New indication for PXS-5505

Pharmaxis lead clinical asset, PXS-5505, is currently in a Phase 2a trial in patients with bone marrow cancer myelofibrosis.

Separately, independent research conducted at the University of Rochester Medical Centre, New York State in a model of the liver cancer cholangiocarcinoma (CCA), has shown that the addition of PXS-5505 to current chemotherapy standard of care improved efficacy.

An Investigational New Drug application (IND) submitted by the investigator has now been accepted by the FDA clearing the way for trial of PXS-5505 in patients with the liver cancer hepatocellular carcinoma, HCC.

The trial design approved by the FDA allows PXS-5505 to be added to current chemotherapy standard of care (combination of a PD-L1 inhibitor and an anti-VEGF drug) as first line therapy in newly diagnosed patients with unresectable HCC carcinoma. Timing of the trial is yet to be finalized but will include a dose escalating phase designed to measure the impact of PXS-5505 on fibrosis and drug perfusion when used in combination. This will be followed by a 6-month trial of the selected dose with both safety and efficacy endpoints.

Liver cancer – High fibrotic component

Primary liver malignancies are now the 4th leading cause of cancer related mortality worldwide with a poor 5-year survival rate of around 20%. Currently only about 20-30% of HCC are resectable (able to be removed with surgery) when first diagnosed with the remainder of patients given chemotherapy as a first line therapy.

HCC is characterised by the presence of highly fibrotic tissue which leads to tumour stiffness and a decrease in the ability of drugs to penetrate in the tumour.

Valuation – Significant upside

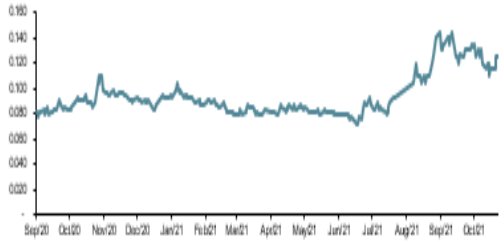
The investigator led trial in liver cancer potentially expands the clinical indication opportunity set and augurs well for other cancers in combination with current chemotherapy protocols. We see the advance into liver cancer as positive in enhancing economic potential of PXS-5505 and validation of the technology, however, our fair value estimate remains unchanged at this point at A$243m or A$0.53 per share based on sum-of-the-parts comprising the two clinical programs (PXS-5505 and PXS-6302) and its mannitol division. PXS-5505 for myelofibrosis is our highest value program at A$116m.

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 (such as 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® and Aridol®, now sold globally.

Stock	PXS.ASX
Price	A$0.12
Market cap	A$55m
Valuation	A$0.53

Company data	
Net cash	A$16.1m
Shares on issue	454.4m
Code ASX	PXS
Catalysts	
PXS-5505 trial	Myelofibrosis
PXS-6302 trial	Anti-scarring

PXS Share Price (A$)



Source: FactSet

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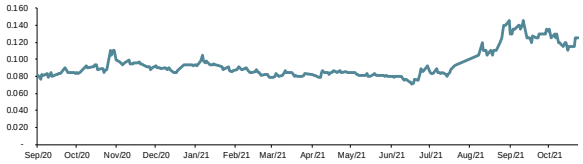
Financials

Pharmaxis PXS-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA		
Price	**$**	**0.12**
52 week high / low	$	0.07-0.14
Valuation	**$**	**0.53**
Market capitalisation	$m	55.4
Shares on issue (basic)	**m**	454.4
Options / rights	m	18.1
Other equity	m	0.0
Shares on issue (diluted)	**m**	**472.5**

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**	**20.5**	**nm**	**nm**
FCF Yield	%	nm	nm	4.9%	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**	**31.5**	**48.8**	**43.0**	**48.5**	**47.6**
EV/EBITDA	x	(1.7)	(3.7)	85.9	(3.8)	(28.3)
EV/EBIT	x	(1.5)	(3.0)	(16.2)	(3.4)	(16.2)
Price to book (NAV)	x	3.2	33.7	19.5	132.5	25.2
Price to NTA	x	3.4	98.4	32.0	(65.4)	72.0

