Pharmaxis

PXS.AX

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Useful FDA feedback paves way for new arm of lead clinical trial

NEED TO KNOW

- Helpful FDA feedback – supports adding an arm to current Phase 2 clinical trial for PXS-5505
- Current trial is monotherapy for myelofibrosis (bone cancer); new arm will combine PXS-5505 with SOC

FDA feedback outlines key features of a PXS-5505 + SOC trial for myelofibrosis: Pharmaxis (PXS) has announced that the US Food and Drug Administration (FDA) has provided helpful feedback based on the safety data for MF-101 – an ongoing monotherapy trial for PXS-5505 in myelofibrosis (MF) which is PXS's lead clinical trial program. This interim data showed that PXS-5505 is well tolerated while stabilising or improving symptoms, haematological cell counts and fibrosis grades. The feedback included guidance on the number of patients, dosage, study duration and endpoints for a potential study of PXS-5505 in combination with the current standard of care (SOC), a JAK inhibitor.

Additional arm to widen existing trial; recruitment to start by end-CY23: PXS has indicated that the FDA feedback supports starting an additional arm of its lead clinical trial program, combining PXS-5505 with the SOC. The design of the additional arm is yet to be disclosed, but PXS aims to use existing trial sites and initiate the combination arm at the same dose as in the monotherapy arm, with recruitment to commence by end-CY23. Further details will be provided after regulatory feedback, expected 2QCY23. PXS has also stated that it will not progress its liver cancer initiatives, in order to maintain a focus on blood cancer 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 is currently in Phase 2 clinical trials. PXS-5505 is a novel small molecule and irreversible inhibitor to key enzymes involved in the formation of collagen, specifically the lysyl oxidase (LOX) family of proteins, whose overproduction is implicated in many conditions of chronic inflammation and pathological fibrosis.

Valuation

Our valuation is A$0.34/share, using a DCF-based sum-of-the-parts approach for the clinical programs (PXS-5505, PXS-6302) and the mannitol division.

Risks

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

Equities Research Australia

Pharmaceuticals, Biotechnology & Life Sciences

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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$35m**
Cash on hand	**A$16.5m (31 Dec 22)**

Upcoming Catalysts / Newsflow

1HCY23	PXS-4728, neurodegenerative disease Phase 2 trial: to start recruiting patients
4QFY23	PXS-6302, scarring: results from placebo-controlled phase of study
mid-2023	PXS-5505, MF: Interim data from Phase 2 study

Share Price (A$)

Source: FactSet, MST Access.

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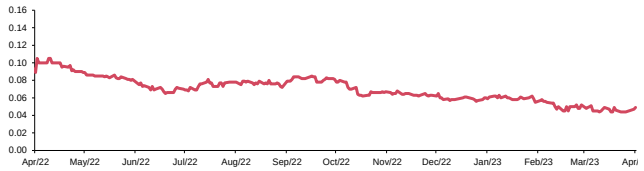
Financial Summary

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	35.3
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		FY19A	FY20A	FY21A	FY22A	FY23E
Reported NPAT	$m	(20.1)	(13.9)	(3.0)	(1.9)	(11.7)
Underlying NPAT	**$m**	**(20.1)**	**(13.9)**	**(3.0)**	**(1.9)**	**(11.7)**
Reported EPS (diluted)	¢	(5.3)	(3.5)	(0.7)	(0.3)	(2.1)
Underlying EPS (diluted)	**¢**	**(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	¢	(5.2)	(3.4)	0.8	(2.9)	(1.3)
Free cash flow per share	¢	(5.4)	(3.5)	0.6	(2.9)	(3.0)
Price to free cash flow per share	**x**	**nm**	**nm**	**8.2**	**nm**	**nm**
FCF Yield	%	nm	nm	12.2%	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**	**11.3**	**28.6**	**22.9**	**30.6**	**39.1**
EV/EBITDA	x	(0.6)	(2.2)	45.6	(2.5)	(3.7)
EV/EBIT	x	(0.5)	(1.7)	(8.6)	(2.0)	(3.4)
Price to book (NAV)	x	1.3	13.5	7.8	2.5	8.6
Price to NTA	x	1.4	39.5	12.9	2.8	11.2

KEY RATIOS		FY19A	FY20A	FY21A	FY22A	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)	(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		FY19A	FY20A	FY21A	FY22A	FY23E
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		FY19A	FY20A	FY21A	FY22A	FY23E
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**		

