

Diabetic foot ulcer trial good to go

Cynata has now met all requirements to commence its Phase 1 clinical trial of CYP-006TK in patients with diabetic foot ulcers (DFUs) after receiving ethics approval from the Central Adelaide Local Health Network Human Research Ethics Committee and clearance from the Therapeutic Goods Administration, and successfully completing the Site Initiation Visit (SIV).

Diabetic foot ulcers (DFUs):

Common and costly; high unmet need

DFUs are one of the most severe consequences of diabetes. The global prevalence of DFUs in diabetic patients averages 6.4%, varying from 3% in Oceania to 13% in North America. The condition is more frequent in older patients. The annual incidence of DFUs and necrosis¹ in diabetic patients is known to be about 2%–5%, and the lifetime risk ranges from 15% to 20%. Treatment of DFUs involve a multidisciplinary approach and costs the US healthcare system an average of US\$8,659 per patient annually in diabetic foot care. The total medical cost for the management of diabetic foot disease in the United States is US\$9–US\$13bn.

CYP-006TK: topically applied MSCs

CYP-006TK is a polymer-coated silicon wound dressing seeded with Cymerus™ mesenchymal stem cells (MSCs) to facilitate topical application to the wound. Cynata has exclusively licensed the dressing technology from leading manufacturer of innovative biomedical coatings, TekCyte Limited.

Clinical trial design: 30 patients, 4 weeks

In the Phase I DFU trial (protocol number CYP-DFU-P1-01), 30 adult patients with DFUs will be randomly assigned to receive either CYP-006TK or standard of care² (SOC) treatment over 4 weeks. Each patient will be evaluated for a total of 24 weeks. The trial will take place at Royal Adelaide Hospital and The Queen Elizabeth Hospital, Adelaide, under the leadership of Professor Robert Fitridge (Professor of Vascular Surgery at the University of Adelaide and Consultant Vascular Surgeon with the Central Adelaide Local Health Network).

Valuation

We value Cynata Therapeutics at A\$396m or A\$2.76 per share on an undiluted basis (143.3m shares as at 30 June 2021), using a risk-adjusted net present value (rNPV) method to discount future cash flows through to 2034, consistent with the expiry of current patent families. Our fair value estimate incorporates a probability weighting of 58% for finding a new development partner for Japan in graft-versus-host disease (GvHD) near term and an AUD/USD exchange rate of 0.78.

¹ Necrosis is the death of body tissue

² Typically, a standard wound dressing product



Cynata Therapeutics Limited is a clinical-stage stem cell and regenerative medicine company. It is leveraging its proprietary therapeutic stem cell platform technology, Cymerus™, originally based on discoveries made at the University of Wisconsin–Madison (UWM), a global centre of excellence in stem cell research, to develop allogeneic (off the shelf) induced pluripotent stem cell (iPSC)-derived MSC therapeutic products.

Stock	CYP
Price	A\$0.54
Market cap	A\$78m
Valuation	A\$2.76

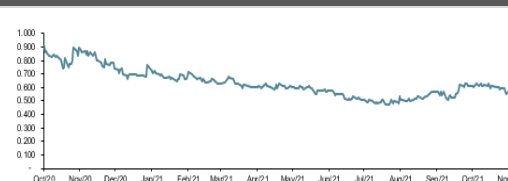
Company data

Net cash	A\$23.9m (Sept 2021)
Shares on issue	143.3m
Code ASX	CYP

Next news

CYP-001	Phase 2 in respiratory failure
CYP-004	Phase 2 in knee osteoarthritis
CYP-001	Phase 2 in aGvHD
CYP-006TK	Phase 1 in diabetic foot ulcers

CYP share price (A\$)



