Pharmaxis Ltd

PXS.ASX

MST Access

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Pleasing results from established scars, Phase 1c – more to come

NEED TO KNOW

- Primary endpoint of safety/tolerability met
- Meaningful change to scar composition, with 30% reduction in collagen – proof of mechanism of action
- No improvement in scar appearance at 3 months – but results suggest longer study will bear fruit

Phase 1c in PXS-6302 establishes safety, plus shows meaningful change to scar composition with strongly reduced LOX activity – Pharmaxis has announced promising results in Phase 1c for PXS-6302 in established scars, in which PXS-6302 or a placebo were applied as a cream 3 times per week. The trial met its primary endpoint of safety and tolerability. PXS-6302 reduced LOX activity by 66% (measured 2 days after last dose) vs. baseline and placebo. Also, a surrogate for collagen (hydroxyproline), measured via biopsies at the start of the study and post 3 months of treatment, showed a mean reduction of 30%.

Next step: extension of collaboration with study team to investigate effects of longer-term treatment – Pharmaxis has indicated that it will shortly announce the next steps for its work with Fiona Wood AM and the team at the University of Western Australia, study leaders for Phase 1c. Prof Wood indicated that she is confident of an improvement in scar appearance over a longer time period. The company is encouraged by the trial's support of previous research about the role of LOX enzymes in scars, and aims to develop future clinical research with the aid of these Phase 1c findings. Possible areas of investigation may include younger scars, post-surgical scars, and new skin fibrosis indications.

Investment Thesis

A rare combination of skills and assets to facilitate bench-to-bedside research. PXS has brought a combination of assets and skills to its drug discovery platform. As a result, the company has a powerful capability to harness in-house scientific research to develop clinical trial programs and create novel treatments, a 'bench-to-bedside' process known as 'translational research'.

Amine oxidase platform generating multiple candidates, with many more possibilities: PXS's drug discovery platform focuses on amine oxidases, an important class of regulatory enzymes widespread in the body whose biological function depends on cofactors and location in human tissue and organs.

Deep clinical pipeline: The Company's most advanced clinical asset, PXS-5505, targeting primary myelofibrosis (a rare bone marrow cancer involving fibrosis), is currently in Phase 2 clinical trials. PXS-5505 is a novel small molecule and irreversible inhibitor to key enzymes involved in forming collagen, specifically the lysyl oxidase (LOX) family of proteins, whose overproduction is implicated in many conditions of chronic inflammation and pathological fibrosis.

Valuation

Our fair value estimate remains at A$0.34/share, using a DCF-based SOTP. This comprises the two clinical programs (PXS-5505, PXS-6302) and the mannitol division. We place the most value on the PXS-5505 (MF) program at A$116m.

Risk

Our valuation is most sensitive to clinical risk associated with the PXS-5505 and PXS-6302 programs at this point.

Equities Research Australia

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pharmaxis

Pharmaxis is a clinical-stage drug discovery company developing novel small molecule drugs for inflammatory and fibrotic diseases with major unmet medical need. It is a leader in mechanism-based inhibitors of amine oxidases. It is targeting cancers (e.g., myelofibrosis, pancreatic and liver cancer), diseases of organs including the liver (NASH, liver fibrosis), lungs (pulmonary fibrosis) and kidneys (chronic kidney disease), and fibrotic scarring from burns and other trauma. Pharmaxis previously commercialised two respiratory products (Bronchitol®, Aridol®) now sold globally.

Valuation	**A$0.34** *(unchanged)*
Current price	**A$0.05**
Market cap	**A$36m**
Cash on hand	**A$14.7m (31 March 2023)**

Upcoming Catalysts/Newsflow

Period	
1HCY23	PXS-4728, neurodegenerative disease Phase 2 trial: to start recruiting patients
mid-2023	PXS-5505, MF: Interim data from Phase 2 study
2HCY23	PXS-6302: scarring program update

Share Price (A$)

Source: FactSet, MST Access.

