New capital extends cash runway

Pharmaxis has raised A$7.2m (approximately 68.2m shares) via a placement to institutional investors, lifting net cash on hand to about A$23.3m (using net cash at end-1Q22 of A$16.1m). Further, a share purchase plan currently underway and closing 15 December could raise up to an additional A$2m. As such, the company's cash runway now extends to the start of CY23, not accounting for any potential licencing deals of clinical assets in the interim. The bolstered cash position will assist with a number of important initiatives: sponsoring the PXS-5505 liver cancer trial; adding trial sites to the current myelofibrosis (MF) trial; and offsetting any temporary weakness in the mannitol business.

Sponsoring PXS-5505 liver cancer trial

Preclinical data from independent research conducted at the University of Rochester showed PXS-5505 with or without chemotherapy treatment in a pre-clinical model of liver cancer significantly improves survival, delays tumour growth, and reduces intertumoral pressure. An Investigational New Drug (IND) application subsequently cleared by the FDA has allowed the commencement of a Pharmaxis-sponsored clinical trial at a cost of ~US$2.5m.

Adding trial sites to current MF trial

The increased cash on hand will allow the expansion of trial sites to 22 sites (from 14 previously) for the 24-patient Phase 2a trial of PXS-5505 in bone marrow cancer MF. This should help to facilitate patient recruitment given the rarity of the cancer.

Offsetting mannitol business weakness

A stronger cash position allows the company to weather any temporary volatility in sales of Bronchitol®, given COVID-19 related uncertainties, following its launch in the United States in March 2021 by commercialisation partner Chiesi.

Valuation: $0.46/share on 522.6m shares

The investigator-led trial in liver cancer 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 the economic potential of PXS-5505 and in validating the technology. However, our fair value estimate remains unchanged, pending commencement of the PXS-5505 liver cancer trial, at A$243m or A$0.46 per share based on sum-of-the-parts comprising the two clinical programs (PXS-5505 and PXS-6302) and its mannitol division given increased shares on issue of 522.6m. PXS-5505 for MF is the program on which we place the highest value 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$0.10
Market cap	A$54m
Valuation	A$0.46

Company data	
Net cash (end-1Q22)	A$16.1m
Shares on issue	522.6m
Code ASX	PXS

Upcoming news flow	
PXS-5505 trial	Myelofibrosis
PXS-6302 trial	Anti-scarring

PXS share price (A$)

Source: FactSet

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Financials

Exhibit 1: Financial summary

Pharmaxis — **PXS-AU**

Year end 30 June, AUD unless otherwise noted

MARKET DATA		
Price	**$**	**0.11**
52 week high / low	$	0.07-0.14
Valuation	**$**	**0.46**
Market capitalisation	$m	54.9
Shares on issue (basic)	**m**	522.6
Options / rights	m	18.1
Other equity	m	0.0
Shares on issue (diluted)	**m**	**540.6**

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**	**17.6**	**nm**	**nm**
FCF Yield	%	nm	nm	5.7%	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**	**30.9**	**48.3**	**42.5**	**46.6**	**45.7**
EV/EBITDA	x	(1.7)	(3.6)	84.8	(3.7)	(27.2)
EV/EBIT	x	(1.5)	(2.9)	(16.0)	(3.3)	(15.6)
Price to book (NAV)	x	2.8	29.0	16.8	111.3	21.2
Price to NTA	x	2.9	84.7	27.5	(54.9)	60.5

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	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)

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: Pharmaxis, MST Access.

Capital injection extends cash runway to CY23

In August 2021, preclinical data from independent research conducted at the University of Rochester Medical Center (New York state), in a model of the liver cancer cholangiocarcinoma, showed that the addition of PXS-5505 to current chemotherapy standard of care (SOC) improved efficacy. An Investigational New Drug (IND) application subsequently submitted to and cleared by the FDA paved the way for a trial of PXS-5505 in patients with the liver cancer hepatocellular carcinoma (HCC).

Liver cancer – high fibrotic component

Primary liver malignancies are now the fourth-leading cause of cancer-related mortality worldwide with a poor 5-year survival rate of around 20%. Currently only about 20-30% of HCCs 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 the tumour.

Investigator-led HCC clinical trial design now posted on clinicaltrials.gov

Dr Nabeel Badri is Principal Investigator at the University of Rochester Wilmot Cancer Center. The FDA-approved trial design allows PXS-5505 to be added to current chemotherapy SOC (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 finalised 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.

Exhibit 2: PXS-5505 in unresectable or metastatic hepatocellular carcinoma (cancer of liver)

Name of trial	A Phase 1b/2 Trial of PXS-5505 Combined With First Line combination therapy Atezolizumab Plus Bevacizumab For Treating Patients With Unresectable Hepatocellular Carcinoma
Trial number	NCT05109052
Blinding status	Open label
Placebo controlled	No
Trial design	This trial will assess the safety and tolerability of PXS-5505 incorporating first-line combination therapy Atezolizumab and Bevacizumab in unresectable or metastatic hepatocellular carcinoma. Phase 2 will assess the efficacy of this combination therapy in unresectable or metastatic hepatocellular carcinoma.
Treatment route	Oral
Treatment frequency	Twice daily
Dose level	(PXS-5505) 100-200mg twice daily (Atezolizumab) 1200mg every 3 weeks (Bevacizumab) 15mg/kg every 3 weeks
Number of subjects	48 patients
Subject selection criteria	Patients (18 Years and older) with histological or radiographically confirmed unresectable or metastatic hepatocellular carcinoma.
Trial locations	TBC
Comments	Investigator (University of Rochester): Estimated completion date 31 December 2028

Source: Clinicaltrials.gov.

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 (a topical formulation for scarring). 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 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 indicate 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 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

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 launches of Bronchitol® and Aridol® demonstrate the company's 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 SOC or if the cost of using the drug 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' solid cash position should be adequate to meet near-term goals given the prioritisation of clinical programs and strategic partnerships established to date. However, trial costs and operational expenses may overrun estimates, requiring additional capital raising. This is largely offset by cash flow from 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 of its pricing power in the market should a competitor product emerge.

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