

1QFY23 release shows diverse pipeline continuing to deliver news flow

Pharmaxis has provided its 1QFY23 (September-quarter) results and updates on the current status of its multiple drug assets. Lead asset PXS-5505 for myelofibrosis has seen positive interim data with its Phase 2a trial due to complete mid-2003, and Phase 1c is coming up shortly for PXS-5505 in liver cancer. Initial results from the PXS-6302 trial in established scars look promising. Pharmaxis ended the quarter with a proforma cash balance of A\$21m (to increase to A\$26m assuming shareholder approval of a second placement tranche). We remain positive on the stock, and see value given its diversified clinical pipeline and the potential for medium-term data flow.

Lead asset PXS-5505 (MF): positive interim data

Pharmaxis's primary drug development focus, PXS-5505 for rare blood cancer myelofibrosis (MF), is in the dose expansion Phase 2a. Positive interim data has been delivered for the first 6 patients (out of 15) to have completed the full twice-daily 24-week treatment. Key highlights:

- **safety:** no serious treatment-related adverse effects
- **efficacy:** improved fibrosis, blood counts, symptom scores – 2/6 patients show clinically important symptom improvement; 5/6 have stable or improved bone marrow fibrosis scores of ≥ 1 grade; 5/6 have stable or improved platelet and/or haemoglobin scores; no reduction in spleen volume

Globally, 18 trial sites are recruiting, with 2 additional sites likely to be included in the study. The trial aims to finish recruitment by late 2022.

PXS-5505 (liver cancer): Phase 1c to start shortly

The investigator-initiated clinical trial of PXS-5505 in HCC (liver cancer) will start Phase 1c shortly. The study aims to have PXS-5505 added to the current standard of care. Phase 1c, to be conducted by Pharmaxis and Wilmot Cancer Institute (U of Rochester), is budgeted to cost Pharmaxis ~US\$1.2m. A 6-month Phase 2a trial will follow with the selected dose.

PXS-6302 (scars): first 8 trial patients show results

PXS-6302, for potential topical use in modifying established scars/scar prevention, showed promising preclinical results in inhibiting the lysyl oxidase (LOX) enzymes that help develop scar tissue. Phase 1a/b trials have successfully completed. Pharmaxis is working with University of WA and Fiona Stanley Hospital to progress to 2 patient trials: established scars and post-surgical scar prevention.

Preliminary results have been released on the first 8 patients to complete treatment for established scars, with evidence of reduced scarring biomarker levels and scarring-related enzyme inhibition. Final results are due in 1H2023, with a view to a follow-up study on scar prevention.

Valuation: Lowered to A\$34/share post cap raise

Our fair value estimate moves to A\$0.34/share (previously A\$0.45/share) given the dilutionary impact of the A\$10m capital raise. We use a sum-of-the-parts approach, based on DCF methodology, comprising Pharmaxis's two clinical programs (PXS-5505 and PXS-6302) and its mannitol division. PXS-5505 for MF is the program on which we place the highest value at A\$116m. As such, our valuation is most sensitive to clinical risk associated with both PXS-5505 and PXS-6302 programs at this point.



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.

Stock	PXS.ASX
Price	A\$0.07
Market cap	A\$47m
Valuation	A\$0.34 (previously A\$0.45)

Company data

Net cash (end-1QFY23)	\$11.6m
Shares on issue (post cap raise)	718.8m

Upcoming news flow

PXS-5505 MF trial: recruitment to finish late 2022

PXS-5505, liver cancer: Phase 1c starting soon

PXS-6302, scarring: results for established scars and scar prevention studies

PXS share price (A\$)



Source: FactSet.

