New collaboration to study PXS-4728 for early neurodegenerative treatment

Pharmaxis has announced a collaboration with Parkinson's UK (the largest European charitable funder of Parkinson's research) and leading neurologists. The collaboration will pursue a Phase 2 study of PXS-4728 to treat patients at the earliest possible time who are at risk of developing Parkinson's disease and other neurodegenerative conditions.

We view this announcement as positive because:

- it advances a drug that was not being investigated previously by Pharmaxis, widening its current slate of potential candidates
- the neurological conditions under investigation are a new indication for Pharmaxis.

Details of the Phase 2 study

The study will receive £2.9m (~A$5m) in funding from the Parkinson's UK drug discovery arm, Parkinson's Virtual Biotech. The funding will be received in advance payments as the trial progresses, with the study expected to cost ~A$5.8m. Pharmaxis will provide the drug and the compound to be used to measure inflammation in the brain scans of trial participants. The study will be conducted by neurologists from the Universities of Sydney and Oxford, working in collaboration. The 40-patient clinical trial will begin recruiting patients in 1H CY?2023.

The study is based on previous research which has indicated that the development of isolated Rapid Eye Movement Sleep Behaviour Disorder (iRBD) is a very strong predictor of Parkinson's and dementia with Lewy Bodies, with over 70% of iRBD patients developing a neurodegenerative disease. The study will seek to determine whether PXS-4728 can reduce neuroinflammation in iRBD patients.

Background on PXS-4728: previous off-target effect now a positive for further investigations

PXS-4728 is a potent inhibitor of the inflammatory enzyme SSAO (semicarbazide-sensitive amine oxidase), which was discovered by the Pharmaxis research team. It had promising results in clinical trials but was returned to Pharmaxis by licensee Boehringer Ingelheim after it was found that the drug had an off-target effect on an additional inflammatory enzyme in the brain, MAO-B (monoamine oxidase B).

However, this trial will aim to reduce inflammation by inhibiting **both** SSAO and MAO-B. More broadly, Pharmaxis sees PXS-4728 as an ideal candidate for studies in neurodegenerative conditions. It has passed all long-term toxicity studies and has been well tolerated in clinical trials.

Valuation: A$0.45/share

Our fair value estimate remains unchanged 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. Key risks to our valuation include both clinical and funding risk.

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.

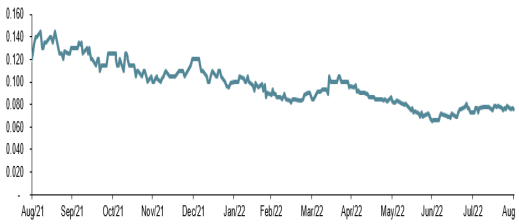
Stock	PXS.ASX
Price	A$0.08
Market cap	A$42m
Valuation	A$0.45 (unchanged)

Company data	
Net cash (end June 2022)	$4.6m
Shares on issue	549.1m
Code ASX	PXS

Upcoming news flow

- PXS-5505 MF trial: data by end-CY22
- PXS-5505, liver cancer: Phase 1c commencement
- PXS-6302 scar trial: report on established scars by year-end; recruitment for burns in 2HCY22
- PXS-4728 neurodegenerative disease Phase 2 trial: to start recruiting patients in 1HCY2023

PXS share price (A$)



Source: FactSet.

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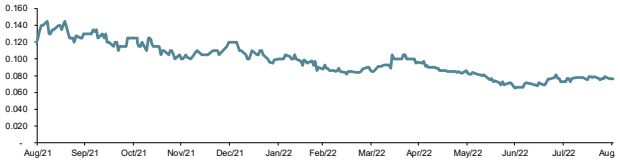
Financials

Pharmaxis PXS-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA		
Price	**$**	**0.08**
52 week high / low	$	0.07-0.14
Valuation	**$**	**0.45**
Market capitalisation	$m	41.2
Shares on issue (basic)	**m**	549.1
Options / rights	m	25.0
Other equity	m	0.0
Shares on issue (diluted)	**m**	**574.1**

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**	**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**	**36.5**	**39.1**
EV/EBITDA	x	(1.0)	(2.6)	57.5	(3.0)	(3.7)
EV/EBIT	x	(0.8)	(2.1)	(10.9)	(2.3)	(3.4)
Price to book (NAV)	x	2.0	20.7	12.0	3.8	8.6
Price to NTA	x	2.1	60.5	19.7	4.2	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**
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	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	$m	6.5	5.6	16.9	8.3	3.1
Total Revenue	**$m**	**12.2**	**12.7**	**23.6**	**15.8**	**12.6**
Operating expenses	$m	(30.3)	(25.9)	(23.1)	(28.1)	(23.2)
EBITDA	**$m**	**(18.1)**	**(13.2)**	**0.5**	**(12.3)**	**(10.7)**
Depreciation & Amortisation	$m	(2.6)	(3.2)	(3.2)	(3.2)	(0.8)
EBIT	**$m**	**(20.7)**	**(16.5)**	**(2.7)**	**(15.5)**	**(11.4)**
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)	(20.3)
EBITDA	%	(290.7)	(26.9)	(103.8)	(2,557.1)	(13.3)
EBIT	%	(424.7)	(20.6)	(83.9)	486.5	(26.4)
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	$m	15.7	14.0	10.7	(0.1)	(2.0)
Non current liabilities	**$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	386.1
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	5.0
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**	**5.0**
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, MST Access.

Exhibit 1: Trial design

Name of trial	A Phase 2A, Multi Centre, Double-blind, Randomised, Placebo-controlled, Parallel-group Study to Assess the Effect of 12 Weeks Treatment with Oral PXS-4728A on Microglia Activation, as Measured by Positron Emission Tomography (PET), in Patients With Isolated Rapid Eye Movement Sleep Behaviour Disorder (iRBD)
Trial number	TBD
Primary endpoint	Reduction of the distribution volume across nigrostriatal regions in TSPO PET imaging comparing the active arm at 12 weeks to baseline
Secondary endpoints	Reduction in the total distribution volume in the active arm at 12 weeks Clinical and patient reported outcomes related to iRBD To explore the utility of novel biomarkers in the evaluation of target engagement / biological activity and benefits of PXS-4728
Blinding status	Blinded
Trial design	Randomised, Double-blind, Placebo Controlled Clinical Trial with iRBD receiving 12 weeks of treatment with oral PXS-4728A a 3:1 randomisation
Treatment route	Oral
Treatment frequency	Once daily
Dose level	One dose
Number of subjects	40 (up to 48 to be screened)
Subject selection criteria	Male or female aged 60 to 80 with REM sleep behaviour disorder according to ICSD-3 criteria and objective evidence of one or more features of parkinsonism, impaired olfaction and/or impaired colour vision discrimination, which have been associated with an increased risk for transitioning to a synucleinopathy
Trial locations	Multicentre – 2 sites. NSW, Australia and United Kingdom
Commercial partners involved	No commercial partner

Source: Pharmaxis.

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