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**

HALF YEARLY DATA		2H20	1H21	2H21	1H22	2H22
Total Revenue	$m	8.6	13.7	9.9	7.3	7.3
Operating expenses	$m	(13.5)	(11.8)	(11.3)	(13.7)	(13.7)
EBITDA	$m	(4.8)	1.9	(1.4)	(6.4)	(6.4)
EBIT	$m	(4.8)	0.3	(1.4)	(7.1)	(7.1)
PBT	$m	(3.6)	0.0	(3.0)	(7.2)	(7.2)
Reported NPAT	$m	(3.6)	0.0	(3.0)	(7.2)	(7.2)

Source: Company reports, MST Access estimates

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)**

Sensitivities and Risks

Pharmaxis is subject to all the risks typically associated with drug development, including the possibility of unfavourable outcomes in clinical trials, regulatory decisions, success of competitors, financing, and commercial decisions by partners or potential partners. In addition, key stock-specific sensitivities include:

Clinical risk

The company's medicinal chemistry expertise and proprietary assays underpin substantial drug discovery capabilities and provide significant opportunities to design, test, and optimise potential drug candidates in preclinical settings. This has been demonstrated by the development of a broad portfolio of small molecule amine oxidase inhibitors over the last five years.

However, drug development carries a raft of associated clinical risks including clinical trial delays or failures which could have a significant impact on the progress of individual assets and related candidates in the pipeline. The most important near-term development sensitivity is related to PXS-5505, given its Orphan Drug Designation status, and to a lesser extent PXS-6302. Both assets are pan-LOX inhibitors and are entering Phase 2a and Phase 1c trials respectively designed to demonstrate efficacy in patients. Clinical asset specific clinical risk considerations also include:

Clinical target risk: Although PXS-5505 was shown to be well tolerated at the highest dose given and has delivered complete inhibition of the target enzymes Phase 2a will answer the question of whether the disease modifying effect seen in animal models can be replicated in patients.

Clinical development path risk: Targeting of keloid scarring using PXS-6302 could be face additional challenges from a clinical development perspective given the heterogeneity of these scars, variability in patient and skin types, and the less objective measures available to monitor progress.

As such, success at this stage will determine the next leg of development activities and have a major bearing on partnering and commercialisation prospects for both clinical assets.

Key person risk is also a consideration for the company, given its reliance on its drug discovery engine and the highly experienced team currently in place.

Regulatory risk

Market approval will depend on satisfying the requirements of multiple regulators. As in the case of Bronchitol®, this can result in additional data requirements and lead to time delays and increased funding needs. However, the company's experience in bringing Bronchitol® to market despite such delays bodes well for future submissions.

Commercialisation risk

The launch of Bronchitol® and Aridol® demonstrate the ability to develop a drug candidate through to commercialisation. Nonetheless, and notwithstanding competition, adoption of the company's amine oxidase inhibitors, if successful in reaching the market, could be lower than expected. This could occur if clinical findings are not compelling compared to the standards of care or if the cost of using the drug if in combination outweighs the added clinical benefit. A related issue in commercialisation risk is the company's reliance on appropriate partners and/or government grants for ongoing development of its assets.

Funding risk

Pharmaxis' currently solid cash position should be adequate to meet near-term goals given the prioritisation of clinical programs and strategic partnerships established to date. However, cost of trials and operational expenses may overrun estimates and require additional capital to be raised. This is offset to a large degree by the cash flow provided by the growing sales of Bronchitol® and Aridol® globally, along with the restructuring of costs in that business.

Bronchitol®

Despite the launch in multiple countries in 2020, sales of Bronchitol® are still ramping up. Although promising to date, there is no long-term visibility on the peak levels of the product or pricing power in the market should a competitor product emerge.

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