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Pharmaxis Ltd. (PXS)

FDA clears IND for myelofibrosis study

FDA IND clearance validates pre-clinical and Phase 1 data

The US FDA has cleared PXS' IND application for PXS-5505, allowing PXS to proceed with its planned Phase 1/2 trial for the treatment of myelofibrosis (a bone marrow cancer) in adults. PXS also has orphan drug designation from the FDA. PXS-5505 is a pan-LOX inhibitor which broadly inhibits all the LOX family of enzymes. The IND application included data generated from Phase 1 study in healthy volunteers and pre-clinical cancer models, toxicology studies and manufacture of drug.

Myelofibrosis study expected to start in 4QCY20

The trial is expected to start in 4QCY20 and conclude in 2022. PXS is well advanced in preparatory activities including manufacture of drug, assignment of CRO to run the trial and site selection (given COVID-19 is impacting availability of trial sites). The trial will be open label (data will be available at various time points during the study), have a 1 month dose escalation phase, followed by 6 months of treatment. It will recruit patients with intermediate or high-risk myelofibrosis of all types. The trial is designed to assess the safety and efficacy of the drug as a monotherapy in myelofibrosis patients. PXS is also planning follow up combination studies with SOC JAK inhibitors in future. The myelofibrosis market is estimated to be >US\$1bn and PXS believes its mechanism of action will differentiate it from the current standard of care drugs. PXS expects to announce further details of the upcoming trial in the coming months. We expect to get more details around the trial design, size, cost and endpoints of the trial. We do not ascribe any value to it as yet and it represents upside risk to our valuation.

Retain Buy (speculative) and Valuation of \$0.20

No change to earnings. We retain Buy (Spec) and Valuation of A\$0.20/sh. PXS' current price is largely supported by our valuation for the Bronchitol + Aridol segment, with the market ascribing minimal value to its drug development business. Key catalysts: a) FDA approval decision for Bronchitol on 1st Nov'20, triggering US\$7m milestone in 4QCY20 and US\$3m on product shipment in 1QCY21 from partner Chiesi; b) decision by partner Boehringer Ingelheim on further development of BI_1467335 for Diabetic Retinopathy in 4QCY20; c) a partnering deal for LOXL-2 before end of CY20 and d) Initiation of Phase 1/2 myelofibrosis trial in Dec'20.

Recommendation
Buy (unchanged)
Price
\$0.115
Valuation
\$0.20 (unchanged)
Risk
Speculative

GICS Sector
Pharmaceuticals & Biotechnology

Expected Return

Capital growth	73.9%
Dividend yield	0.0%
Total expected return	73.9%

Company Data & Ratios

Enterprise value	\$38.8m
Market cap	\$45.5m
Issued capital	395.3m
Free float	98.7%
Avg. daily val. (52wk)	\$65,729
12 month price range	\$0.053- \$0.285

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.08	0.09	0.21
Absolute (%)	30.95	26.44	-46.34
Rel market (%)	29.67	13.44	-39.33



SOURCE: IRESS

Earnings Forecast

Year end 30th June	2019A	2020A	2021E	2022E	2023E
Revenue (A\$m)	12.2	12.7	31.4	20.2	17.7
EBITDA (A\$m)	-15.7	-12.1	6.2	-5.7	-4.4
NPAT (reported) (A\$m)	-20.1	-13.9	1.9	-10.0	-8.7
NPAT (normalised) (A\$m)	-19.0	-13.4	2.8	-8.9	-7.7
EPS (reported) (cps)	-5.1	-3.4	0.5	-2.5	-2.1
EPS (adjusted) (cps)	-4.8	-3.3	0.7	-2.2	-1.9
EPS growth (%)	N/A	N/A	NM	N/A	N/A
PER (x)	N/A	N/A	16.5	N/A	N/A
EV/EBITDA (x)	-2.5	-3.2	6.3	-6.8	-8.9
Dividend (cps)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
ROE (%)	-128.1%	NM	66.4%	NM	62.1%

