BELL POTTER

Speculative
See Key Risks on Page 8 & Biotechnology Risk Warning on Page 10
Speculative securities may not be suitable for Retail clients

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Pharmaxis Ltd. (PXS)

FDA approval for Bronchitol revamps the business, improves outlook

Recommendation
Buy (Hold)
Price
$0.093
Valuation
$0.14 (previously $0.09)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**50.5%**
Dividend yield	**0.0%**
Total expected return	**50.5%**
Company Data & Ratios	
Enterprise value	**$20.7m**
Market cap	**$36.9m**
Issued capital	**397.2m**
Free float	**98.7%**
Avg. daily val. (52wk)	**$211,183**
12 month price range	**$0.053- $0.17**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.09	0.08	0.15
Absolute (%)	6.82	11.90	-37.33
Rel market (%)	6.77	-0.76	-36.50

Absolute Price

SOURCE: IRESS

Bronchitol nearing US launch, PXS focus now myelofibrosis

We view the FDA approval for Bronchitol as a key milestone for the company and an important turning point for the business. US accounts for >65% of global cystic fibrosis market. With target market for Bronchitol significantly expanded with US entry, the mannitol business (Bronchitol+Aridol) is expected to become profitable from FY21. Launch by partner Chiesi in US is expected in 2QCY21. In FY22 we expect mannitol business revenue to almost double from FY20 levels to $13.2m. The US$10m milestone from Chiesi (US$7m received on approval and US$3m due on product shipment in 1QCY21) strengthens PXS' balance sheet, with proforma cash of ~A$29m. These funds along with cash generated from mannitol business is expected to fund Phase 1c/2a trial of PXS' lead development asset PXS-5505 for myelofibrosis, which will start in 1QCY21 and results from which are due in 2HCY22. IND has been approved by FDA. PXS-5505 development has been prioritised for myelofibrosis, a rare bone marrow cancer with estimated market worth >US$1bn. PXS-5505 has the potential to be disease modifying in a market currently served by therapies which provide mainly symptomatic relief and have poor tolerability. We model US$567m in peak sales and a US$500m licensing deal post Phase 2b trial.

Valuation lifted to $0.14, Switch to Buy (speculative)

Revisions to our model led to a large decrease in our FY21 NPAT forecast and large increases in our FY22 and FY23 net loss forecasts. These were driven primarily by removal of LOXL-2 and its associated deal upfronts and milestones from our model, partially offset by higher Bronchitol revenue forecasts and inclusion of R&D rebate for FY22. Earnings changes, longer term earnings impact of including PXS-5505 for myelofibrosis in our model, reducing our WACC to 16% (was 19%) and adjusting our DCF for time creep have led to a material increase in our valuation for PXS to A$0.14/sh (was A$0.09/sh). We are switching to Buy (spec.) on valuation. Our PXS valuation continues to be weighted towards the mannitol business, with modest value ascribed to its drug development business. **Key catalysts:** a) receipt of US$3m milestone from Chiesi in 1QCY21 and b) interim data from Phase 1c/2a myelofibrosis trial with PXS-5505 in 2HCY21 and top-line results in 2HCY22.

Earnings Forecast

Year end 30th June	2019A	2020A	2021E	2022E	2023E
Revenue (A$m)	12.2	12.7	25.3	16.9	18.9
EBITDA (A$m)	-15.7	-12.1	-0.5	-7.4	-5.9
NPAT (reported) (A$m)	-20.1	-13.9	-4.7	-11.8	-10.1
NPAT (normalised) (A$m)	-19.0	-13.4	-4.1	-10.8	-9.2
EPS (reported) (cps)	-5.1	-3.4	-1.1	-2.7	-1.9
EPS (adjusted) (cps)	-4.8	-3.3	-1.0	-2.5	-1.7
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
PER (x)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA (x)	-1.3	-1.7	-38.5	-2.8	-3.5
Dividend (¢ps)	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%	-935.2%	153.7%	123.9%	-851.1%

NOTE: REVENUE INCLUDES R&D TAX INCENTIVE AND MILESTONES FROM CHIESI DEAL. SOURCE: BELL POTTER SECURITIES ESTIMATES

Earnings and Valuation Changes

We have reviewed our assumptions for PXS and made adjustments to our forecasts following FDA approval for Bronchitol in the US and refocus of the business to myelofibrosis, which have impacted earnings and valuation.

