Clinical trials on track; news flow ahead

Pharmaxis has provided a clinical update on its two key drugs, PXS-5505 (myelofibrosis and liver cancer) and PXS-6302 (topical treatment for established and burns scars). The update has confirmed our positive view on the stock, which appears undervalued given the diversified clinical pipeline, the potential for medium-term data flow.

PXS-5505 myelofibrosis (MF) trial – significant Phase 2 data expected by year-end

The open-label MF trial is currently in Phase 2a. In this trial, 24 patients will be treated for 6 months.

All sites in Australia and Korea are actively recruiting patients, with the first site in Taiwan also commencing recruitment. Recruitment is expected to complete by mid-CY2022.

The company expects to release significant data before end-CY2022.

PXS-5505 in liver cancer – U. of Rochester files IND, Phase 1c coming up

The recent IND filed by University of Rochester has paved the way for a Phase 1c/2a trial in hepatocellular carcinoma (HCC), a type of liver cancer. The FDA cleared an application for a Phase 1c/2a clinical trial in HCC patients in 4QCY21. The study aims to have PXS-5505 added to the current chemotherapy standard of care. Negotiation with the Wilmot Centre Institute, University of Rochester Medical Center, has reached an agreement, which will see Phase 1c commence in the coming months. The Phase 1c trial is expected to cost Pharmaxis ~US$1.2m over FY23 and FY24.

PXS-6302 for scars – two-part trial on established and burns scars

Pharmaxis has successfully completed Phase 1a/b clinical trials, which showed promising results for PXS-6302 in inhibiting the enzymes that play a critical role in the development of scar tissues. The company is working with the University of Western Australia and the Fiona Stanley Hospital to progress into two 3-month patient trials in established scars and burns scars. Part 1 enrolled its first established scar patient in January, with recruitment for remaining patients commencing this quarter. A study report is expected before year-end. The second clinical trial in burn scars is in preparation, with recruitment of patients expected in the second half of the year.

Valuation: remains unchanged at A$0.45/share

Our fair value estimate remains unchanged, pending commencement of the PXS-5505 liver cancer trial, at A$243m or A$0.45 per share based on sum-of-the-parts 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. Our valuation remains sensitive to various risks common to specialty pharmaceutical companies engaged in drug development, including clinical development delays and the unpredictable outcome of trials, regulatory decisions, financing, and commercialisation.

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$0.08
Market cap	A$42m
Valuation	A$0.45

Video Link

Video Link - Interview with Gary Phillips, CEO

Company data	
Net cash (end-3Q22)	$14.8m
Shares on issue	548.9m
Code ASX	PXS

Upcoming news flow

- PXS-5505 MF trial: significant data by end-CY22
- PXS-5505, liver cancer: Phase 1c commencemen
- PXS-6302 scar trial: report on established scars b year-end; recruitment for burns in 2HCY22

PXS Share Price (A$)

Source: FactSet.

Chris Kallos, CFA
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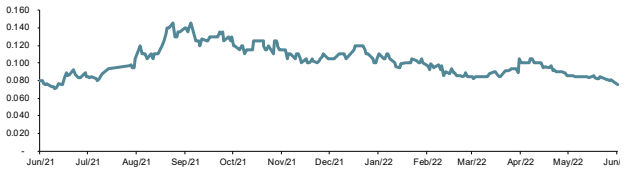
Financials

Pharmaxis PXS-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA		
Price	**$**	**0.08**
52 week high / low	$	0.07-0.14
Valuation	**$**	**0.45**
Market capitalisation	$m	41.2
Shares on issue (basic)	**m**	548.9
Options / rights	m	25.0
Other equity	m	0.0
Shares on issue (diluted)	**m**	**574.0**

12-MONTH SHARE PRICE PERFORMANCE (A$)