NOTE: REVENUE INCLUDES R&D TAX INCENTIVE. MILESTONES FROM BI DEAL AND CHIESI DEAL AND FY21/22 REVENUE INCLUDES RISK ADJUSTED UPFRONT AND MILESTONES FROM LICENSING DEAL FOR LOXL-2. SOURCE: BELL POTTER SECURITIES ESTIMATES

Pharmaxis Ltd. (PXS)

COMPANY DESCRIPTION

Pharmaxis, is a biopharmaceutical company focused on the development of drugs for inflammatory and fibrotic diseases. Its lead assets Phase 2 SSAO/VAP-1 inhibitor BI_1467335 partnered in a multi-million dollar deal with Boehringer Ingelheim is targeting Diabetic Retinopathy an area of unmet need and a large market, and currently unpartnered Phase 1 LOXL-2 inhibitors are targeting Non-alcoholic Steatohepatitis (NASH), a multibillion dollar market, estimated to grow to be ~US\$20bn-US\$35bn. The LOXL-2 drug while not first-in-class, has evidence that it is best-in-class and can be useful in other fibrotic diseases and we forecast it to be a blockbuster (i.e. have over US\$1bn in peak sales). NASH market is expected to grow with rise in obesity and surpass HCV as the leading cause of liver transplant. There are currently no approved drugs which make the market largely untapped and underserved. The multifactorial aspect of NASH and future treatments likely to be a combination of therapies ensures that companies remain on the lookout for promising assets to license, which bodes well for licensing prospects for PXS' LOXL-2 inhibitors. PXS is also focusing on developing its earlier stage pipeline (LOX assets) targeting scarring and myelofibrosis (est. >\$1bn market). PXS also has two marketed respiratory products Bronchitol and Aridol which is approaching a key inflexion point with the US approval for Bronchitol expected on 1st Nov'20. US approval will see the segment generate cash (milestone from partner Chiesi) and become profitable.

INVESTMENT STRATEGY

We have a Buy (speculative) recommendation on Pharmaxis. Our investment thesis is based on:

\$0.20 valuation: We value PXS using a risk adjusted DCF at \$0.20. The valuation is approximately a 73.9% premium to the previous closing share price of \$0.115/sh.

Turnaround prospects are strong in FY21: PXS had a disappointing set back in 4QCY19 which caused a significant fall in its stock price, when partner Boehringer Ingelheim (BI) decided to discontinue further development of the partnered SSAO/VAP-1 drug BI_1467335 for NASH. We believe current price levels are not attributing much value to PXS' drug development business which is approaching key inflexion points in 4QCY20 which could drive a turnaround for PXS. These include: a) Results from phase 2A trials for BI_1467335 partnered with BI in Diabetic Retinopathy and BI's commercial decision regarding further development of the asset in 4QCY20; b) LOXL-2 asset has successfully completed Phase 1 trials and longer term toxicology studies, as well as added to the data package with further supporting studies providing evidence around its utility in fibrotic disease but also its best in class characteristics. PXS has been in partnering discussions for a while (since Jan'19) which have taken longer than it initially expected. The discussions and due diligence by interested parties are ongoing and we now expect a conclusion of the partnering process in 4QCY20; and c) Initiation of Phase 1/2 myelofibrosis trial with PXS-5505 in Dec'20, for which we currently do not assign any value. Also in 4QCY20 we expect FDA approval decision on Bronchitol, which will trigger a US\$7m milestone from PXS' partner Chiesi in 4QCY20 and another US\$3m in 1QCY21.

LOXL-2 targeting NASH has blockbuster potential: Pharmaxis' Phase 1 LOXL-2 asset is targeting Non-alcoholic Steatohepatitis (NASH), a multibillion dollar market, estimated to grow to be ~US\$20bn-US\$35bn. We model US\$1.45bn peak worldwide sales (pre risk adjustment) for LOXL-2 in NASH.