Source: FactSet

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Financials

Cynata						CYP-AU											
Year end 30 June, AUD unless otherwise noted																	
MARKET DATA						12-MONTH SHARE PRICE PERFORMANCE (A\$)											
Price	\$	0.54															
52 week high / low	\$	0.47-0.91															
Valuation	\$	2.76															
Market capitalisation	\$m	78.3															
Shares on issue (basic)	m	143.3															
Options / rights	m	3.2															
Other equity	m	0.0															
Shares on issue (diluted)	m	146.4															
INVESTMENT FUNDAMENTALS																	
Reported NPAT	\$m	(8.5)	(3.6)	(7.7)	(0.9)	(5.4)	PROFIT AND LOSS	FY19A	FY20A	FY21A	FY22E	FY23E					
Underlying NPAT	\$m	(8.5)	(3.6)	(7.7)	(0.9)	(5.4)	Revenue	\$m	0.0	0.0	0.0	0.0	2.3				
Reported EPS (diluted)	c	(8.5)	(3.5)	(5.9)	(0.6)	(3.8)	Other income	\$m	1.3	7.0	1.6	8.3	1.4				
Underlying EPS (diluted)	c	(8.5)	(3.5)	(5.9)	(0.6)	(3.8)	Total Revenue	\$m	1.3	7.0	1.6	8.3	3.7				
Growth	%		-58.9%	69.3%	-89.3%	498.1%	Operating expenses	\$m	(10.0)	(10.8)	(9.4)	(9.4)	(9.4)				
Underlying PER	x	nm	nm	nm	nm	nm	EBITDA	\$m	(8.5)	(3.5)	(7.5)	(0.8)	(5.4)				
Operating cash flow per share	c	-6.8	-3.2	-4.0	-0.4	-3.6	Depreciation & Amortisation	\$m	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)				
Free cash flow per share	c	-6.8	-3.2	-4.0	-0.4	-3.6	EBIT	\$m	(8.7)	(3.8)	(7.8)	(1.0)	(5.7)				
Price to free cash flow per share	x	nm	nm	nm	nm	nm	Net interest	\$m	0.3	0.1	0.1	0.1	0.3				
FCF Yield	%	nm	nm	nm	nm	nm	Pretax Profit	\$m	(8.5)	(3.6)	(7.7)	(0.9)	(5.4)				
Dividend	c	0.0	0.0	0.0	0.0	0.0	Tax expense	\$m	0.0	0.0	0.0	0.0	0.0				
Payout	%	0.0%	0.0%	0.0%	0.0%	0.0%	Reported NPAT	\$m	(8.5)	(3.6)	(7.7)	(0.9)	(5.4)				
Yield	%	0.0%	0.0%	0.0%	0.0%	0.0%	Weighted average diluted shares	m	99.9	104.5	130.4	143.3	143.3				
Franking	%	0.0%	0.0%	0.0%	0.0%	0.0%	GROWTH PROFILE						FY19A	FY20A	FY21A	FY22E	FY23E
Enterprise value	\$m	71.4	64.7	51.6	52.3	57.4	Revenue	%	nm	435.8	(77.2)	422.3	(55.4)				
EV/EBITDA	x	(8.4)	(18.5)	(6.9)	(68.5)	(10.7)	EBIT DA	%	nm	(58.6)	114.3	(89.8)	605.9				
EV/EBIT	x	(8.2)	(17.1)	(6.6)	(50.1)	(10.1)	EBIT	%	nm	(56.7)	105.8	(86.6)	443.2				
Price to book (NAV)	x	5.0	3.7	2.7	2.8	3.5	Reported NPAT	%	nm	nm	nm	nm	nm				
Price to NTA	x	7.1	4.5	3.0	3.1	3.8	DPS	%	nm	nm	nm	nm	nm				
KEY RATIOS							BALANCE SHEET						FY19A	FY20A	FY21A	FY22E	FY23E
EBITDA margin	%	nm	nm	nm	nm	nm	Cash	\$m	7.0	13.6	26.7	26.1	21.0				
EBIT margin	%	nm	nm	nm	nm	nm	Receivables	\$m	0.1	0.0	0.1	0.1	0.1				
NPAT margin	%	nm	nm	nm	nm	nm	Inventory	\$m	0.0	0.0	0.0	0.0	0.0				
ROE	%	nm	nm	nm	nm	nm	Other	\$m	0.3	0.2	0.5	0.5	0.5				
ROA	%	nm	nm	nm	nm	nm	Current assets	\$m	7.3	13.9	27.3	26.7	21.5				
Net tangible assets per share	\$	0.1	0.1	0.2	0.2	0.1	PPE	\$m	0.0	0.0	0.0	0.0	0.0				
