

Cynata Therapeutics Limited (CYP.AX)
Rating: Buy

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Positive CYP-001 Two-Year Long-Term Follow-Up Clinical Data; Reiterate Buy

Stock Data		07/31/2020		
Price		A\$0.63		
Exchange		ASX		
Price Target		A\$2.00		
52-Week High		A\$1.80		
52-Week Low		A\$0.58		
Enterprise Value (M)		A\$67		
Market Cap (M)		A\$73		
Public Market Float (M)		82.7		
Shares Outstanding (M)		117.1		
3 Month Avg Volume		324,250		
Balance Sheet Metrics				
Cash (M)		A\$5.90		
Total Debt (M)		A\$0.00		
Total Cash/Share		A\$0.05		
Book Value/Share		A\$0.09		
EPS Diluted				
Full Year - Jun	2019E	2020E	2021E	
FY	(0.06)A	(0.07)	(0.04)	



Impressive CYP-001 long-term efficacy data in GvHD. Late last week, Cynata announced positive results from the two-year follow-up of patients who were originally enrolled in the Phase 1 clinical trial of its lead candidate CYP-001. As a reminder, this study was designed to evaluate the safety and efficacy of CYP-001—an induced pluripotent stem cell (iPSC)-derived Cymerus™ platform-generated mesenchymal stem cell (MSC) product—in treatment of patients with steroid-resistant acute graft-vs. host disease (aGvHD). The long-term dataset indicated that the overall survival rate after two years was 60% (nine out of a total 15 patients), which compares very favorably to historical published outcomes in this patient population. Notably, a 34% six-month (i.e., 180-day) survival rate was previously disclosed for remestemcel-L despite 8-12 infusions being administered in that program vs. only two infusions of CYP-001 received per patient in Cynata's trial. In another recently-published Phase 3 trial of an investigational drug (ruxolitinib)—currently sold under the trade names Jakafi and Jakavi by Incyte Pharmaceuticals (INCY; not rated) and Novartis (NVS; not rated) for the treatment of the hematological disorders myelofibrosis and polycythemia vera—in patients with steroid-resistant aGvHD, overall survival after 12 months was 38%, while there were insufficient surviving patients remaining to calculate the survival rate at later time points. A two-year overall survival rate of just 17% has been reported for patients receiving standard-of-care therapy. Cynata also reported that no treatment-related serious adverse events (SAEs) or safety concerns were identified with CYP-001 in the GvHD trial. Despite the small sample size, we are encouraged by CYP-001's long-term efficacy and safety profile and look forward to the initiation of Phase 2 testing. We reiterate our Buy rating and 12-month target of A\$2.00 per share.

Prior data from primary evaluation underscored efficacy. We note that in late 2018 Cynata announced primary evaluation data from this Phase 1 study of CYP-001 at 100 days. On Day 100, the complete response and overall response rates observed were 53% and 87% respectively, while the overall survival rate was at least 87%. As a reminder, all clinical endpoints were stated to have been met in the Phase 1 study; Cynata's partner FUJIFILM is making preparations to advance CYP-001 into Phase 2 development in the GvHD indication. Investors may recall that, in September 2019, FUJIFILM exercised its option to execute a worldwide exclusive license to CYP-001. We believe that FUJIFILM is committed to advancing the product and ought to be highly enthused by the two-year data from the Phase 1 trial.

Valuation and risks. We have used a discounted cash flow (DCF)-based approach that assigns a value of A\$200M to Cynata, based upon the valuation of the platform on collaboration-based revenue only, with a 12 - 18% royalty rate range, along with an 11% discount rate. Our valuation translates into a price objective of A\$2.00 per share, based on 120M fully-diluted shares outstanding. This includes the exercise of roughly 3.2M outstanding options. Risks include, but are not limited to: (1) delays in trial enrollment; (2) inability to consummate further partnerships; and (3) adverse results from other clinical trials.