NASH represents significant commercial opportunity: NASH is a large market, growing rapidly with an increasing obese population. NASH is now the fastest growing reason for a liver transplant in the US and is expected to surpass Hepatitis C Virus (HCV) as the leading cause of liver transplants. There are currently no drugs approved for NASH, which

makes this market largely untapped and underserved and a lucrative market opportunity for PXS to target. There are several drugs in development and interest and competition has both heated up. However, we note that a string of keenly awaited trials have been unsuccessful and the first of the drugs awaiting approval was recently knocked back by the FDA. There have been a number of high value deals in this space and active companies are looking to license or acquire to build a portfolio of assets targeting different stages of NASH. Average deal sizes are ~US\$860m, however some have also been over \$1bn.

Scarcity of anti-fibrotic assets in development for NASH: Drugs targeting NASH fall under 3 groups based on their mechanism of action and stage of NASH they target – metabolic modifiers, anti-inflammatory agents and anti-fibrotic agents. It is expected that the future treatment for NASH is likely to be a cocktail of therapies as was seen earlier with HCV. Therefore we see drugs from each of the 3 categories to complement each other and competition likely to be restricted to drugs within the same category. Pharmaxis' LOXL-2 asset is an anti-fibrotic agent and therefore should complement other drugs in advanced development. There are very few drugs in development in this category and as far as we are aware it is the only one in its class being actively developed for NASH.

Drugs not first-in-class but potentially best-in-class: PXS' LOXL-2 inhibitors are not the first in their class. However based on pre-clinical data and Phase 1 data, we believe the drugs possess a more favourable PK/PD profile which position them as best-in-class. Data so far provides evidence of good safety profile, good oral bioavailability and potent, long lasting inhibition of targeted enzyme.

Potential exists to expand the use of lead drugs into broader fibrotic diseases: Both the lead drugs have potential to be used across fibrotic diseases with both SSAO and LOXL-2 enzymes upregulated in other areas such as lung and kidney, implying a broader utility in treating other diseases such as pulmonary fibrosis (IPF) and kidney fibrosis.

Partnership with Boehringer Ingelheim validates chemistry platform: PXS signed a multi-million dollar product acquisition deal with Boehringer Ingelheim (BI) in 2015, which marked the start of the turnaround for the company, strengthened its balance sheet and validated its amine oxidase chemistry platform and its ability to execute valuable deals. Although, the company had a disappointing set back in 4QCY19 with BI choosing to not pursue NASH for the partnered asset anymore, the deal has delivered to date €57m (A\$83m) in upfronts and milestones to PXS and BI is still continuing to develop the asset at this stage for Diabetic Retinopathy. Should BI continue to proceed with further development for DR, PXS stands to receive €177m (~A\$292m) in Phase 3 initiation, filing, approval and pricing milestones. Commercial milestones on reaching sales thresholds and royalties on net sales post approval are also part of the deal as it currently stands.

Early stage pipeline assets represent future value: PXS' oral pan LOX inhibitor PXS-5505 is targeting the bone marrow cancer myelofibrosis with an estimated market value of >\$1bn per year. Phase 1 trial is complete and PXS has been granted orphan drug designation by the FDA. IND for a Phase 1/2 trial has been approved by the FDA, with trial expected to start in 4QCY20. Pre-clinical studies for the topical LOX asset PXS-6302 targeting scarring is now complete. Investigator initiated clinical studies to assess safety and efficacy of the drug in burns related scars and pre-existing scars is expected to start in 2HCY20. We do not assign any value to these assets currently, however they represent future upside on progression into mid stage trials.

12 months cash runway with near term boost expected: PXS' had cash at end of FY20 of ~A\$14.8m, which along with the ~\$4.9m R&D rebate expected for FY20, in our view, provides PXS ~12 months cash runway. A US\$10m Milestone from Chiesi for Bronchitol (US\$7m in 4QCY20 and US\$3m in 1QCY21) and upfront from a LOXL-2 deal in 4QCY20 should further extend this cash runway. The company has a modest debt (related to finance lease) of A\$8.2m.