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Financials

Pharmaxis						PXS-AU
Year end 30 June, AUD unless otherwise noted						
MARKET DATA						12-MONTH SHARE PRICE PERFORMANCE (A\$)
Price	\$	0.07				
52 week high / low	\$	0.06-0.13				
Valuation	\$	0.34				
Market capitalisation	\$m	47.4				
Shares on issue (basic)	m	718.8 <i>(incorporates capital raising)</i>				
Options / rights	m	30.0				
Other equity	m	0.0				
Shares on issue (diluted)	m	748.8				
INVESTMENT FUNDAMENTALS						
Reported NPAT	\$m	FY19A	FY20A	FY21A	FY22A	
Underlying NPAT	\$m	(20.1)	(13.9)	(3.0)	(1.9)	(11.7)
Reported EPS (diluted)	c	(5.3)	(3.5)	(0.7)	(0.3)	(2.1)
Underlying EPS (diluted)	c	(5.3)	(3.5)	(0.7)	(0.3)	(2.1)
Growth	%		-32.8%	-79.4%	-52.8%	517.3%
Underlying PER	x	nm	nm	nm	nm	nm
Operating cash flow per share	c	(5.2)	(3.4)	0.8	(2.9)	(1.3)
Free cash flow per share	c	(5.4)	(3.5)	0.6	(2.9)	(3.0)
Price to free cash flow per share	x	nm	nm	11.1	nm	nm
FCF Yield	%	nm	nm	9.0%	nm	nm
Dividend	c	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	23.5	40.8	35.1	42.8	39.1
EV/EBITDA	x	(1.3)	(3.1)	70.0	(3.5)	(3.7)
EV/EBIT	x	(1.1)	(2.5)	(13.2)	(2.8)	(3.4)
Price to book (NAV)	x	1.8	18.2	10.5	3.4	8.6
Price to NTA	x	1.9	53.2	17.3	3.7	11.2
KEY RATIOS						
EBITDA margin	%	nm	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	0.01	0.0	0.0
Net debt/(cash)	\$m	(24.0)	(6.6)	(12.4)	(4.6)	(2.1)
Interest cover (EBIT/net interest)	x	nm	nm	nm	nm	nm
Gearing (net debt/EBITDA)	x	nm	nm	nm	nm	nm
Leverage (net debt/(net debt + equity))	x	nm	nm	nm	nm	nm
DUPONT ANALYSIS						
Net Profit Margin	%	nm	nm	nm	nm	nm
Asset Turnover	x	0.1	0.2	0.2	0.3	0.4
Return on Assets	%	nm	nm	nm	nm	nm
Financial Leverage	x	484.1	5,698.1	2,222.1	397.1	891.0
Return on Equity	%	nm	nm	nm	nm	nm
KEY PERFORMANCE INDICATORS						
Bronchitol	\$m	2.6	5.3	5.2	5.8	7.8
Aridol	\$m	3.1	1.8	1.4	1.6	1.6
Clinical development pipeline	Indication	Status				
PXS-5505	Myelofibrosis	Phase 2a				
PXS-6302	Anti-scarring	Phase 1c completed				
PXS-5505	Liver Cancer	Phase 1c ready				
HALF YEARLY DATA						
Total Revenue	\$m	2H20	1H21	2H21	1H22	2H22
Operating expenses	\$m	8.6	13.7	9.9	8.5	1.6
EBITDA	\$m	(13.5)	(11.8)	(11.3)	(14.9)	(13.2)
EBIT	\$m	(4.8)	1.9	(1.4)	(6.4)	(11.6)
PBT	\$m	(4.8)	0.3	(1.4)	(7.9)	(13.1)
Reported NPAT	\$m	(3.6)	0.0	(3.0)	(8.1)	0.6
Reported NPAT	\$m	(3.6)	0.0	(3.0)	(8.1)	0.6
PROFIT AND LOSS						
Revenue	\$m	FY19A	FY20A	FY21A	FY22A	FY23E
Other income	\$m	5.7	7.0	6.7	7.4	9.4