Key changes to our modelling assumptions

- Following FDA approval, we have removed the risk adjustment for Bronchitol revenue (product sales and milestones from Chiesi) for the US market, assigning 100% POS to it (vs. 90% earlier). This has increased our forward revenue forecasts for Bronchitol.
- We have modestly increased our Bronchitol revenues for Western Europe for FY22 which is also partnered with Chiesi.
- Our mannitol business (Bronchitol + Aridol) revenues for FY22 are now almost double that of FY20 levels at $13.2m, which is slightly below the $14m company guidance. We also expect EBITDA to grow over the next 5 years to generate ~$11.2m EBITDA in FY26 (in line with company guidance of >$10m EBITDA).
- PXS is eligible to receive 3 undiclosed sales milestones (totaling up to US$15m) from Chiesi subject to meeting certain annual sales thresholds for Bronchitol in the US market. We now model 50% of these commercial milestones i.e. US$7m which are part of the US deal with Chiesi for Bronchitol. At this stage we assume the first of these commercial milestones will be received in FY26.
- **PXS-5505 is now PXS' lead asset from its new drug development segment.** The company has prioritised its development for myelofibrosis. A Phase 1c/2a trial is expected to start in 1QCY21 for which IND is already approved by the FDA. This is expected to complete by end CY22. We expect PXS will proceed to a Phase 2b combination trial with a standard of care JAK inhibitor following positive results from the Phase 1c/2a trial. **We now model revenues for this drug in myelofibrosis** (intermediate or high risk MF patients) in a second line setting (in combination with a JAK inhibitor) for use in patients who become refractory to JAK inhibitor for both the US and EU markets. We estimate addressable patients population in US at ~8,500 patients and in EU at ~13,100 patients. We assume a treatment cost of US$100k per patient in US and US$70k in EU, with peak penetration in US at 35% and in EU at 25% **to arrive at peak sales forecast of US$567m. We conservatively assume a US$500m licensing deal for the drug post Phase 2b combination trial in FY25 with a partner funding subsequent registrational trials.** We assume launch in US in FY28 and in EU in FY29. We assume a royalty rate of 15% and assign a POS of 22% by which our royalty revenues and upfront/milestones from a potential deal are risk adjusted.
- We also model cost of clinical trials for PXS-5505 Phase 1c/2a of US$5m over FY21-FY22 and for Phase 2b of US$8m over FY23-FY25. Our clinical trial cost forecasts have reduced for FY21 and FY22 by ~$0.7m each year due to currency impact of converting the US$5m spend into AUD for the Phase 1c/2a trial, assuming equal distribution of trial costs between FY21 and FY22 and partly due to assuming a lower spend on the topical asset as that would be investigator initiated and will start in FY22 vs.earlier estimate of FY21. The clinical trial cost forecasts have increased for FY23-FY25 (vs. nil before), due to including the cost of a Phase 2b myelofibrosis trial.
- The timing for a potential deal for PXS' LOXL-2 asset has once again moved. PXS is now guiding to a transaction in 1HCY21 (vs. 2HCY20 assumed earlier). We note that this process to partner the drug started in Jan'19. Given this has taken much longer than we expected with timelines continuing to move and given the revised focus of the company on myelofibrosis which becomes its lead drug development asset, **we now**

choose to remove LOXL-2 from our model. Should a deal take place in future for the asset, it will be an upside to our estimates.

