Research Update
Paradigm Bio Limited (ASX:PAR)
FDA clearance for Phase 3

Price: $0.535 | Valuation: $2.07 | Implied Return: 287% |10 December, 2024

Business Summary

Paradigm Biopharmaceuticals (PAR) is investigating injectable Pentosan polysulfate sodium (iPPS), a previously Food and Drug Administration (FDA) approved drug to treat Osteoarthritis (OA). PPS is a semi-synthetic drug manufactured from beech-wood hemicellulose and has been used in humans for decades. Over 31m people suffer from OA in the US alone and this is expected to increase by 86% to 67m by 2030. Paradigm is looking to market the drug as a subcutaneous injectable, trademarked ZILOSUL®, with phase III studies currently underway.

Update – Phase 3 trial design FDA approved

After the FDA type D meeting response in April, PAR received a clearer pathway for progression for the phase 3 clinical program. As previously outlined, PARA_005 and PARA_OA_008 demonstrated significant improvements in pain, function and overall WOMAC measures compared to placebo. Both top line results were achieved using 2mg per kg iPPS once or twice weekly or placebo. Post discussion around the results of optimal dosage as a result of PARA_OA_002 PAR use the dosing regime to 2mg/kg iPPS administered twice weekly. Post feedback from the FDA in September, PAR submitted trial amendments to the FDA regarding the monitoring and mitigation plan, and statistical guidance.

In October, PAR submitted an updated protocol to the FDA under the open investigational New Drug (IND) application for its updated phase 3 PARA_OA_012 trial. The FDA raised no questions or concerns, and PAR is now ready to proceed with its pivotal phase 3 trial. Patient enrolment will commence Q1 CY2025, with the primary endpoint being the change from baseline in pain. Key secondary endpoints are the change in pain and function assessment from baseline up to day 404 and the patient global impression of change. The trail will look to enroll 466 participants randomized 1:1 between iPPS and placebo and run for 52 weeks. Initially enrolment will be at 10 clinical sites in Australia followed by sites in the USA. Patient global impression of change and structural changes will be measured by MRI and X-ray. An interim analysis is planned when 50% of subjects reach the Day 112 follow-up. This will show potential early efficacy.

To fund the trial PAR has raised $16m at an issue price of $0.40 which gives it a cash balance of $26.9m

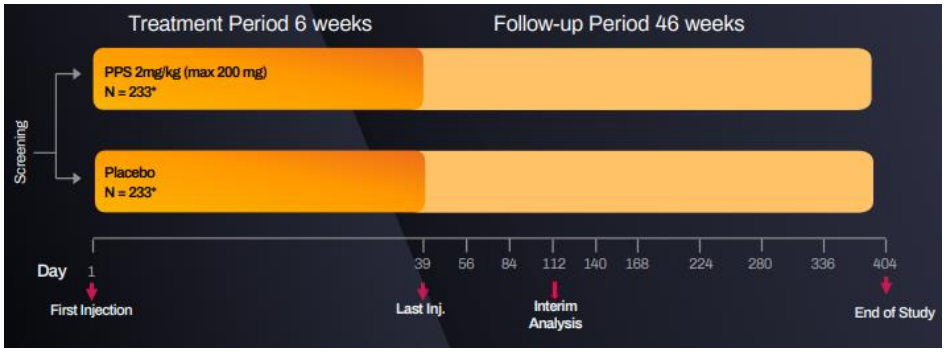

Figure 1 source: Company Data

Recommendation

FDA clearance for PAR's pivotal phase 3 trial ends a 12+ month approval process. This delay has caused additional dilution of the share price at lower prices and will push out commercialization and first sales milestones, should the phase 3 trial be successful. We still see the huge potential, with a market size of US$10bn+ per annum and lack of non-opioid based treatments as key components to recognizing growing market share. We still hold the assumption that the company could charge US$2,500 per patient per year for Zilosul®. PARA_OA_012 top line results are likely due at the beginning of CY26 with efficacy and safety readout middle of CY26. We now see commercialisation and first sales occurring in CY28, two years later than our previous forecast. PAR has recently undertaken a funding round to fund the upcoming trial which may see it through the phase 3 trial and additional funding risk cannot be ruled out. However, we have not factored in any additional equity funding in our valuation but the additional dilution and delay in potential commercialisation has lowered our valuation to $2.07. The upside from current levels is still significant at 287%.

Company Data

Recommendation: BUY
ASX Code: PAR
Shares on Issue: 389.3m
Market capitalization: $208.3m
Enterprise Value: $181.4m
12-month price range: $0.17-$0.61

Board Structure

Paul Rennie: Chairman & Managing Director
Matthew Fry: Non-Exec Director
Amos Meltzer: Non-Exec Director

Major Shareholders

HSBC Custody Nominees: 4.59%
Citicorp Nominees Pty Ltd 4.34%
Collins St Value Fund: 4.32%
Total Top 20: 33.31%