Total Revenue	\$m	6.5	5.6	16.9	8.3	4.9
Operating expenses	\$m	12.2	12.7	23.6	15.8	14.3
EBITDA	\$m	(30.3)	(25.9)	(23.1)	(28.1)	(23.2)
Depreciation & Amortisation	\$m	(18.1)	(13.2)	0.5	(12.3)	(8.9)
EBIT	\$m	(2.6)	(3.2)	(3.2)	(3.2)	(0.8)
Net interest	\$m	(20.7)	(16.5)	(2.7)	(15.5)	(9.7)
Pretax Profit	\$m	0.9	0.4	0.1	0.2	0.0
Tax expense	\$m	(20.1)	(13.9)	(3.0)	(1.9)	(11.7)
Reported NPAT	\$m	0.0	0.0	0.0	0.0	0.0
Reported NPAT	\$m	(20.1)	(13.9)	(3.0)	(1.9)	(11.7)
Weighted average diluted shares	m	381.4	394.7	407.3	562.9	549.1
GROWTH PROFILE						
Revenue	%	FY19A	FY20A	FY21A	FY22A	FY23E
EBITDA	%	(75.8)	4.1	86.5	(33.3)	(9.1)
EBIT	%	(290.7)	(26.9)	(103.8)	(2,557.1)	(27.6)
Reported NPAT	%	(424.7)	(20.6)	(83.9)	486.5	(37.7)
DPS	%	(412.0)	(30.5)	(78.7)	(34.8)	502.1
DPS	%	nm	nm	nm	nm	nm
BALANCE SHEET						
Cash	\$m	FY19A	FY20A	FY21A	FY22A	FY23E
Receivables	\$m	31.1	14.8	18.7	8.9	6.3
Other	\$m	7.3	7.1	3.0	8.0	4.2
Current assets	\$m	2.1	2.6	3.6	2.3	5.1
PPE	\$m	40.6	24.5	25.3	19.2	15.6
Intangible assets	\$m	10.3	8.9	6.2	3.2	2.6
Other	\$m	0.8	0.9	1.1	1.0	1.1
Non current assets	\$m	1.1	1.1	0.9	1.7	1.7
Total assets	\$m	12.1	10.9	8.3	6.0	5.5
Trade and other payables	\$m	52.7	35.4	33.6	25.2	21.1
Borrowing	\$m	4.8	3.5	3.8	2.7	5.3
Other	\$m	1.2	1.8	2.0	2.0	2.0
Current liabilities	\$m	2.1	1.5	2.1	1.4	0.7
Borrowing and leases	\$m	8.1	6.8	7.9	6.1	8.0
Other liability	\$m	6.0	6.3	4.3	2.3	2.3
Non current liabilities	\$m	15.7	14.0	10.7	(0.1)	(2.0)
Total liabilities	\$m	29.7	27.2	22.9	8.3	8.3
Net assets	\$m	37.9	34.0	30.7	14.4	16.3
Share capital	\$m	14.8	1.4	2.8	10.8	4.8
Retained earnings	\$m	367.3	367.3	371.4	380.4	391.1
Other	\$m	(374.2)	(388.2)	(391.2)	(393.1)	(404.8)
Total equity	\$m	21.8	22.3	22.6	23.5	23.5
CASH FLOW						
Net loss for period	\$m	FY19A	FY20A	FY21A	FY22A	FY23E
Depreciation & Amortisation	\$m	(20.1)	(13.9)	(3.0)	(1.9)	(11.7)
Changes in working capital	\$m	2.9	3.2	3.2	3.2	0.8
Other	\$m	(5.1)	(1.6)	4.0	(5.9)	3.6
Operating cash flow	\$m	2.5	(1.0)	(1.1)	(11.5)	0.0
Payments for PPE	\$m	(19.8)	(13.3)	3.1	(16.1)	(7.3)
Other	\$m	(0.6)	(0.3)	(0.3)	(0.1)	(0.1)
Investing cash flow	\$m	(0.4)	(0.3)	(0.3)	(0.2)	(0.2)
Equity	\$m	(1.0)	(0.6)	(0.6)	(0.3)	(0.3)
Lease liability payments	\$m	22.7	0.0	4.1	9.1	10.0
Other	\$m	(1.6)	(2.2)	(2.3)	(2.4)	0.0
Financing cash flow	\$m	(0.3)	(0.3)	(0.2)	(0.1)	0.0
Cash year end	\$m	20.8	(2.5)	1.5	6.6	10.0
Free cash flow	\$m	31.1	14.8	18.7	8.9	6.3
Free cash flow	\$m	(20.8)	(13.9)	2.4	(16.4)	(16.4)