- Our drug development costs for FY21 have increased due to expected spend on the Duchenne Muscular Dystrophy Drug, half of which will be funded by the $1m Australian Govt. grant through their Biomedical Translation Bridge (BTB) program. The grant requires matched spend by PXS on the program and is expected to make the drug ready for Phase 1 trials within 12 months. We have now also included the $1m grant as other income for FY21. We have reduced our drug development costs for FY22 and FY23, assuming minimal spend on programs outside of myelofibrosis in those years.
- Based on our revised revenue forecasts we now expect an R&D rebate in FY22 and in FY24 as well of $3.2m each (vs. nil earlier).
- Our interest income forecasts have reduced due to lower interest rates.
- We now reduce the WACC used in our DCF to 16% (was 19%) given the FDA approval for Bronchitol and cash milestone of US$10m from Chiesi has negated the need for the company to raise capital at least for the next 12 months and also transitioned the Bronchitol+Aridol segment to profitability.
- We assume a $5m capital raise in CY22 @$0.10/sh to strengthen the balance sheet ahead of Top-line results from the Phase 1c/2a myelofibrosis trial. We also assume a larger raise of $20m in CY23 at a higher price of $0.12/sh following positive results to fund a subsequent Phase 2b combination trial in myelofibrosis which we expect to cost ~$11m. We have not accounted for the dilution from these in our valuation as these are more than 12 months away. **We note** that PXS has the opportunity to extend its cash runway through restructuring initiatives aimed at driving further cost savings in the mannitol business (up to $3m pa) as well as licensing fees via licensing out additional territories for bronchitol, which could negate the need for the modest cap raise prior to myelofibrosis trial results.
- We have adjusted our DCF for time creep.

We value PXS at $0.14/sh

Revisions to our model led to a large decrease in our NPAT forecast for FY21, an 18% and 16% increase in our Net loss forecasts for FY22 and FY23 respectively. We now expect a Net loss in FY21. These were driven primarily by removal of LOXL-2 and its associated deal upfronts and milestones from our model, partially offset by higher bronchitol revenue forecasts and inclusion of R&D rebate for FY22. Our opex forecasts reduced for FY22 due to lower clinical trial costs and increased for FY23 due to inclusion of spend for a Phase 2b myelofibrosis trial. Earning changes, longer term earnings impact of including PXS-5505 for myelofibrosis in our model, reducing our WACC to 16% (was 19%) and adjusting our DCF for time creep have led to a material increase in our valuation for PXS to A$0.14/sh (was A$0.09/sh). **We switch to Buy (Speculative) on valuation** (was Hold, spec).

Table 1 - Changes to our FY21-23 Forecasts

	FY2021E			FY2022E			FY2023E		
	Old	New	Change (%)	Old	New	Change (%)	Old	New	Change (%)
Revenues	31.4	25.3	-19%	20.2	16.9	-16%	17.7	18.9	7%
Interest Income	0.3	0.1	-64%	0.3	0.1	-73%	0.1	0.1	-38%
Operating Costs	25.2	25.9	3%	25.9	24.3	-6%	22.1	24.8	12%
EBITDA	6.2	-0.5	-109%	-5.7	-7.4	30%	-4.4	-5.9	35%
EBIT	3.0	-3.7	-226%	-8.9	-10.6	19%	-7.6	-9.1	19%
NPAT (adjusted)	2.8	-4.1	-245%	-8.9	-10.8	21%	-7.7	-9.2	20%
Adjusted Diluted EPS	0.7	-1.0	-245%	-2.2	-2.5	14%	-1.9	-1.7	-10%
NPAT (reported)	1.9	-4.7	-349%	-10.0	-11.8	18%	-8.7	-10.1	16%
Reported Diluted EPS	0.5	-1.1	-349%	-2.5	-2.7	11%	-2.1	-1.9	-13%

ALL AMOUNTS IN AUD IN MILLIONS EXCEPT EPS. SOURCE: BELL POTTER SECURITIES ESTIMATES

Our DCF valuation model is based on a WACC of 16.0% and a terminal growth rate of 1%.

Table 2 - Summary of Valuation

Forecasts	Base case
Enterprise value from DCF (AUDm)	37.8
Add: Proforma cash incl. US$10m receivable from Chiesi (AUDm)	29.0
Less: Current Debt (related to finance lease on manufacturing/office premises)	7.7
Equity value (AUDm)	59.1
Total diluted shares (million)	416.2
Value per share (AUD)	**$0.14**
Current Share price (AUD)	$0.093
Expected Capital Growth	50.5%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 3 - PXS Sum-of-parts DCF Valuation Summary