Book value per share	\$	0.1	0.1	0.2	0.2	0.2	Right-of-use assets	\$m	0.0	0.0	0.0	0.0	0.0				
Net debt/(cash)	\$m	(7.0)	(13.6)	(26.7)	(26.1)	(21.0)	Intangible assets	\$m	3.3	3.0	2.7	2.4	2.2				
Interest cover/ (EBIT/net interest)	x	nm	nm	nm	nm	nm	Other	\$m	1.7	0.7	0.0	0.0	0.0				
Gearing (net debt/EBIT DA)	x	nm	nm	nm	nm	nm	Non current assets	\$m	4.9	3.6	2.7	2.4	2.2				
Leverage (net debt/(net debt + equity))	x	nm	nm	nm	nm	nm	Total assets	\$m	12.2	17.5	30.0	29.1	23.7				
DUPONT ANALYSIS							Trade and other payables	\$m	1.2	0.6	1.4	1.4	1.4				
Net Profit Margin	%	nm	nm	nm	nm	nm	Borrowing and leases	\$m	0.0	0.0	0.0	0.0	0.0				
Asset Turnover	x	0.1	0.4	0.1	0.3	0.2	Other	\$m	0.0	0.1	0.2	0.2	0.2				
Return on Assets	%	nm	nm	nm	nm	nm	Current liabilities	\$m	1.3	0.7	1.6	1.6	1.6				
Leverage	x	1.1	1.0	1.1	1.1	1.1	Borrowing and leases	\$m	0.0	0.0	0.0	0.0	0.0				
Return on Equity	%	nm	nm	nm	nm	nm	Other liability	\$m	0.0	0.0	0.0	0.0	0.0				
KEY PERFORMANCE INDICATORS							Non current liabilities	\$m	0.0	0.0	0.0	0.0	0.0				
Clinical development pipeline		Indication	Status				Total liabilities	\$m	1.3	0.7	1.6	1.6	1.6				
CYP - 001		acute Graft vs host disease/organ transplantation	Phase 2 ready				Net assets	\$m	11.0	16.8	28.4	27.5	22.1				
CYP - 001		Respiratory failure (inc ARDS)	Phase 2				Share capital	\$m	48.0	57.2	74.9	74.9	74.9				
CYP - 002		Critical limb ischaemia	Phase 2 ready				Retained earnings	\$m	(41.5)	(45.2)	(52.9)	(53.8)	(59.1)				
CYP - 004		Knee Osteoarthritis	Phase 3				Other	\$m	4.5	4.8	6.3	6.3	6.3				
CYP-006TK		Diabetic foot ulcers	Phase 1				Total equity	\$m	11.0	16.8	28.4	27.5	22.1				
HALF YEARLY DATA							CASH FLOW						FY19A	FY20A	FY21A	FY22E	FY23E
Total Revenue	\$m	0.1	0.1	0.1	4.2	4.2	Net loss for period	\$m	(8.5)	(3.6)	(7.7)	(0.9)	(5.4)				
Operating expenses	\$m	(9.6)	(5.0)	(8.2)	(4.7)	(4.7)	Depreciation & Amortization	\$m	0.3	0.3	0.3	0.3	0.3				
EBITDA	\$m	(9.4)	(4.7)	(7.9)	(0.4)	(0.4)	Changes in working capital	\$m	0.6	(0.6)	0.8	0.0	0.0				
EBIT	\$m	(9.6)	(4.9)	(8.1)	(0.5)	(0.5)	Other	\$m	0.8	0.6	1.5	0.0	0.0				
PBT	\$m	(9.5)	(4.8)	(8.0)	(0.5)	(0.5)	Operating cash flow	\$m	(6.8)	(3.4)	(5.2)	(0.6)	(5.1)				
Reported NPAT	\$m	(9.5)	(4.8)	(8.0)	(0.5)	(0.5)	Payments for PPE	\$m	0.0	0.0	0.0	0.0	0.0				
Source: Company reports, MST Access estimates							Other	\$m	0.0	0.0	0.0	0.0	0.0				
							Investing cash flow	\$m	0.0	0.0	0.0	0.0	0.0				
							Equity	\$m	(0.1)	(0.4)	(0.6)	0.0	0.0				
							Borrowing and Lease liability net payment	\$m	0.0	0.0	0.0	0.0	0.0				
							Other	\$m	1.6	10.5	18.8	0.0	0.0				
							Financing cash flow	\$m	1.5	10.1	18.2	0.0	0.0				
							Cash year end	\$m	7.0	13.6	26.7	26.1	21.0				
							Free cash flow	\$m	(6.8)	(3.4)	(5.2)	(0.6)	(5.1)				

Source: Company reports, MST Access estimates

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