Source: Company, MST Access.

PXS-6302: Skin Scarring Trials – Modifying and Preventative Studies

Pharmaxis is working with the University of Western Australia (UWA) and the Fiona Stanley Hospital on a trial program for PXS-6302, a drug that has been developed for topical application with the potential to modify existing scars as well as to prevent scarring, according to promising pre-clinical results.

Two separate trials will be conducted for PXS-6302: a trial in modifying established scars (the ‘Modifying Study’, currently in train), and a trial in scar prevention post surgery (the ‘Preventative Study’, currently in the planning stages).

Modifying Study (SOLARIA2)

Pharmaxis has released interim data part of the Modifying Study on PXS-6302 in established scars. The study is being conducted by UWA and led by Professor Fiona Wood AM, Director of the Western Australia Burns Service.

Cohort snapshot: eligibility and treatment protocol

A total of 50 patients will be treated in this trial. Adult patients with scars that are more than a year old and more than 10cm² in size are eligible.

The first cohort of 8 patients have been treated for up to 3 months with the active drug, PXS-6302. The following 42 patients (31 of whom have been recruited) will be randomised 1:1 to receive either the active drug or a placebo. Four patients withdrew from the study after experiencing redness and inflammation at the application site – this ceased after treatment was stopped. The study team has also modified the treatment regimen in response to this adverse skin reaction, reducing it from once daily to three times a week.

Interim data snapshot

The interim (preliminary) results from the first 8 patients treated with the active drug include the following information from skin punch biopsies taken 24 hours after application at the end of the treatment period:

- high LOX inhibition; according to pre-clinical models, LOX enzymes are fundamental to the scarring process
- reduced levels of scarring biomarkers hydroxyproline and LOX, which Pharmaxis characterises as showing normalised physiological processes and a disease-modifying effect
- increased pliability and improved appearance.

Next steps

The team expects to provide final results in 1H2023, at which time Pharmaxis hopes it will be able to confirm an acceptable safety profile, improvements in the appearance of established scars, better functionality of scar tissue, and evidence that LOX inhibition is working to modify scar tissue at the structural and biochemical level.

Preventative Study

Pharmaxis is also considering the protocol for a follow-up study on post-surgery scar prevention (the Preventative Study). Objective endpoints are being developed for the Preventative Study in order to address expected regulatory requirements and refine the patient criteria for PXS-6302. The plan is to commence recruitment for this study in 1Q2023, with final data to be released in 1H2024.

Nature Communications: publication of pre-clinical studies that underpin PXS-6302 trials

UWA researchers have recently published the pre-clinical studies on pan-LOX topical treatment of scars in *Nature Communications*. These studies, on which the PXS-6302 trials are based, show that LOX enzymes are critical to the scar formation/maintenance process because they help to stabilise collagen and stiffen scars. The studies demonstrate how PXS-6302 helps to reduce collagen deposition and cross-linking and decrease fibrosis in various scar types (scleroderma, burn, hypertrophic), all while maintaining tissue strength.

These pre-clinical studies formed a critical part of the IND discussions between the FDA and Pharmaxis.

Exhibit 2: Active pipeline

Asset	Indication	Addressable market (US\$)	Trial design	# patients	Status	Data
PXS-5505	Myelofibrosis (MF)	\$1b	Phase 2a open label 6 month study in JAK intolerant /ineligible myelofibrosis patients	24	Recruiting	Full data 1H CY23
	Hepatocellular Carcinoma (HCC)	\$7b	Phase 1c/2a open label dose escalation study in newly diagnosed patients with unresectable HCC on top of standard of care (PD L1 inhibitor anti VEGF)	18	First Patient 4Q CY22	1H CY24
PXS-6302	Modification of established scars	\$3.5b	Phase 1c 3 month placebo controlled study in patients with established scars (>1 year old)	50	Recruiting	1H CY23
	Scar prevention post surgery	\$3.5b	Phase 1c 3 month placebo controlled study in patients with scarring subsequent to a burns injury	50	First patient 1H CY23 2022	1HCY24
PXS-4728	REM sleep disorder and neuro inflammation	\$3.5b	Phase 2 double blind, placebo controlled study in patients with IBD	40	First patient 1H CY23	1H CY25

Source: Pharmaxis.

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