Asset	Probability adjusted NPV (A$m)	Value per share (A$)	% Mix	Probability of success/Risk adjustment	Current Phase
Bronchitol and Aridol	$51	**$0.12**	86.1%	Bronchitol - (100%)	Marketed for Aridol, Marketed for Bronchitol (Ex-US and Canada), US to be launched in 1HCY21
New Drug Development	$8	**$0.02**	13.0%	PXS-5505 (MF -22.0%)	PXS-5505 (Phase 1c/2a to start in 1QCY21)
Corporate/Non-Allocated	($21)	**-$0.05**	-35.1%	NA	NA
Proforma Cash (incl Chiesi milestone and R&D tax rebate)	$29	**$0.07**	49.0%	NA	NA
Reported Debt	($8)	**-$0.02**	-13.0%	NA	NA
Equity Value	**$59.1**	**$0.14**	**100.0%**		

SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 4 – PXS- Key assumptions used in New Drug Development segment

Asset	Indication	Stage	Partnering Status	First Fiscal Year of sales (Est.)	Peak Market share	Peak Global Sales (US$m)	Probability of success
PXS-5505	Myelofibrosis (intermediate or high risk), refractory to SOC JAK inhibitor	Phase 1c/2a to start in 1QCY21	Expect to partner following successful Phase 2B combination trial	2028	35% (US), (25% EU)	$567	22.0%

GLOBAL PEAK SALES ARE PRE-RISK ADJUSTMENT AND ROYALTIES. SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 5 – Deal Assumptions for PXS-5505

Asset	Indication	Stage at Licensing	Licensee	Fiscal Year Timing of deal (Est.)	Total Deal Value in USDm (upfront plus milestones)	Upfront (USDm)	Other developmental & regulatory Milestones (USDm)	Commercial Milestones Est (USDm)	Royalty Rate (%)
PXS-5505	Myelofibrosis	Phase 2B complete	TBC	2025	500	30	220	250	15.0%

NOTE: ROYALTIES ARE LIKELY TO BE TIERED. WE ASSUME A FLAT RATE FOR NOW. SOURCE: BELL POTTER SECURITIES ESTIMATES

Upside Risk to our valuation

- **Clinical success will allow for increased probability of success:** We currently assign a 22.0% probability of success (of reaching the market) to PXS-5505 in Myelofibrosis, given the imminent start of its Phase 1c/2a trial. We envisage that successful results from the trial and subsequent advancement of the asset into Phase 2b combination trial with standard of care JAK inhibitor, will allow us to assign a higher POS and therefore could lead to material upgrades in our numbers.
- **We do not model other indications for PXS-5505 presently:** At this stage we do not model any expanded use of PXS-5505 in other cancer indications beyond myelofibrosis. There is interest from the clinical community to explore the drug in other difficult to treat cancers such as pancreatic cancer, liver cancer, myelodysplastic

syndrome etc. with protocol and funding discussions ongoing with independent investigators for liver and pancreatic cancer. We expect investigator initiated trials in one or more of these indications could expand the potential utility of the drug without additional cost to PXS. Should PXS in future focus on and progress clinical development of PXS-5505 in any indication beyond myelofibrosis, it is likely to increase the market opportunity for this asset, in which case it's likely to be a source of considerable upside to our valuation in future.