INVESTMENT FUNDAMENTALS		FY19A	FY20A	FY21A	FY22E	FY23E
Reported NPAT	$m	(20.1)	(13.9)	(3.0)	(14.4)	(3.2)
Underlying NPAT	**$m**	**(20.1)**	**(13.9)**	**(3.0)**	**(14.4)**	**(3.2)**
Reported EPS (diluted)	¢	(5.3)	(3.5)	(0.7)	(3.2)	(0.7)
Underlying EPS (diluted)	**¢**	**(5.3)**	**(3.5)**	**(0.7)**	**(3.2)**	**(0.7)**
Growth	%		-32.8%	-79.4%	335.1%	-78.0%
Underlying PER	x	**nm**	**nm**	**nm**	**nm**	**nm**
Operating cash flow per share	¢	(5.2)	(3.4)	0.8	(3.4)	(0.8)
Free cash flow per share	¢	(5.4)	(3.5)	0.6	(3.5)	(3.5)
Price to free cash flow per share	**x**	**nm**	**nm**	**12.6**	**nm**	**nm**
FCF Yield	%	nm	nm	7.9%	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**	**17.2**	**34.6**	**28.8**	**32.9**	**32.0**
EV/EBITDA	x	(1.0)	(2.6)	57.4	(2.6)	(19.0)
EV/EBIT	x	(0.8)	(2.1)	(10.9)	(2.3)	(10.9)
Price to book (NAV)	x	2.0	20.7	12.0	79.5	15.1
Price to NTA	x	2.1	60.5	19.7	(39.2)	43.2

KEY RATIOS		FY19A	FY20A	FY21A	FY22E	FY23E
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)	(8.3)	(9.2)
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		FY19A	FY20A	FY21A	FY22E	FY23E
Net Profit Margin	%	nm	nm	nm	nm	nm
Asset Turnover	x	0.1	0.2	0.2	0.4	0.4
Return on Assets	%	nm	nm	nm	nm	nm
Financial Leverage	x	484.1	5,698.1	2,222.1	14,751.2	2,809.6
Return on Equity	%	nm	nm	nm	nm	nm

KEY PERFORMANCE INDICATORS		FY19A	FY20A	FY21A	FY22E	FY23E
Bronchitol	$m	2.6	5.3	5.2	10.3	13.8
Aridol	$m	3.1	1.8	1.4	2.0	2.0

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		2H20	1H21	2H21	1H22*	2H22
Total Revenue	$m	8.6	13.7	9.9	8.5	6.5
Operating expenses	$m	(13.5)	(11.8)	(11.3)	(14.3)	(13.1)
EBITDA	$m	(4.8)	1.9	(1.4)	(5.8)	(6.6)
EBIT	$m	(4.8)	0.3	(1.4)	(7.4)	(6.3)
PBT	$m	(3.6)	0.0	(3.0)	(7.5)	(6.4)
Reported NPAT	$m	(3.6)	0.0	(3.0)	(7.5)	(6.4)

PROFIT AND LOSS		FY19A	FY20A	FY21A	FY22E	FY23E
Revenue	**$m**	**5.7**	**7.0**	**6.7**	**12.3**	**15.8**
Other income	$m	6.5	5.6	16.9	2.3	3.9
Total Revenue	**$m**	**12.2**	**12.7**	**23.6**	**14.6**	**19.7**
Operating expenses	$m	(30.3)	(25.9)	(23.1)	(27.4)	(21.4)
EBITDA	**$m**	**(18.1)**	**(13.2)**	**0.5**	**(12.8)**	**(1.7)**
Depreciation & Amortisation	$m	(2.6)	(3.2)	(3.2)	(1.4)	(1.3)
EBIT	**$m**	**(20.7)**	**(16.5)**	**(2.7)**	**(14.2)**	**(2.9)**
Net interest	$m	0.9	0.4	0.1	0.0	0.0
Pretax Profit	**$m**	**(20.1)**	**(13.9)**	**(3.0)**	**(14.4)**	**(3.2)**
Tax expense	$m	0.0	0.0	0.0	0.0	0.0
Reported NPAT	**$m**	**(20.1)**	**(13.9)**	**(3.0)**	**(14.4)**	**(3.2)**
Weighted average diluted shares	m	381.4	394.7	407.3	454.4	454.4