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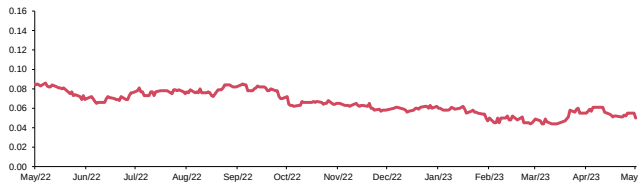
Pharmaxis — PXS-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	**$**	**0.05**
52 week high / low	$	0.04-0.11
Valuation	**$**	**0.34**
Market capitalisation	$m	36.0
Shares on issue (basic)	**m**	719.6
Options / rights	m	38.2
Other equity	m	0.0
Shares on issue (diluted)	**m**	**757.8**

12-MONTH SHARE PRICE PERFORMANCE (A$)



INVESTMENT FUNDAMENTALS		FY21A	FY22A	FY23E	FY24E	FY25E
Reported NPAT	$m	(3.0)	(1.9)	(9.9)	(10.3)	(4.9)
Underlying NPAT	**$m**	**(3.0)**	**(1.9)**	**(9.9)**	**(10.3)**	**(4.9)**
Reported EPS (diluted)	¢	(0.7)	(0.3)	(1.8)	(1.4)	(0.6)
Underlying EPS (diluted)	**¢**	**(0.7)**	**(0.3)**	**(1.8)**	**(1.4)**	**(0.6)**
Growth	%		-52.8%	421.6%	-24.5%	-52.4%
Underlying PER	x	**nm**	**nm**	**nm**	**nm**	**nm**
Operating cash flow per share	¢	0.8	(4.1)	(1.3)	(1.8)	(1.0)
Free cash flow per share	¢	0.6	(4.2)	(1.4)	(1.9)	(1.0)
Price to free cash flow per share	**x**	**8.4**	**nm**	**nm**	**nm**	**nm**
FCF Yield	%	11.9%	nm	nm	nm	nm
Dividend	**¢**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Payout	%	0.0%	0.0%	0.0%	0.0%	0.0%
Yield	**%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**
Franking	%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterprise value	**$m**	**23.6**	**31.3**	**27.1**	**37.8**	**43.4**
EV/EBITDA	x	47.1	(2.4)	54.1	(3.1)	(4.9)
EV/EBIT	x	(8.9)	(1.9)	(10.2)	(2.4)	(4.5)
Price to book (NAV)	x	8.0	2.5	3.1	26.5	(10.2)
Price to NTA	x	13.1	2.8	3.4	284.0	(7.4)

KEY RATIOS		FY21A	FY22A	FY23E	FY24E	FY25E
EBITDA margin	%	7.5	nm	7.5	nm	nm
EBIT margin	%	nm	nm	nm	nm	nm
NPAT margin	%	nm	nm	nm	nm	nm
ROE	%	nm	nm	nm	nm	nm
ROA	%	nm	nm	nm	nm	nm
Net tangible assets per share	$	0.0	0.0	0.0	0.0	(0.0)
Book value per share	$	0.0	0.0	0.0	0.0	(0.0)
Net debt/(cash)	$m	(12.4)	(4.6)	(8.9)	1.8	7.5
Interest cover/ (EBIT/net interest)	x	nm	nm	nm	nm	nm
Gearing (net debt/EBITDA)	x	nm	nm	nm	(0.1)	(0.8)
Leverage (net debt/(net debt + equity))	x	nm	nm	nm	0.6	1.9

DUPONT ANALYSIS		FY21A	FY22A	FY23E	FY24E	FY25E
Net Profit Margin	%	nm	nm	nm	nm	nm
Asset Turnover	x	0.2	0.3	0.2	0.4	0.6
Return on Assets	%	nm	nm	nm	nm	nm
Financial Leverage	x	2,222.1	397.1	369.1	3,160.6	(1,216.0)
Return on Equity	%	nm	nm	nm	nm	nm

KEY PERFORMANCE INDICATORS		FY21A	FY22A	FY23E	FY24E	FY25E
Bronchitol	$m	5.2	5.8	7.8	9.7	12.1
Aridol	$m	1.4	1.6	1.6	1.6	1.6
Clinical development pipeline	**Indication**			**Status**		
PXS-5505	**Myelofibrosis**			**Phase 2a**		
PXS-6302	**Anti-scarring**			**Phase 1c completed**		

