Last Steps to Approval & Re-rating?

The submission of Paradigm Biopharma (PAR.AX)'s Investigational New Drug (IND) application to the US FDA has started a 30 day clock to approval to commence the Phase 3 trials of its drug, Zilosul™, in knee osteoarthritis (KOA). PAR also plans a Phase 3 trial in the EU. Positive trial results will potentially open markets of MSTe of US$5bn.

The FDA has until April 25 to review the IND and raise any queries. PAR appears well prepared. It has held a number of meetings with both the FDA and EMA to discuss their requirements including animal pharmacology and toxicology studies, manufacturing information and the proposed clinical protocols. As a repurposed drug, Zilosul™, carries long term safety data and it has been prescribed in KOA to some 400+ patients under the Australian Special Access Scheme and the US Expanded Access program. To date, no safety concerns have been raised.

Data Support Significant Market Opportunity

The US KOA trial program from Q2CY21 will comprise a Phase 2b trial to confirm once or twice weekly dosing, and then follow with the pivotal Phase 3 trial, OA_002. Approval by the FDA and EMA requires a confirmatory trial. OA_003 of 700 patients in the EU is planned to start in Q4CY22.

While the final results of OA_002 are not expected until CY24, an interim readout is planned for Q1CY23. The results are likely to be viewed as indicative of the final outcome and if positive, see a significant appreciation of the stock. MST estimates FDA approval in FY24 with market entry in FY25. The current treatment options for the OA market are lacking and present a strong opportunity for Zilosul™ if the trials confirm its trial data to date - extended, meaningful pain relief with no significant side effects.

Valuation, Risks and Sensitivities

There is no change to MST valuation of A$974m, $4.25ps m. It 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.

Paradigm Biopharma (PAR) is an ASX-listed biotechnology company with a strategy 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$2.51ps
Market cap	A$575m
Valuation	A$974m

Company data	
Net cash (31/12/20)	$85.92m
Shares on issue	229m
Options/ and rights outstanding	2.9m
Primary exchange	ASX

Next steps

Q1/2CY21: Clinical trial OA_008 to start
Q2CY21: 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)

For further details please visit MST Access Research Notes - PAR.AX Report 02.02.2021 **www.mstaccess.com.au**

- Repurposing polysulphate pentosan (Zilosul) for knee & hip osteoarthritis -lower safety risk
- Zilosul™ trial data have shown more effective relief and lower side effects to current therapies
- Positive results in Phase 3 trials will support application for US and EU approval
- Phase 3 Trial readout planned for Q1CY23
- PAR owns the IP creating 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. Data from the OA_008 trial to support disease-modifying ability are also likely to drive strong interest from licensing partners 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 risk-adjusted discounted cash flow valuation of $974m or $4.25 per share compares to $559m market capitalisation, $2.44ps. 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 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 based on 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.

Expected CY21 Newsflow

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

Q1CY21 – Commence clinical trial OA_008 - 18.02.21 Ethics approval for Phase 2 study

Q2CY21 – Commence Phase 2b/3 OA 002

Q4CY21 – Commence OA_006 trial in treatment extension

Disclaimers

MST Access is a registered business name of MST Financial Services Pty Ltd (ACN 617 475 180 "MST Financial") which is a limited liability company incorporated in Australia on 10 April 2017 and holds an Australian Financial Services Licence (Number: 500 557). This research is issued in Australia through MST Access which is the research division of MST Financial. The research and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by MST Access is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a particular financial product you should read any relevant Product Disclosure Statement or like instrument.

This report has been commissioned by Paradigm Biopharma and prepared and issued by Rosemary Cummins of MST Access in consideration of a fee payable by Paradigm Biopharma, MST Access receives fees from the company referred to in this document, for research services and other financial services or advice we may provide to that company. The analyst has received assistance from the company in preparing this document. The company has provided the analyst with communication with senior management and information on the company and industry. As part of due diligence, the analyst has independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in the report. Diligent care has been taken by the analyst to maintain an honest and fair objectivity in writing this report and making the recommendation. Where MST Access has been commissioned to prepare Content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid will either directly or indirectly impact the Content provided.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of MST Access at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, MST Access shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained on this note. No guarantees or warranties regarding accuracy, completeness or fitness for purpose are provided by MST Access, and under no circumstances will any of MST Financials' officers, representatives, associates or agents be liable for any loss or damage, whether direct, incidental or consequential, caused by reliance on or use of the content.

General Advice Warning

MST Access Research may not it be construed as personal advice or recommendation. MST encourages investors to seek independent financial advice regarding the suitability of investments for their individual circumstances and recommends that investments be independently evaluated. Investments involve risks and the value of any investment or income may go down as well as up. Investors may not get back the full amount invested. Past performance is not indicative of future performance. Estimates of future performance are based on assumptions that may not be realised. If provided, and unless otherwise stated, the closing price provided is that of the primary exchange for the issuer's securities or investments. The information contained within MST Access Research is published solely for information purposes and is not a solicitation or offer to buy or sell any financial instrument or participate in any trading or investment strategy. Analysis contained within MST Access Research publications is based upon publicly available information and may include numerous assumptions. Investors should be aware that different assumptions can and do result in materially different results.

MST Access Research is distributed only as may be permitted by law. It is not intended for distribution or use by any person or entity located in a jurisdiction where distribution, publication, availability or use would be prohibited. MST makes no claim that MST Access Research content may be lawfully viewed or accessed outside of Australia. Access to MST Access Research content may not be legal for certain persons and in certain jurisdictions. If you access this service or content from outside of Australia, you are responsible for compliance with the laws of your jurisdiction and/or the jurisdiction of the third party receiving such content. MST Access Research is provided to our clients through our proprietary research portal and distributed electronically by MST to its MST Access clients. Some MST Access Research products may also be made available to its clients via third party vendors or distributed through alternative electronic means as a convenience. Such alternative distribution methods are at MST's discretion.

Access and Use

Any access to or use of MST Access Research is subject to the Terms and Conditions of MST Access Research. By accessing or using MST Access Research you hereby agree to be bound by our Terms and Conditions and hereby consent to MST collecting and using your personal data (including cookies) in accordance with our Privacy Policy (https://mstfinancial.com.au/privacy-policy/), including for the purpose of a) setting your preferences and b) collecting readership data so we may deliver an improved and personalised service to you. If you do not agree to our Terms and Conditions and/or if you do not wish to consent to MST's use of your personal data, please do not access this service.

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

MST ACCESS