GROWTH PROFILE		FY19A	FY20A	FY21A	FY22E	FY23E
Revenue	%	(75.8)	4.1	86.5	(38.0)	34.7
EBITDA	%	(290.7)	(26.9)	(103.8)	(2,646.6)	(86.8)
EBIT	%	(424.7)	(20.6)	(83.9)	434.5	(79.3)
Reported NPAT	%	(412.0)	(30.5)	(78.7)	385.4	(78.0)
DPS	%	nm	nm	nm	nm	nm

BALANCE SHEET		FY19A	FY20A	FY21A	FY22E	FY23E
Cash	$m	31.1	14.8	18.7	14.6	15.5
Receivables	$m	7.3	7.1	3.0	5.5	7.0
Other	$m	2.9	3.6	5.0	9.2	11.8
Current assets	**$m**	**55.7**	**33.6**	**34.7**	**36.7**	**42.7**
PPE	$m	10.3	8.9	6.2	5.3	4.6
Intangible assets	$m	0.8	0.9	1.1	1.3	1.5
Other	$m	1.1	1.1	0.9	0.9	0.9
Non current assets	**$m**	**12.1**	**10.9**	**8.3**	**7.6**	**7.0**
Total assets	**$m**	**52.7**	**35.4**	**33.6**	**34.3**	**38.1**
Trade and other payables	$m	4.8	3.5	3.8	6.9	8.9
Borrowing	$m	1.2	1.8	2.0	2.0	2.0
Other	$m	2.1	1.5	2.1	2.1	2.1
Current liabilities	**$m**	**8.1**	**6.8**	**7.9**	**11.1**	**13.0**
Borrowing and leases	$m	6.0	6.3	4.3	4.3	4.3
Other liability	$m	15.7	14.0	10.7	7.5	5.5
Non current liabilities	**$m**	**29.7**	**27.2**	**22.9**	**22.9**	**22.9**
Total liabilities	**$m**	**37.9**	**34.0**	**30.7**	**33.9**	**35.9**
Net assets	**$m**	**14.8**	**1.4**	**2.8**	**0.4**	**2.3**
Share capital	$m	367.3	367.3	371.4	383.4	388.4
Retained earnings	$m	(374.2)	(388.2)	(391.2)	(405.6)	(408.8)
Other	$m	21.8	22.3	22.6	22.6	22.6
Total equity	**$m**	**14.8**	**1.4**	**2.8**	**0.4**	**2.3**

CASH FLOW		FY19A	FY20A	FY21A	FY22E	FY23E
Net loss for period	**$m**	**(20.1)**	**(13.9)**	**(3.0)**	**(14.4)**	**(3.2)**
Depreciation & Amortisation	$m	2.9	3.2	3.2	1.4	1.3
Changes in working capital	$m	(5.1)	(1.6)	4.0	(2.4)	(1.5)
Other	$m	2.5	(1.0)	(1.1)	0.0	0.0
Operating cash flow	**$m**	**(19.8)**	**(13.3)**	**3.1**	**(15.4)**	**(3.4)**
Payments for PPE	$m	(0.6)	(0.3)	(0.3)	(0.4)	(0.4)
Other	$m	(0.4)	(0.3)	(0.3)	(0.4)	(0.4)
Investing cash flow	**$m**	**(1.0)**	**(0.6)**	**(0.6)**	**(0.7)**	**(0.7)**
Equity	$m	22.7	0.0	4.1	12.0	5.0
Lease liability payments	$m	(1.6)	(2.2)	(2.3)	0.0	0.0
Other	$m	(0.3)	(0.3)	(0.2)	0.0	0.0
Financing cash flow	**$m**	**20.8**	**(2.5)**	**1.5**	**12.0**	**5.0**
Cash year end	**$m**	**31.1**	**14.8**	**18.7**	**14.6**	**15.5**
Free cash flow	**$m**	**(20.8)**	**(13.9)**	**2.4**	**(16.1)**	**(16.1)**