HALF YEARLY DATA		2H20	1H21	2H21	1H22	2H22
Total Revenue	$m	8.6	13.7	9.9	8.5	1.6
Operating expenses	$m	(13.5)	(11.8)	(11.3)	(14.9)	(13.2)
EBITDA	$m	(4.8)	1.9	(1.4)	(6.4)	(11.6)
EBIT	$m	(4.8)	0.3	(1.4)	(7.9)	(13.1)
PBT	$m	(3.6)	0.0	(3.0)	(8.1)	0.6
Reported NPAT	$m	(3.6)	0.0	(3.0)	(8.1)	0.6

Source: Company reports, MST Access estimates

PROFIT AND LOSS		FY21A	FY22A	FY23E	FY24E	FY25E
Revenue	**$m**	**6.7**	**7.0**	**6.7**	**7.4**	**9.4**
Other income	$m	16.9	5.6	16.9	8.3	4.9
Total Revenue	**$m**	**23.6**	**12.7**	**23.6**	**15.8**	**14.3**
Operating expenses	$m	(23.1)	(25.9)	(23.1)	(28.1)	(23.2)
EBITDA	**$m**	**0.5**	**(13.2)**	**0.5**	**(12.3)**	**(8.9)**
Depreciation & Amortisation	$m	(3.2)	(3.2)	(3.2)	(3.2)	(0.8)
EBIT	**$m**	**(2.7)**	**(16.5)**	**(2.7)**	**(15.5)**	**(9.7)**
Net interest	$m	0.1	0.4	0.1	0.2	0.0
Pretax Profit	**$m**	**(3.0)**	**(13.9)**	**(3.0)**	**(1.9)**	**(9.9)**
Tax expense	$m	0.0	0.0	0.0	0.0	0.0
Reported NPAT	**$m**	**(3.0)**	**(13.9)**	**(3.0)**	**(1.9)**	**(9.9)**
Weighted average diluted shares	m	407.3	394.7	407.3	562.9	549.1

GROWTH PROFILE		FY21A	FY22A	FY23E	FY24E	FY25E
Revenue	%	86.5	4.1	86.5	(33.3)	(9.1)
EBITDA	%	(103.8)	(26.9)	(103.8)	(2,557.1)	(27.6)
EBIT	%	(83.9)	(20.6)	(83.9)	486.5	(37.7)
Reported NPAT	%	(78.7)	(30.5)	(78.7)	(34.8)	408.8
DPS	%	nm	nm	nm	nm	nm

BALANCE SHEET		FY21A	FY22A	FY23E	FY24E	FY25E
Cash	$m	18.7	8.9	13.2	2.5	(3.2)
Receivables	$m	3.0	8.0	4.2	5.0	6.1
Other	$m	3.6	2.3	5.1	6.2	7.5
Current assets	**$m**	**25.3**	**19.2**	**22.5**	**13.6**	**10.4**
PPE	$m	6.2	3.2	2.6	2.2	1.8
Intangible assets	$m	1.1	1.0	1.1	1.2	1.3
Other	$m	0.9	1.7	1.7	1.7	1.7
Non current assets	**$m**	**8.3**	**6.0**	**5.5**	**5.1**	**4.8**
Total assets	**$m**	**33.6**	**25.2**	**27.9**	**18.7**	**15.2**
Trade and other payables	$m	3.8	2.7	5.3	6.4	7.7
Borrowing	$m	2.0	2.0	2.0	2.0	2.0
Other	$m	2.1	1.4	0.7	0.7	0.7
Current liabilities	**$m**	**7.9**	**6.1**	**8.0**	**9.1**	**10.5**
Borrowing and leases	$m	4.3	2.3	2.3	2.3	2.3
Other liability	$m	18.6	6.0	6.0	6.0	6.0
Non current liabilities	**$m**	**22.9**	**8.3**	**8.3**	**8.3**	**8.3**
Total liabilities	**$m**	**30.7**	**14.4**	**16.3**	**17.4**	**18.7**
Net assets	**$m**	**2.8**	**10.8**	**11.6**	**1.4**	**(3.5)**
Share capital	$m	371.4	380.4	391.1	391.1	391.1
Retained earnings	$m	(391.2)	(393.1)	(402.9)	(413.2)	(418.1)
Other	$m	22.6	23.5	23.5	23.5	23.5
Total equity	**$m**	**2.8**	**10.8**	**11.6**	**1.4**	**(3.5)**