Chart

Source: Iress

Year ending June	2024A	2025E	2026E	2027E	2028E
NPAT	(59.3)	(23.6)	(23.6)	(23.6)	76.4
EPS_{adj} (¢)	**(0.2)**	**(0.1)**	**(0.1)**	**(0.1)**	**0.20**
EPS growth		**0.0%**	**0.0%**	**0.0%**	**424%**
P/E ratio	**N/A**	**N/A**	**N/A**	**N/A**	**2.7 x**
Enterprise Value (m)	190	197	219	242	163.5
EV/Sales (x)	0.00 x	0.00 x	0.00 x	0.00 x	0.47 x
EV / EBIT (x)	-3.2 x	-8.4 x	-9.3 x	-10.2 x	2.1 x
EV / EBITDA (x)	-2.9 x	-6.6 x	-7.3 x	-8.0 x	2.3 x
DPS ($)	0.00	0.00	0.00	0.00	0.00
Dividend Yield	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**
Payout Ratio	0.0%	0.0%	0.0%	0.0%	0.0%
Franking	N/A	N/A	N/A	N/A	N/A
FCFPS (¢)	(0.15)	(0.06)	(0.06)	(0.06)	0.20
P/FCFPS	(3.51)	(8.83)	(8.83)	(8.83)	2.73

Cashflow (A$m)

Year ending June	2024A	2025E	2026E	2027E	2028E
Receipts	0.08	0.00	0.00	0.00	349.53
Payment to suppliers	(74.19)	(30.19)	(30.19)	(30.19)	(279.60)
Interest on lease	0.00	0.00	0.00	0.00	0.00
Interest received	0.85	0.85	0.85	0.85	0.85
R&D	7.33	7.33	7.33	7.33	7.33
Income Tax	0.00	0.00	0.00	0.00	0.00
Operating cashflow	**(65.94)**	**(22.03)**	**(22.03)**	**(22.03)**	**78.09**
Investing cashflows					
Purchase of intangibles	0.00	0.00	0.00	0.00	0.00
Purchase of PPE	0.00	0.00	0.00	0.00	0.00
Financing activities					
Proceeds of shares	30.12	16.00	0.00	0.00	0.00
Share issue costs	(1.84)	0.00	0.00	0.00	0.00
Net cashflow	**(37.77)**	**(6.97)**	**(22.07)**	**(22.07)**	**78.05**
Cash at beginning year	56.33	17.82	10.85	(11.21)	(33.28)
Cash at 30/06	**17.82**	**10.85**	**(11.21)**	**(33.28)**	**44.77**

Revenue Split (A$m)

Year ending June	2024A	2025E	2026E	2027E	2028E
Sales Revenue	-	-	-	-	349.45
Other	6.52	6.52	6.52	6.52	6.52
Group Revenue	**6.52**	**6.52**	**6.52**	**6.52**	**355.97**

Profit and loss (A$m)

Year ending June	2024A	2025E	2026E	2027E	2028E
Operating revenue	0.0	0.0	0.0	0.0	349.5
EBITDA	(65.1)	(30.1)	(30.1)	(30.1)	69.9
D&A	0.0	0.0	0.0	0.0	0.0
EBIT	**(59.3)**	**(23.6)**	**(23.6)**	**(23.6)**	**76.4**
Net interest income	0.0	0.0	0.0	0.0	0.0
NPBT	(59.3)	(23.6)	(23.6)	(23.6)	76.4
Tax Expense (benefit)	0.0	0.0	0.0	0.0	0.0
NPAT	**(59.3)**	**(23.6)**	**(23.6)**	**(23.6)**	**76.4**
Significant Items	0.0	0.0	0.0	0.0	0.0
NPAT	**(59.3)**	**(23.6)**	**(23.6)**	**(23.6)**	**76.4**
EBITDA Margin	N/A	N/A	N/A	N/A	20.0%
EBIT Margin	N/A	N/A	N/A	N/A	21.9%
NPAT Margin	N/A	N/A	N/A	N/A	21.9%

Balance sheet (A$m)

Year ending June	2024A	2025E	2026E	2027E	2028E
Bank Balance	17.8	10.9	(11.2)	(33.3)	44.8
Receivables	5.1	5.1	5.1	5.1	5.1
Inventories	0.0	0.0	0.0	1.3	1.3
Other	0.05	0.05	0.05	0.05	0.05
Current assets	24.25	17.29	-4.78	-26.85	51.20
Net PPE	0.0	0.0	0.0	0.0	0.0
Intangibles	2.95	2.95	2.95	2.95	2.95
Right of use assets	0.16	0.16	0.16	0.16	0.16
Non-current assets	**3.14**	**3.14**	**3.14**	**3.14**	**3.14**
Total assets	**27.39**	**20.42**	**(1.64)**	**(23.71)**	**54.34**
Payables	2.82	2.82	2.82	2.82	2.82
Lease liabilities	0.24	0.23	0.23	0.23	0.23
Employee benefits	0.42	0.42	0.42	0.42	0.42
Total liabilities	**3.58**	**3.58**	**3.58**	**3.58**	**3.58**
NET ASSETS	**23.80**	**16.84**	**(5.23)**	**(27.29)**	**50.76**

Balance Sheet Ratios

Year ending June	2024A	2025E	2026E	2027E	2028E
Net Debt	(18)	(11)	11	34	(45)
NTA	23.80	16.84	-5.23	-27.29	50.76
Price / NTA (x)	0.022 x	0.032 x	-0.102 x	-0.020 x	0.011 x
Return on assets	-216.6%	-115.5%	1435.3%	99.5%	140.5%
Return on equity	-249.2%	-11289.0%	100.9%	50.2%	259.9%

Valuation

Year ending June			
Discounted Cash Flow	WACC		15.00%
	Discount Period		6 years
	Price Target	**$**	**2.07**

Rating

BUY – anticipated stock return is greater than 10%

SELL – anticipated stock return is less than -10%

HOLD - anticipated stock return is between -10% and +10%

SPECULATIVE BUY – high risk stock with price likely to fluctuate by 50% or more and anticipated return is greater than 10%

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