Source: Company, MST Access

Clinical Pipeline and Active Trials

Exhibit 1: Development pipeline

Category		Indication	Preclinical	Phase 1	Phase 2	Phase 3	Marketed
Oral pan-LOX Inhibitor	PXS-5505	Myelofibrosis			Phase 2a commenced		
Oral pan-LOX Inhibitor	PXS-5505	44588		Phase 1c/2a ready			
	PXS-5505	Other indications including some cancers					
Topical pan-LOX Inhibitor	PXS-6302	Established scars		Phase 1c commenced			
	PXS-6302	Post burns scarring		Phase 1 completed			
LOXL2 Inhibitors	PXS-5382	Chronic kidney disease			Phase 2 ready		
	PXS-5382	Idiopathic pulmonary fibrosis			Phase 2 ready		
	PXS-5382	Non-alcoholic steatohepatisi (NASH)			Phase 2 ready		
SSAO Inhibitor	PXS-4728	Neuro inflammatory/Neurodegenrative			Phase 2 ready		
Dual SSAO/MPO inhibitor	PXS-5370	Anti-inflammatory for multiple indications		Phase 1 ready			
Bronchitol		Cystic fibrosis					On market
Aridol		Asthma diagnosis					On market

Source: Pharmaxis.

Exhibit 2: Active 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	Year end 2022
	Hepatocellular Carcinoma (HCC)	$7 billion	Phase 1c 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 mid 2022	2H 2023
PXS-6302	Modification of established scars	$3.5 billion	**SOLARIA 2 trial** - Phase 1c 3 month placebo controlled study in patients with established scars (>1 year old)	Part 1 (n = 8): Part 2 (n = 42)	Recruiting	Q4 2022
	Scar prevention post surgery	$3.5 billion	Phase 1c 3 month placebo controlled study in patients with scarring subsequent to a burns injury	50	First patient 3Q CY22	1H 2023

Source: Pharmaxis.

Pharmaxis Clinical Update – the Active Pipeline

PXS-5505: Myelofibrosis and Liver Cancer

Fibrotic bone marrow cancer myelofibrosis (MF) – significant Phase 2 data expected by end-CY22

Background: Phase 1 data demonstrated >90% inhibition of LQX enzymes. The drug is safe and well tolerated. A Phase 1c/2a clinical trial was cleared by the FDA under the Investigational New Drug scheme and commenced dosing in the March quarter of 2021 at sites in Australia and South Korea.

The primary endpoint of the trial is to demonstrate that PXS-5505 can be used as a monotherapy on patients without access to treatment with approved JAK inhibitor drugs. The study also aims to explore the impact of inhibiting lysyl oxidase enzymes on important disease parameters such as bone marrow fibrosis, cytopenia and spleen volume.

Current status: The open-label trial is currently in Phase 2a, where 24 patients will be treated for 6 months.

All sites in Australia and Korea are actively recruiting patients, with the first site in Taiwan also commencing recruitment. Recruitment is expected to complete by mid-CY2022. The company expects to release significant data before the end of CY2022.

