FDA queries not to affect trial outcome timeline

- PAR has received the FDA queries regarding its Investigational New Drug (IND) application to commence its pivotal Phase 3 trial, PAR_002, in the US.
- The queries relate principally to a recently completed animal study. The study was undertaken as part of the feedback PAR received from in its pre-IND meeting with the FDA in April CY20. As announced, the FDA recommended that PAR repeat a number of studies under Good Laboratory Practice (GLP) standards. The original studies had been completed before GLP was implemented.
- PAR believes its responses in combination with mitigation strategies suggested by the FDA will satisfy the queries. It does not believe the trial's timeline will be materially affected. It was planned to start in Q2CY21.
- PAR plans to submit its responses over the next two weeks. The trial is expected to commence recruitment and screening in August CY21, should there be no further queries from the FDA.

In MST's view, the result of the preclinical study is unlikely to reflect a potential safety issue. The view is based on:

- PAR's Zilosul® is an injectable form of Pentosan Polysulphate Sodium (PPS). PPS has been on the market since the 1950's with no serious side effects reported.
- Some 400+ patients have received Zilosul® under compassionate programs in Australia and US with no serious safety concerns raised by the regulators.

Valuation, Risks and Sensitivities

There is no change to MST's valuation of A$974m, $4.25ps. PAR is subject to the usual drug development risks including demonstration of drug efficacy and safety, regulatory approval, timing delays, new competing therapies, funding and market uptake. The model is based on positive results triggering a licensing agreement with milestone payments and royalties to follow.

For further details please visit MST Access Research Notes - **www.mstaccess.com.au**

ASX-listed biotechnology company, Paradigm Biopharma's (PAR) 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 in the knee (KOA) and hip (HOA) and mucopolysaccharidosis (MPS), a genetic enzyme disease. Management presents a strong background in drug development.

Stock	ASX: PAR
Price	A$2.11ps
Market cap	A$481m
Valuation	A$974m

Company data	
Net cash (31/03/21)	$81.1m
Shares on issue	229m
Options / Rights outstanding	2.9m
Primary exchange	ASX

Next steps

Q3CY21: Phase 2b/3 OA_002 to start
Q4CY21: OA_006 trial in treatment extension to start

PAR share price (12 months)

Source: FactSet

Rosemary Cummins
rosemary.cummins@mstaccess.com.au

Financial Summary

Paradigm Biopharma

PROFIT AND LOSS $A	2019A	2020A	2021F	2022F	2023F
Income	3,245,628	4,695,494			43,500,000
R&D Tax Rebate Incentive			43,500	10,000,000	
Research and development expenses	-7,896,708	-12,793,576	-30,000,000	-40,000,000	-45,000,000
Employee expenses	-2,575,983	-1,226,649	-5,000,000	-5,000,000	-5,000,000
General and administration expenses	-1,471,497	-2,939,988	-5,000,000	-5,000,000	-5,000,000
Impairment loss	-6,928,984				
Operating Profit/ Loss	-15,627,544	-12,264,719	-39,956,500	-40,000,000	-11,500,000
Interest Income/Expense	261,710	-34,168	840,875	448,188	195,847
Profit/Loss before income tax	-15,365,834	-12,298,887	-49,669,418	-39,551,812	-11,304,153
Income tax expense / (benefit)					
Net Operating Profit/Loss	-15,627,544	-12,298,887	-49,669,418	-39,551,812	-11,304,153
Other comprehensive Income					

BALANCE SHEET	2019A	2020A	2021F	2022F	2023F
ASSETS					
Current assets					
Cash and cash equivalents	78,836,173	103,922,241	64,806,616	25,254,804	13,950,651
Trade and other receivables	3,532,227	3,509,777	3,553,277	3,553,277	3,553,277
Prepaid expense	137,113	192,380	100,000	100,000	100,000
Financial assets held at amortized cost	6,500,000	746,200		-	
Total current assets	82,505,513	108,370,598	68,459,893	28,908,081	17,603,928
Non-current assets					
Intangible assets	2,981,359	2,947,588	3,000,000	3,000,000	3,000,000
Right-of-use assets		832,917			
Security Deposits Receivable		102,616			
Other	24,029	109,913	24,000	24,000	24,000
Total non-current assets	3,005,388	3,993,034	3,024,000	3,024,000	3,024,000
LIABILITIES					
Current liabilities					
Trade and other payables	2,315,992	2,784,324	1,797,355	1,797,355	1,797,355
Employee benefits	388,591	455,510	400,000	400,000	400,000
Lease Liabilities		124,731			
Total current liabilities	2,704,583	3,364,565	2,197,355	2,197,355	2,197,355
Non Current Liabilities		817,348	220,444	220,444	220,444
Net assets	82,806,318	108,181,719	69,066,094	29,514,282	18,210,129
EQUITY					
Issued capital	109,468,292	145,865,076	145,865,076	145,865,076	145,865,076
Share based payments reserve	4,072,844	3,585,189	3,585,189	3,585,189	3,585,189
Accumulated losses	-30,734,818	-41,268,546	-80,384,171	-119,935,983	-131,240,136
TOTAL EQUITY	82,806,318	108,181,719	69,066,094	29,514,282	18,210,129