- **No sales milestones from PXS-5505 deal included in our model:** At this stage we do not model PXS' share of the assumed US$250m sales milestones from a potential PXS-5505 deal in our model. We intend to include it in our model once a deal is inked by PXS, in which case it's likely to be a source of upside to our valuation.
- **No value assigned to Phase 2 ready anti-fibrotic candidate LOXL-2**. The 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 it's best in class characteristics. Partnering discussions to move this candidate to Phase 2 is ongoing. Process has taken much longer than we or the company expected (in partnering discussions since Jan 2019). Timelines have repeatedly moved and now company expects a conclusion of this process in 1HCY21. At this stage we have removed this asset from our model and should this get partnered in future and move into Phase 2 trials, it would represent a material upside to our valuation.
- **We do not include any value for PXS' early stage pan LOX inhibitor PXS-6302 (topical):** This drug which broadly inhibits all the LOX family of enzymes, has potential anti-fibrotic application in scarring. Preclinical development for PXS-6302 was completed in 2QCY20, including initial stability studies of the formulation. Investigator initiated studies to assess the drug in burn related scars and pre-existing scars are being discussed with an Australia based hospitals' burn unit and expected to start in 2HCY21. PXS believes that the LOX PXS-6302 asset may have higher potential and value add if developed to Phase 2A or 2B before partnering, vs. the strategy with its later stage assets targeting NASH which it looked to partner at or after Phase 1. Progress of this asset into Phase 2 trials in future is likely to be a source of upside to our valuation.
- **We also do not include any value for PXS's early stage SSAO/MAOB PXS-4699:** This is being targeted at Duchenne Muscular Dystrophy (DMD) for which a $1m matched funding grant was received by PXS recently from the australian govt. through their Biomedical Translation Bridge (BTB) program. The funding aims to complete all pre-clinical work required to move the drug into the clinic (Phase 1 trials) in 1HCY22.
- **We model only half of the sales milestones under the deal with Chiesi for US for Bronchitol:** For Bronchitol, PXS' partner Chiesi is responsible for its commercialisation in the US. PXS has received a US$7m milestone from Chiesi following approval of the drug by the FDA and will receive another US$3m on shipment of product for the US launch in 1QCY21. An additional US$15m sales milestones is also part of the deal on meeting certain undisclosed sales thresholds. At this stage we only model half of the sales milestones. If the likelihood of the remaining half becomes more of a certainty then that would represent an upside to our valuation. We note that mid to high teen percentage of royalties on net sales and long term supply contract for bronchitol are also part of the Chiesi deal, which we model.
- **We model limited markets for Aridol:** For Aridol, we model the existing markets of Australia, Europe and South Korea and US where the company relaunched Aridol in Dec'18 following FDA approval of its manufacturing facility. We also model revenue from Canada. Aridol received approval in Canada in June 2019 and supplied its first (launch) order to Methapharm for Canada in 2QFY20.

Pharmaxis Ltd. (PXS)

COMPANY DESCRIPTION

Pharmaxis, is a biopharmaceutical company focused on the development of drugs for inflammatory and fibrotic diseases. It also has two marketed respiratory products Bronchitol and Aridol collectively referred to as the mannitol business. Bronchitol recently achieved a key milestone by obtaining FDA approval to market in US, the largest market for cystic fibrosis. This will now see the mannitol segment generate near term cash (milestone from partner Chiesi) and become profitable, which in turn will help fund PXS' drug development pipeline. Until recently, the company was focused on Non-alcoholic Steatohepatitis (NASH). However, following the recent termination of partnership with Boehringer Ingelheim focused on NASH and Diabetic Retinopathy and dragging of timeline for partnering its Phase 1 LOXL-2 inhibitors, the company has now shifted its focus to myelofibrosis (rare bone marrow cancer, est. >US$1bn market) with its lead asset PXS-5505. PXS-5505, with its unique mechanism of action (MOA) has the potential to be disease modifying in a market currently served by therapies which provide mainly symptomatic relief and have poor tolerability. It's MOA also complements current standard of care and we believe can be used in conjunction with the SOC to further improve outcomes for patients, which bodes well for its licensing prospects. PXS is also focusing on developing its earlier stage pipeline a drug targeting scarring and a drug for Duchenne Muscular Dystrophy which recently received a grant from the Australian government.

INVESTMENT STRATEGY

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

$0.14 valuation: We value PXS using a risk adjusted DCF at $0.14. The valuation is approximately a 50.5% premium to the previous closing share price of $0.093/sh.

FDA approval of bronchitol for cystic fibrosis transitions mannitol business to profitability: We expect PXS' mannitol (bronchitol + aridol) segment which together generated sales of $7m in FY20 (bronchitol alone was $5.3m sales) to become profitable and cash flow positive from FY21, driven primarily by US sales of bronchitol. In FY22 we expect mannitol business revenue to almost double from FY20 levels to $13.2m. We also expect EBITDA to grow over the next 5 years to generate ~$11.2m EBITDA in FY26 (in line with company guidance of >$10m EBITDA).