Exhibit 3: Competing development programs for primary myelofibrosis

Product	Company	Product type	Comments	Target date	Clinical ID	Phase
GB2064	Galecto Biotech AB	LOXL2 inhibitor	Study of orally administered GB2064 a LOXL-2 inhibitor over 9 months. Subjects will receive doses of GB2064, given twice per day.	Dec-22	NCT04679870	2
Imetelstat	Geron Corp	Telomerase inhibitor	A Study Comparing Imetelstat Versus Best Available Therapy for the Treatment of Intermediate-2 or High-risk MF Who Have Not Responded to JAK-Inhibitor Treatment.	May-24	NCT04576156	3
Navitoclax/Ruxolitinib	AbbVie	BCL-2 inhibitor /JAK inhibitor	Study of Oral Navitoclax Tablet in Combination With Oral Ruxolitinib Tablet to Assess Change in Spleen Volume in Adult Participants With Relapsed/Refractory MF	Feb-31	NCT04468984	3
Pacritinib	CTI BioPharma	JAK2 inhibitor	Study of Pacritinib in Patients With Primary MF, Post Polycythemia Vera MF, or Post-Essential Thrombocythemia MF	Dec-25	NCT03165734	3
Fedratinib	Celgene	JAK2 inhibitor	Safety Trial of Fedratinib in Subjects with Intermediate or High-Risk Primary MF, Post-Polycythemia Vera MF, or Post-Essential Thrombocythemia MF and Previously Treated With Ruxolitinib With Concomitant Luspatercept for Subjects With Anemia	Dec-23	NCT03755518	3
Momelotinib/Danazol	Sierra Oncology	JAK1 inhibitor/hormone	A Study of Momelotinib Versus Danazol in Symptomatic and Anemic MF Patients (MOMENTUM)	Apr-28	NCT04173494	3
Parsaclisib/Ruxolitinib	Incyte Corp	PI3Kδ Inhibitor/JAK inhibitor	Evaluate the Efficacy and Safety of Parsaclisib and Ruxolitinib in Participants With MF (LIMBER-313)	May-26	NCT04551066	3
KRT-232	Kartos Therapeutics	MDM2 antagonist	KRT-232 Versus Best Available Therapy for the Treatment of Subjects With MF Who Are Relapsed or Refractory to JAK Inhibitor Treatment	Dec-25	NCT03662126	3
CPI-0610	Constellation Pharm.	BET inhibitor	Comparing CPI-0610 and ruxolitinib with placebo and ruxolitinib in MF patients that have not been exposed previously to Janus kinase inhibitors.	Apr-27	NCT04603495	3

Source: Clinicaltrials.gov

Liver cancer (HCC) – inbound interest remains high, with University of Rochester filing IND

Background: The recent IND filed by University of Rochester has paved the way for a Phase 1c/2a trial in hepatocellular carcinoma (HCC), a type of liver cancer.

An application for a Phase 1c/2a clinical trial in HCC patients was cleared by the FDA in 4QCY21. The study aims to have PXS-5505 added to the current chemotherapy standard of care, combining it with PD-L1 inhibitor and an anti-VEGF drug as a first-line therapy in newly diagnosed HCC.

Current status: Negotiation with the Wilmot Centre Institute, University of Rochester Medical Center, has reached an agreement, which will see Phase 1c commence in the coming months. The Phase 1c trial is expected to cost Pharmaxis ~US$1.2m over FY23 and FY24.

PXS-6302: Established and Burns Injury Scars

Background: Pharmaxis has successfully completed Phase 1a/b clinical trials. In these trials, PXS-6302 showed promising results in inhibiting the enzymes that play a critical role in the development of scar tissues.

Current status: The company is currently working with the University of Western Australia and the Fiona Stanley Hospital to progress into two 3-month patient trials in established scars (part 1) and burn scars (part 2).

Solaria 2 trial outline: part 1 – established scars (Professor Fiona Wood, principal investigator)

The first patient with established scars was enrolled for monitoring and review in January 2022. Recruitment for the remaining patients commenced this quarter. A report of the study is expected before the end of the year.

Target population	Patients with established scar (more than one year old), >10cm^2 area, 18–60 years old
Cohort 1	8 patients receive 2% PXS-6302 cream Applied once daily to 10cm^2 area of scar (self-administered)
Cohort 2	42 patients, randomised into two groups (placebo or PXS 6302 cream) Applied once daily to 10cm^2 area of scar (self-administered) Samples collected at day 1 (commence treatment), 3 months only (final treatment)
Primary outcome measures	Safety-adverse events
Secondary outcome measures	Image assessment, POSAS, ultrasound, histology

Solaria 2 trial outline: part 2 – acute setting – improving healing after a burn injury

The second clinical trial in burn scars is in preparation, with recruitment of patients expected in the second half of the year.

Study design	Randomised controlled trial with placebo or treatment cream 3 months –once per day treatment
Target population	Adults with non-severe burn injury, recruited at 2–3 weeks post-injury
Primary outcome measures	Adverse events
Secondary outcome measures	3D scar scans, POSAS, ultrasound, histology, requirement for secondary intervention for scar (eg laser therapy)

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