CASHFLOW	2019A	2020A	2021F	2022F	2023F
Cash flows from operating activities					
Operational Income					43,500,000
Research and development tax incentive received	2,318,718	3,621,355	43,500	10,000,000	
Payments for Phase III and II/III Trials			-30,000,000	-40,000,000	-45,000,000
Payments to suppliers and employees (Inclusive of GST)	-8,773,072	-14,797,407	-10,000,000	-10,000,000	-10,000,000
Interest received	89,259	1,120,163	840,875	448,188	195,847
Net cash outflow from operating activities	-6,365,095	-10,090,057	-39,115,625	-39,551,812	-11,304,153
Cash flows from investing activities					
Payments for intangible assets	-4,198	-3,353			
Payments for plant and equipment	-17,781	-127,537			
Payments for financial assets held at amortized cost	-6,500,000	5,753,800			
Net cash outflow from investing activities	-6,521,979	5,622,910			
Cash flows from financing activities					
Proceeds from the issue of share capital	86,962,482	35,000,000			
Proceeds from exercise of share options	1,084,854	1,839,328			
Payments of share issue costs	-5,269,719				
Net cash inflow from financing activities	82,777,617	36,053,215			
Net increase/ (decrease) in cash and cash equivalents	69,890,543	31,586,068	-39,115,625	-39,551,812	-11,304,153
Cash at the beginning of the financial period	2,445,630	72,336,173	103,922,241	64,806,616	25,254,804
Cash at the end of the financial period	72,336,173	103,922,241	64,806,616	25,254,804	13,950,651

Source: PAR reports, MST estimates

Snapshot of Paradigm Biopharma (PAR.AX)

- Repurposing polysulphate pentosan (Zilosul®) for knee & hip osteoarthritis, presenting a lower safety risk
- Zilosul® trial data have demonstrated more effective relief and lower side effects to current therapies
- Positive results in Phase 3 trials will support application for US and EU approval
- Pivotal Phase 3 Trial, PAR_002 readout is planned for Q1CY23
- PAR owns the IP presenting licensing opportunities

Investment thesis

1. **Zilosul® carries lower risk** as a re purposed drug and a later stage asset as it enters Phase 3 trial.
2. **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 repeat a statistically significant Phase 2b result.
3. **Large market with current drugs offering only short-term relief and significant adverse effects:** Market opportunity is significant if the Phase 3 data confirm the data to date of meaningful pain relief and limited adverse effects. If the data from the OA_008 trial support Zilosul's disease-modifying ability, as potentially the first approved OA drug to do so, there is also likely to be very strong interest from licensing partners as well as from clinicians and patients.
4. **Funding**: MST model assumes that a licensing agreement before or on the news of positive results of the KOA pivotal trial in Q1CY23 will help fund the expanded trial program.
5. **Revenues**: First revenues are expected over CY21 from post Ross River Virus arthralgia patients under the Australian SAS. The model assumes revenue from a KOA licensing deal on release of Phase 3 data over CY23, with sales revenues in late CY24/early CY25. TGA provisional approval sales for KOA are expected from CY24.

Valuation

MST's risk-adjusted discounted cash flow valuation of $974m or $4.25 per share compares to its $481m market capitalisation or $2.11 per share. The valuation includes assumptions of probability of approval, commercial performance and is subject to the usual sensitivities/risks regarding trial delay, competitor activity, market size, pricing, patient usage, product supply, timing of regulatory approval and reimbursement. They present upside and downside risk to our valuation assumptions. The ongoing COVID pandemic presents risk of delay and potential further costs.

The model assumes sufficient funding for OA_002 and OA_003 with further funding needed …) to complete the total trial program. MST believes that the target indication and novel aspects of Zilosul® are likely to attract corporate and investor interest. The valuation includes the use of iPPS as Zilosul® in both knee and hip OA and in mucopolysaccharidosis (MPS). It does not ascribe any value to other potential clinical applications.

CY21 Newsflow

***√* Q1CY21 – Commence clinical trial OA_008**

√ Q1CY21 – Investigational New Drug (IND) submission to FDA - in progress

Q3CY21 – Commence Phase 2b/3 OA 002

Q4CY21 – Commence OA_006 trial in treatment extension

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Level 13, 14 Martin Place, Sydney, NSW 2000
Main +61 2 8999 9988
www.mstfinancial.com.au

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