Risks

The key risks specific to Pharmaxis include, but are not limited to, the following:

- **Clinical risk:** There is a risk that PXS' clinical trials for its pipeline assets fail to reach their endpoints, which would in turn impact its commercial and partnering prospects.
- **Timing and clinical risk on partnered product:** For its partnered product BI_1467335, PXS is reliant on Boehringer Ingelheim (BI) for development timelines. The ability of PXS' product to finally reach the market and translate into royalty revenue streams for it depends on BI. Delays in timelines will affect medium term milestone payments to PXS as well as its long-term revenue flow. Also if the product fails at any stage of clinical development or BI decides to discontinue its development for DR (as it has already done for NASH) it will have a material adverse effect on our valuation.
- **Reliance on partnerships to unlock value:** The success of PXS' business model is underpinned by its ability to ultimately attract valuable partnering deals for its assets, given PXS lacks the commercial infrastructure to support commercialisation. Our valuation in part is underpinned by PXS' ability to ultimately attract a valuable partnering deal for its LOXL-2 asset. Failure to attract partners for this asset or to negotiate attractive deal terms as we have postulated will impact our forecasts.
- **Bronchitol US approval decision will affect our valuation:** Bronchitol and Aridol, (PXS' currently marketed products) account for ~34% of our current valuation for PXS. US Bronchitol sales are the key driver for revenue and the segment achieving profitability. Therefore if FDA does not approve Bronchitol, it will adversely affect our valuation. FDA decision is expected on 1st Nov'20. Chiesi has recently resubmitted its NDA addressing the matters detailed in the CRL issued by the FDA in June'19. Key matters pertain to revisions to packaging and user instructions and running a Human Factor Study after these to test their effectiveness in enabling healthcare professionals to properly conduct a mannitol tolerance test (MTT). We currently assign a 90% probability of success to US sales of Bronchitol.
- **Regulatory risk:** Successful commercialisation of PXS' products is ultimately dependent on getting approval from the regulatory authorities to commercially launch the product. While PXS' partner with much more experience in navigating regulatory channels will be responsible for obtaining approvals, failure to satisfy regulatory requirements could mean that the product will fail to reach the market.
- **Commercial risk:** The pharmaceutical market is intensely competitive and in particular the NASH space which PXS is targeting has several companies engaged in drug development. PXS' products are unlikely to be the first to market and therefore would not have first mover advantage. There is no guarantee that mid-late stage clinical trial results of the LOXL-2 drugs, even if they hit the endpoints of the studies, will be viewed as clinically meaningful by clinicians' vis-à-vis other approved NASH drugs by then on the market. Even if the drugs do get approved on successful pivotal studies, commercial adoption might still be hampered by the cost of the combination (especially since in LOXL-2's case we assume an add-on therapy positioning) or the competition in the NASH market having much larger impact than we have postulated.
- **Funding risk:** Delays in partnering of LOXL-2 is likely to impact PXS' funding position in the short term. PXS has cash of A\$14.8m and debt related to finance lease of A\$8.2m. This along with the expected R&D rebate for FY20 should provide ~12 months cash runway. A US\$10m milestone from Chiesi is due over 4QCY20/1QCY21. However, dependent on the size and cost of a phase 2 myelofibrosis trial, PXS may need to raise additional capital to fund it should there be delays in partnering its LOXL-2 asset.