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

PROFIT AND LOSS		FY19A	FY20A	FY21A	FY22A	FY23E
Revenue	**$m**	**5.7**	**7.0**	**6.7**	**7.4**	**9.4**
Other income	$m	6.5	5.6	16.9	8.3	4.9
Total Revenue	**$m**	**12.2**	**12.7**	**23.6**	**15.8**	**14.3**
Operating expenses	$m	(30.3)	(25.9)	(23.1)	(28.1)	(23.2)
EBITDA	**$m**	**(18.1)**	**(13.2)**	**0.5**	**(12.3)**	**(8.9)**
Depreciation & Amortisation	$m	(2.6)	(3.2)	(3.2)	(3.2)	(0.8)
EBIT	**$m**	**(20.7)**	**(16.5)**	**(2.7)**	**(15.5)**	**(9.7)**
Net interest	$m	0.9	0.4	0.1	0.2	0.0
Pretax Profit	**$m**	**(20.1)**	**(13.9)**	**(3.0)**	**(1.9)**	**(11.7)**
Tax expense	$m	0.0	0.0	0.0	0.0	0.0
Reported NPAT	**$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		FY19A	FY20A	FY21A	FY22A	FY23E
Revenue	%	(75.8)	4.1	86.5	(33.3)	(9.1)
EBITDA	%	(290.7)	(26.9)	(103.8)	(2,557.1)	(27.6)
EBIT	%	(424.7)	(20.6)	(83.9)	486.5	(37.7)
Reported NPAT	%	(412.0)	(30.5)	(78.7)	(34.8)	502.1
DPS	%	nm	nm	nm	nm	nm

BALANCE SHEET		FY19A	FY20A	FY21A	FY22A	FY23E
Cash	$m	31.1	14.8	18.7	8.9	6.3
Receivables	$m	7.3	7.1	3.0	8.0	4.2
Other	$m	2.1	2.6	3.6	2.3	5.1
Current assets	**$m**	**40.6**	**24.5**	**25.3**	**19.2**	**15.6**
PPE	$m	10.3	8.9	6.2	3.2	2.6
Intangible assets	$m	0.8	0.9	1.1	1.0	1.1
Other	$m	1.1	1.1	0.9	1.7	1.7
Non current assets	**$m**	**12.1**	**10.9**	**8.3**	**6.0**	**5.5**
Total assets	**$m**	**52.7**	**35.4**	**33.6**	**25.2**	**21.1**
Trade and other payables	$m	4.8	3.5	3.8	2.7	5.3
Borrowing	$m	1.2	1.8	2.0	2.0	2.0
Other	$m	2.1	1.5	2.1	1.4	0.7
Current liabilities	**$m**	**8.1**	**6.8**	**7.9**	**6.1**	**8.0**
Borrowing and leases	$m	6.0	6.3	4.3	2.3	2.3
Other liability	$m	15.7	14.0	10.7	0.0	0.0
Non current liabilities	**$m**	**29.7**	**27.2**	**22.9**	**8.3**	**8.3**
Total liabilities	**$m**	**37.9**	**34.0**	**30.7**	**14.4**	**16.3**
Net assets	**$m**	**14.8**	**1.4**	**2.8**	**10.8**	**4.8**
Share capital	$m	367.3	367.3	371.4	380.4	391.1
Retained earnings	$m	(374.2)	(388.2)	(391.2)	(393.1)	(404.8)
Other	$m	21.8	22.3	22.6	23.5	23.5
Total equity	**$m**	**14.8**	**1.4**	**2.8**	**10.8**	**4.8**

CASH FLOW		FY19A	FY20A	FY21A	FY22A	FY23E
Net loss for period	**$m**	**(20.1)**	**(13.9)**	**(3.0)**	**(1.9)**	**(11.7)**
Depreciation & Amortisation	$m	2.9	3.2	3.2	3.2	0.8
Changes in working capital	$m	(5.1)	(1.6)	4.0	(5.9)	3.6
Other	$m	2.5	(1.0)	(1.1)	(11.5)	0.0
Operating cash flow	**$m**	**(19.8)**	**(13.3)**	**3.1**	**(16.1)**	**(7.3)**
Payments for PPE	$m	(0.6)	(0.3)	(0.3)	(0.1)	(0.1)
Other	$m	(0.4)	(0.3)	(0.3)	(0.2)	(0.2)
Investing cash flow	**$m**	**(1.0)**	**(0.6)**	**(0.6)**	**(0.3)**	**(0.3)**
Equity	$m	22.7	0.0	4.1	9.1	10.0
Lease liability payments	$m	(1.6)	(2.2)	(2.3)	(2.4)	0.0
Other	$m	(0.3)	(0.3)	(0.2)	(0.1)	0.0
Financing cash flow	**$m**	**20.8**	**(2.5)**	**1.5**	**6.6**	**10.0**
Cash year end	**$m**	**31.1**	**14.8**	**18.7**	**8.9**	**6.3**
Free cash flow	**$m**	**(20.8)**	**(13.9)**	**2.4**	**(16.4)**	**(16.4)**

Source: Company reports, MST Access estimates

Methodology & Disclosures

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