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Table 5: Cynata Therapeutics, Inc. (CYP.AX) – Historical Income Statements, Financial Projections

FY end June 30

A\$ in thousands, except per share data

	2019A			2019A	2020E				2020E	2021E	
	1HA	2HA			1HA	2HE					
Revenue											
Interest income	-	129	-	76	205	-	76	-	-	76	-
Other income	-	1,309	-	4,450	5,758	-	4,450	-	-	4,450	5,000
Total revenue	-	1,438	-	4,526	5,964	-	4,526	-	-	4,526	5,000
Operating expenses											
Product development and marketing costs	-	(2,227)	-	(4,431)	(6,658)	-	(4,431)	-	(4,000)	(8,431)	(8,500)
Employee benefits expenses	-	(368)	-	(537)	(906)	-	(537)	-	(550)	(1,087)	(1,250)
Share based payments expenses	-	(699)	-	(274)	(973)	-	(274)	-	-	(274)	-
Depreciation and amortisation expenses	-	(140)	-	(140)	(280)	-	(140)	-	-	(140)	-
Other operational expenses	-	(984)	-	(1,691)	(2,676)	-	(1,691)	-	-	(1,691)	-
Total expenses	-	(4,419)	-	(7,074)	(11,493)	-	(7,074)	-	(4,550)	(11,624)	(9,750)
Gain (loss) from operations	-	(2,981)	-	(2,549)	(5,529)	-	(2,549)	-	(4,550)	(7,099)	(4,750)
Other income (expense)											
Other income (expense)	-	-	-	-	-	-	-	-	-	-	-
Interest income (expense)	-	-	-	-	-	-	-	-	-	-	-
Total investment income and other	-	-	-	-	-	-	-	-	-	-	-
Loss before income tax	-	(2,981)	-	(2,549)	(5,529)	-	(2,549)	-	(4,550)	(7,099)	(4,750)
Income tax expense	-	-	-	-	-	-	-	-	-	-	-
Net loss	-	(2,981)	-	(2,549)	(5,529)	-	(2,549)	-	(4,550)	(7,099)	(4,750)
Net loss per share (basic) in cents	-	(0.03)	-	(0.03)	(0.06)	-	(0.02)	-	(0.04)	(0.07)	(0.04)
Net loss per share (diluted) in cents	-	(0.03)	-	(0.03)	(0.06)	-	(0.02)	-	(0.04)	(0.07)	(0.04)
Weighted average number of shares outstanding (basic)	95,116	98,501	101,885	101,885	99,347	102,452	102,452	102,502	116,461	105,966	117,103
Weighted average number of shares outstanding (diluted)	95,116	98,501	101,885	101,885	99,347	102,452	102,452	102,502	116,461	105,966	117,103

Source: Company reports and H.C. Wainwright & Co. estimates.

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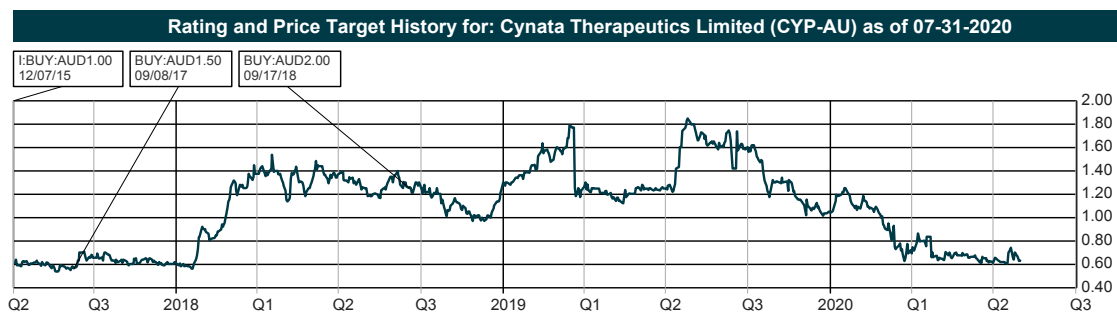
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Ratings	Count	Percent	IB Service/Past 12 Months	
			Count	Percent
Buy	404	90.58%	150	37.13%
Neutral	39	8.74%	9	23.08%
Sell	0	0.00%	0	0.00%
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