Table 1 - Financial summary

Pharmaxis Ltd (PXS)						Share price (A\$)	\$0.115				
As at 19 August 2020						Market cap (A\$m)	45.5				
Profit and Loss						Valuation data					
Y/e June 30 (A\$m)	2019A	2020A	2021E	2022E	2023E	Y/e June 30	2019A	2020A	2021E	2022E	2023E
Product Sales Revenues	5.7	7.0	9.1	12.2	14.2	Net profit -normalised (A\$m)	-19.0	-13.4	2.8	-8.9	-7.7
Other Revenue (commercial)	0.0	0.0	21.8	7.4	0.0	EPS - normalised (c)	-4.8	-3.3	0.7	-2.2	-1.9
Other Income	6.5	5.6	0.5	0.5	3.5	EPS growth (%)	N/A	N/A	NM	N/A	N/A
Total Revenue	12.2	12.7	31.4	20.2	17.7	P/E ratio (x)	N/A	N/A	16.5	N/A	N/A
EBITDA	-15.7	-12.1	6.2	-5.7	-4.4	FCFPS (c)	-5.3	-3.5	2.8	-1.6	-2.2
Depreciation & Amortisation	-2.6	-3.2	-3.2	-3.2	-3.3	Price/FCF (x)	-2.2	-3.3	4.1	-7.1	-5.3
EBIT	-18.3	-15.3	3.0	-8.9	-7.6	DPS (c)	0.0	0.0	0.0	0.0	0.0
Net interest & Other Income/(Expense)	-0.7	1.9	-0.2	0.0	0.0	Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Pre-tax profit	-19.0	-13.4	2.8	-8.9	-7.7	Franking (%)	N/A	N/A	N/A	N/A	N/A
Tax	0.0	0.0	0.0	0.0	0.0	EV/EBITDA	-2.5	-3.2	6.3	-6.8	-8.9
Net profit (loss) normalised	-19.0	-13.4	2.8	-8.9	-7.7	EV/EBIT	-2.1	-2.5	13.0	-4.4	-5.1
Abnormal items	-1.1	-0.6	-1.0	-1.1	-1.1						
Reported Net profit (loss)	-20.1	-13.9	1.9	-10.0	-8.7						
Cashflow						Share price now (A\$) \$0.115					
Y/e June 30 (A\$m)	2019A	2020A	2021E	2022E	2023E	Valuation (A\$):	\$0.20				
Reported NPAT	-20.1	-13.9	1.9	-10.0	-8.7	Premium (discount) to price	73.9%				
Non-cash items	5.6	2.2	4.6	4.6	4.5	Recommendation:	Buy				
Net change in Working capital	-5.4	-1.6	5.1	-0.2	-3.2	Risk Rating	Speculative				
Operating cashflow	-19.8	-13.3	11.6	-5.6	-7.5	Profitability ratios					
Capex	-0.6	-0.3	-0.3	-0.5	-0.7	Y/e June 30	2019A	2020A	2021E	2022E	2023E
Investments	0.0	0.0	0.0	0.0	0.0	EBITDA margin (%)	N/A	N/A	19.8%	N/A	N/A
Investments in intangible assets	-0.4	-0.3	-0.3	-0.3	-0.4	EBIT margin (%)	N/A	N/A	9.5%	N/A	N/A
Other investing cash flow	0.0	0.0	0.0	0.0	0.0	Return on assets (%)	-36.0%	-37.8%	7.9%	-36.4%	-56.0%
Investing cashflow	-1.0	-0.6	-0.6	-0.8	-1.1	Return on equity (%)	-128.1%	NM	66.4%	NM	62.1%
Change in borrowings	-1.6	-2.2	-2.3	-2.0	-2.5	Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Equity issued	22.7	0.0	0.0	0.0	0.0	Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Dividends paid	0.0	0.0	0.0	0.0	0.0	Liquidity and leverage ratios					
Other financing cash flow	-0.3	-0.3	-0.7	-0.8	-1.0	Y/e June 30	2019A	2020A	2021E	2022E	2023E
Financing cashflow	20.8	-2.5	-3.0	-2.7	-3.5	Net debt (cash) (A\$m)	-24.0	-6.6	-16.5	-9.1	0.6
Net change in cash	0.1	-16.4	8.1	-9.1	-12.0	Net debt/equity (%)	N/A	N/A	N/A	N/A	N/A
