world[1] with ~32m patients in the key market of the United States and >40m in Europe. An effective, safe treatment is likely to find a ready market.

3. **Treatment burden/dosing:** In MST's view, the impost of the treatment regimen must be also recognised. The trial's treatment regimens include both weekly and 2X weekly injections by a physician. The statistically significant readout of the PAR-008 study was at Day 56 effectively 14 days post the final injection, the Phase 2b at Day 53 was 11 days post the last dose. Longer term PAR-008 data have been presented as 'persistent response'. In MST's view, the duration of the clinical benefit will be important from both the regulators and patients' viewpoints. MST also notes that KOA is an unmet need and debilitating for many patients.

Investment thesis

- **Zilosul® carries lower development risk**: As a repurposed drug, it offers a higher safety perspective and as a later stage asset commencing Phase 3 trials, lower efficacy risk than earlier stage preclinical/early clinical stage R&D.
- **Higher-than-average probability of approval:** The similarity of the Phase 2b and 3 trials supports a higher probability that the Phase 3 trial will also deliver a statistically significant result – noting MST comments regarding the change in dosing.
- **Large market with current drugs offering only short-term relief and significant adverse effects:** Market opportunity is significant if the Phase 3 trials confirm the data to date of meaningful pain relief and limited adverse effects. If PAR can demonstrate a potential disease-modifying role, there is also likely to be higher market penetration, pricing advantages and potentially longer-term use.

Valuation, Risks, Sensitivities

The safety profile of Zilosul® and clinical data presented to date coupled with the unmet need of OA support MST's DCF valuation of $2.06ps. In MST's view, the share price of $0.96ps reflects both biotechnology sector trends and market concern around the company's ability to fully realise the commercial potential. The unexpected departure its US based CEO, Mr Polizzo sees the company without global commercialisation experience to facilitate a licensing/sale agreement or other commercialisation pathway. In MST's view, the DCF valuation may only be realised on confirmation of the commercialisation pathway. Risk/sensitivities arise from MST's assumptions including - regulatory approval, timing around trials and market entry, licensing/ trade sale metrics, commercial uptake, pricing, market size and PAR's share, drug supply, competitor products, timelines. All may differ to MST assumptions.

1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3519433

Methodology & Disclosures

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