

Factor Therapeutics

Recruitment in VLU Phase IIb expected to build

Clinical trial update

Pharma & biotech

Factor Therapeutics updated the market that at the end of Q117, 12 venous leg ulcer (VLU) patients had been randomised to VF-001 or placebo in its Phase IIb trial, with a further 11 patients undergoing the two-week screening period prior to randomisation. We model the recruitment rate steadily increasing to 50 subjects entering screening per month (33 randomised), with the 168-patient trial being fully recruited by September. This would allow the last patient to complete their 12-week follow-up visit in December, with top-line data for the per cent wound closure primary end point reported in Q118. This timing would represent slight slippage on the company's target of top-line data read-out in Q417, but would leave our key valuation assumptions intact. Our valuation is unchanged at A\$108m or A\$0.15 per share.

Year end	Revenue (A\$m)	PBT* (A\$m)	EPS* (c)	DPS* (c)	P/E (x)	Yield (%)
06/15	0.4	(7.1)	(4.0)	0.0	N/A	N/A
06/16	0.4	(4.1)	(3.0)	0.0	N/A	N/A
06/17e	2.6	(5.4)	(0.8)	0.0	N/A	N/A
06/18e	1.8	(4.6)	(0.6)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Most planned sites actively recruiting

Recruitment in the US-based VF-001 Phase IIb trial began in December 2016. By the end of Q117, 21 of the planned 26 sites were actively recruiting, with most of the sites having been contracted and initiated in February and March. The final five sites were scheduled to undergo a site initiation visit by mid-April and all 26 sites are currently listed as actively recruiting on www.clinicaltrials.gov.

We model randomisation peaking at 33 per month

We routinely model recruitment rates in clinical trials steadily increasing as sites become fully active. Subjects who meet the recruitment criteria in the current trial are screened via two weeks of standard compression therapy – patients with evidence of spontaneous healing or severe deterioration are excluded and do not proceed to randomisation. Twenty-two patients entered screening from 11 sites in March. Using this average of two per site per month across 26 sites, we assume peak recruitment of 50 entering screening per month by July. Based on the 67% (12/18) screening pass rate to date, we assume that 33 patients will be randomised to VF-001 or placebo per month. Combining these assumptions with the 12 patients randomised as at end-March, we model the trial being fully recruited by September.

Valuation: Unchanged at A\$108m or A\$0.15 per share

Our valuation is unchanged at A\$108m or A\$0.15 per share. Although top-line data in Q118 would represent slight slippage on the company's target of a read-out in Q417, it would leave intact our key valuation assumptions of an out-licensing deal in FY19, launch in Europe in FY20 and a US launch in FY22. The A\$12.7m cash balance at 31 December 2016 should be sufficient to fund operations beyond the reporting date for the key Phase IIb trial.

17 May 2017

Price **A\$0.06**

Market cap **A\$46m**

US\$0.76/A\$

Net cash (A\$m) at 31 March 2017 10.2

Shares in issue 730.0m

Free float 92%

Code FTT

Primary exchange ASX

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 0.0 3.3 85.3

Rel (local) 0.7 2.9 70.7

52-week high/low A\$0.1 A\$0.0

Business description

Factor Therapeutics is an Australian biotechnology company that specialises in the development and manufacture of biologics for advanced wound care applications. Its strategy is to use targeted growth factors to renew the wound environment and promote healing.

Next events

Update on recruitment in VLU Phase IIb End Q217

Update on DFU IND preparations End-May 2017

Top-line results VLU Phase IIb Q118

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Exhibit 1: Financial summary

	A\$000s	2014	2015	2016	2017e	2018e
Year end 30 June		AASB	AASB	AASB	AASB	AASB
PROFIT & LOSS						
Sales, royalties, milestones		0	0	0	0	0
Other (includes R&D tax rebate)		518	355	435	2,640	1,840
Revenue		518	355	435	2,640	1,840
R&D expenses		(1,018)	(2,529)	(2,005)	(6,600)	(4,600)
SG&A expenses		(6,381)	(4,946)	(2,545)	(1,827)	(1,923)
Other		0	0	0	0	0
EBITDA		(6,881)	(7,120)	(4,116)	(5,787)	(4,683)
Operating Profit (before GW and except.)		(6,964)	(7,201)	(4,159)	(5,804)	(4,705)
Intangible Amortisation		(68)	(68)	(68)	(56)	(50)
Exceptionals		0	(4,092)	(7,486)	0	0
Operating Profit		(7,032)	(11,361)	(11,712)	(5,860)	(4,755)
Net Interest		217	155	101	431	204
Profit Before Tax (norm)		(6,816)	(7,114)	(4,125)	(5,429)	(4,551)
Profit Before Tax (reported)		(6,816)	(11,206)	(11,611)	(5,429)	(4,551)
Tax benefit		(14)	(13)	(1)	0	0
Profit After Tax (norm)		(6,830)	(7,127)	(4,126)	(5,429)	(4,551)
Profit After Tax (reported)		(6,830)	(11,219)	(11,612)	(5,429)	(4,551)
Average Number of Shares Outstanding (m)		241.8	278.3	381.4	724.3	724.3
EPS - normalised (c)		(2.82)	(4.03)	(3.04)	(0.75)	(0.63)
EPS diluted (c)		(2.82)	(4.03)	(3.04)	(0.75)	(0.63)
Dividend per share (A\$)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets		9,314	8,392	1,326	1,293	1,261
Intangible Assets		342	342	557	502	451
Tangible Assets		8,970	8,048	769	791	809
Investments		2	2	0	0	0
Current Assets		9,519	6,814	15,121	9,725	5,206
Stocks		1,530	649	34	0	0
Debtors		184	120	201	2,407	1,607
Cash		7,077	5,579	14,376	6,808	3,090
Other		728	466	510	510	510
Current Liabilities		(1,777)	(1,806)	(881)	(881)	(881)
Creditors		(1,247)	(1,630)	(710)	(710)	(710)
Short term borrowings		0	0	0	0	0
Other		(530)	(175)	(172)	(172)	(172)
Long Term Liabilities		(196)	(75)	(45)	(45)	(45)
Long term borrowings		0	0	0	0	0
Other long term liabilities		(196)	(75)	(45)	(45)	(45)
Net Assets		16,860	13,325	15,520	10,091	5,541
CASH FLOW						
Operating Cash Flow		(7,669)	(9,650)	(5,263)	(7,958)	(3,883)
Net Interest		173	214	115	431	204
Tax		422	392	413	0	0
Capex		(17)	(5)	(221)	(40)	(40)
Acquisitions/disposals		0	0	0	0	0
Equity Financing		10,120	8,258	14,751	0	0
Dividends		0	0	0	0	0
Other		(804)	(671)	(982)	0	0
Net Cash Flow		2,224	(1,463)	8,813	(7,567)	(3,719)
Opening net debt/(cash)		(4,862)	(7,077)	(5,579)	(14,376)	(6,808)
HP finance leases initiated		0	0	0	0	0
Other		(9)	(36)	(16)	0	0
Closing net debt/(cash)		(7,077)	(5,579)	(14,376)	(6,808)	(3,090)

Source: Factor Therapeutics data, Edison Investment Research

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