Cash at end of period*	31.1	14.8	22.8	13.7	1.7	Net interest cover (x)	NM	N/A	NM	N/A	N/A
<small>* Includes effect of exchange rate fluctuations on cash balance</small>						Current ratio (x)	5.0	3.6	3.7	2.3	1.1
Free cash flow (op. CF less capex and intangibles)	-20.8	-13.9	11.0	-6.4	-8.5	Segmentals					
Balance sheet						Y/e June 30	2019A	2020A	2021E	2022E	2023E
Y/e June 30 (A\$m)	2019A	2020A	2021E	2022E	2023E	Bronchitol and Aridol					
Cash	31.1	14.8	22.8	13.7	1.7	Product Sales	5.7	7.0	9.1	12.2	14.2
Current receivables	7.2	6.9	1.7	1.8	4.9	Other revenue (Clinical trial cost reimbursement)	0.0	0.0	12.9	0.0	0.0
Inventories	2.1	2.6	2.8	3.0	3.2	Other income	0.0	0.0	0.0	0.0	0.0
Other current assets	0.1	0.2	0.2	0.2	0.2	Total Revenues	5.7	7.0	22.0	12.2	14.2
Current assets	40.6	24.5	27.5	18.7	10.0	EBITDA	-5.0	-4.0	10.5	0.3	1.7
PPE	10.3	8.9	6.1	3.5	1.0	New Drug Development					
Non-current receivables	1.1	1.1	1.1	1.1	1.1	Product Sales	0.0	0.0	0.0	0.0	0.0
Intangible assets	0.8	0.9	1.1	1.3	1.6	Other revenue (Milestone+license+royalty)	0.0	0.0	8.9	7.4	0.0
Other non-current assets	0.0	0.0	0.0	0.0	0.0	Other income (R&D tax incentive etc.)	6.0	5.2	0.0	0.0	3.0
Non-current assets	12.1	10.9	8.3	5.9	3.7	Total Revenues	6.0	5.2	8.9	7.4	3.0
Total assets	52.7	35.4	35.8	24.6	13.7	EBITDA	-6.8	-5.1	-1.1	-2.8	-2.8
Payables	4.8	3.5	3.5	3.5	3.5	Corporate					
Debt	7.2	8.2	6.3	4.6	2.3	Other income	0.5	0.5	0.5	0.5	0.5
Provisions	1.1	1.2	1.3	1.4	1.5	EBITDA	-3.9	-3.0	-3.3	-3.3	-3.3
Financial liabilities (Novaquest financing agreement)	23.6	21.2	20.5	19.8	18.8	Total Company					
Deferred Lease Incentive	1.1	0.0	0.0	0.0	0.0	Revenues	12.2	12.7	31.4	20.2	17.7
Other liabilities	0.0	0.0	0.0	0.0	0.0	EBITDA	-15.7	-12.1	6.2	-5.7	-4.4
Total liabilities	37.9	34.0	31.6	29.3	26.0	Interims					
Net Assets	14.8	1.4	4.3	-4.7	-12.3	Y/e June 30 (A\$m)	2H19A	1H20A	2H20A	1H21E	2H21E
Shareholders' equity	367.3	367.3	367.3	367.3	367.3	Revenue	9.7	3.8	8.9	21.7	9.7
Reserves	21.8	22.3	23.3	24.3	25.4	EBITDA	-5.8	-8.0	-4.1	10.2	-4.0
Retained earnings/(losses)	-374.2	-388.2	-386.3	-396.3	-405.0	Depreciation & Amortisation	-1.3	-1.6	-1.6	-1.7	-1.5
Total shareholders equity	14.8	1.4	4.3	-4.7	-12.3	EBIT	-7.2	-9.6	-5.7	8.5	-5.5
						Net interest & Other Expense	0.1	-0.2	2.1	-0.1	-0.1
						Pre-tax profit	-7.1	-9.8	-3.6	8.4	-5.6
						Tax	0.0	0.0	0.0	0.0	0.0
						Net Profit (loss) - normalised	-7.1	-9.8	-3.6	8.4	-5.6
						Net Profit (loss) - reported	-7.5	-10.3	-3.6	8.0	-6.1

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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