CASH FLOW		FY21A	FY22A	FY23E	FY24E	FY25E
Net loss for period	**$m**	**(3.0)**	**(1.9)**	**(9.9)**	**(10.3)**	**(4.9)**
Depreciation & Amortisation	$m	3.2	3.2	0.8	0.7	0.6
Changes in working capital	$m	4.0	(5.9)	3.6	(0.8)	(1.0)
Other	$m	(1.1)	(11.5)	0.0	0.0	0.0
Operating cash flow	**$m**	**3.1**	**(16.1)**	**(5.5)**	**(10.4)**	**(5.3)**
Payments for PPE	$m	(0.3)	(0.1)	(0.1)	(0.1)	(0.1)
Other	$m	(0.3)	(0.2)	(0.2)	(0.2)	(0.2)
Investing cash flow	**$m**	**(0.6)**	**(0.3)**	**(0.3)**	**(0.3)**	**(0.3)**
Equity	$m	4.1	9.1	10.0	0.0	0.0
Lease liability payments	$m	(2.3)	(2.4)	0.0	0.0	0.0
Other	$m	(0.2)	(0.1)	0.0	0.0	0.0
Financing cash flow	**$m**	**1.5**	**6.6**	**10.0**	**0.0**	**0.0**
Cash year end	**$m**	**18.7**	**8.9**	**13.2**	**2.5**	**(3.2)**
Free cash flow	**$m**	**2.4**	**(16.4)**	**(5.8)**	**(10.7)**	**(5.6)**

Figure 1: Diverse and advanced clinical pipeline

	Indication	Addressable market (US$)	Trial design	# patients	Status	Data
PXS-5505	Myelofibrosis (MF)	$1 billion	Phase 2 open label 6 month study in JAK intolerant / ineligible myelofibrosis patients	24	Recruiting	Interim data released Significant data update mid 2023
			Phase 2 open label 6 month study in JAK intolerant / ineligible myelofibrosis patients	TBD	First Patient 2H 2023	TBD
PXS-6302	Modification of established scars	$3.5 billion	Phase 1c 3 month placebo controlled study in patients with established scars (>1 year old)	50	Reported	H1 2023
	Scar prevention	$3.5 billion	Phase 1c 3 month placebo controlled study in patients with scarring subsequent to a burns injury	50	First patient 2023	2024
PXS-4728	Isolated REM sleep behaviours disorder (iRDB) and neuro inflammation	$3.5 billion	Phase 2 double blind, placebo controlled study in patients with iRBD	40	First patient mid-year 2023	H1 2025

Source: Pharmaxis.

Figure 2: Design of Phase 1c trial in PXS-6302

Trial Design		**Results**
Name of trial	PXS-6302 SOLARIA2: A Phase 1c, Single Centre Study Investigating the Safety and Tolerability of a Lysyl Oxidase Inhibitor (PXS-6302) vs Placebo in the Amelioration of Established Scars.	
Trial number	ACTRN12621001545853	
Primary objective	To investigate the safety and tolerability of multiple applications of PXS-6302 vs placebo in a target cohort.	Good safety and tolerability profile No serious adverse events
Secondary objectives	• To investigate the pharmacokinetics of PXS-6302 when administered with multiple applications of a dose of PXS-6302 vs placebo • To investigate the pharmacodynamics of PXS-6302 when administered in multiple applications as a single dose • To obtain preliminary measures of scar changes associated with treatment or placebo	• 66% mean reduction in LOX activity • 30% reduction of hydroxyproline vs placebo • No significant changes in POSAS[1] between active and placebo
Blinding status	Blinded	
Placebo controlled	Yes	
Trial design	Placebo controlled, single centre, 12-week duration phase 1c study randomised 1:1 on active or placebo.	
Treatment route	Topical	
Treatment frequency	3x weekly application	
Dose level	One dose	
Number of subjects	42 patients; 21 on active treatment and 21 on placebo	42 patients recruited; 1 lost to follow-up (active), 2 discontinuations from treatment (both on active)
Subject selection criteria	Adult patients aged between 18 and 60 years with a scar aged >1 year (includes all surgery types).	
Trial locations	Fiona Stanley Hospital, Murdoch, Western Australia	
Commercial partners involved	No commercial partner	

Source: Pharmaxis.

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