PXS now a 'myelofibrosis' company vs. its initial drug development focus on NASH: In its drug development business, PXS had a disappointing set back in Dec'19 and Sep'20 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 and for DR respectively. Partnering of its second key anti fibrotic asset LOXL-2 focused on NASH and IPF has also taken much longer than expected and PXS is now expecting a conclusion of the partnering process in 1HCY21, which could be a bonus upside for the stock and our valuation. **The lead asset now in PXS' drug development business is the systemic pan-LOX inhibitor PXS-5505 targeted at myelofibrosis**, which PXS has now prioritised development of. The milestone payment expected to be received from partner Chiesi shortly following FDA approval of bronchitol and the expected positive cash flows from the mannitol business now funds PXS-5505 through completion of Phase 1c/2 myelofibrosis trial into 2HCY22, which will be a key inflexion point for the stock. This trial is expected to start in 1QCY21. It will be an open label trial and will recruit up to 42 patients with myelofibrosis (intolerant, unresponsive or ineligible for treatment with approved JAK inhibitor drugs) across Australia, South Korea and international sites. The trial will have a dose escalation phase (18 patients), followed by dose expansion phase (24 patients).

PXS-5505 is a first in class, differentiated therapy designed to address significant unmet need in myelofibrosis with a large market opportunity: PXS-5505 is a first-in-class oral pan LOX inhibitor which is targeting the rare bone marrow cancer myelofibrosis (MF) with an estimated market value of >US$1bn per year. It is an underserved market with limited therapeutic options especially for the symptomatic, high risk, intermediate-2 MF group. Current standard of care are 2 oral JAK inhibitors which mainly offer symptomatic relief and have tolerability issues. Discontinuation rate for Ruxolitinib the leading JAK inhibitor for MF is 75% at 5 years, with median overall survival for patients post discontinuation at ~14-16 months. There is currently no approved treatment for patients relapsed/refractory to JAK inhibitors. PXS-5505 is first-in-class pan-LOX inhibitor LOX enzymes are responsible for the cross linking of collagen and elastin fibres which make fibrotic or scar tissue in bone marrow reducing the production of blood cells. Fibrosis in the bone marrow drives the adverse symptoms and mortality associated with MF. Hence, PXS-5505 has disease modifying potential and by targeting a different pathway to JAK inhibition, has the potential to work on top of these SOC's to improve outcomes for patients. It also could work as a monotherapy in refractory JAK patients which could further extend its market opportunity. Commercially the combination positioning with existing SOC bodes well for its licensing prospects. We model US$567m peak sales in US and EU markets (pre risk adjustment) for PXS-5505 in myelofibrosis. We also conservatively assume a US$500m licensing deal for the drug post Phase 2b combination trial in FY25.

Potential exists to expand the use of PXS-5505 into broader myeloproliferative diseases and cancer indications: PXS has prioritised development of PXS-5505 for myelofibrosis, however the Pan-LOX inhibitor has the potential to be used across several other myeloproliferative diseases and fibrotic cancer indications such as pancreatic cancer and liver cancer. Pre-clinical studies have been conducted in several fibrotic disease models and a host of independent scientific and clinical groups have collaborated with PXS to test the drug in other disease indications.

Early stage pipeline assets represent future value: 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 2HCY21. PXS has also recently received an A$1m matched funding grant from the AU government for its SSAO/MAOB drug PXS-4699 targeting Duchenne Muscular Dystrophy (DMD). The drug is expected to move into the clinic in 1HCY22. We do not assign any value to these assets currently, however they represent future upside on progression into mid stage trials.

Partnership with Boehringer Ingelheim validated 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 Dec'19 and Sep'20 with BI choosing to discontinue development of the partnered asset for NASH and DR respectively and terminating the agreement with PXS, the deal has delivered to date €57m (A$83m) in upfronts and milestones to PXS.

Cash runway into 2HCY22: PXS' had cash at end of 1QFY21 of ~A$9.7m, which along with the ~A$5m R&D rebate received in Oct'20 and the ~A$14m milestone from Chiesi for Bronchitol (A$9.2m of which was received in Dec'20), leads to proforma cash of ~A$29m. In our view, this provides PXS cash runway into 2HCY22. PXS has the opportunity to further extend its cash runway through restructuring initiatives aimed at driving cost savings in the mannitol business (up to $3m pa) as well as licensing fees via licensing out additional territories for bronchitol. The company has a modest debt (related to finance lease) of A$7.7m.

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.
- **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 Pan-LOX myelofibrosis asset. Failure to attract partners for this asset or to negotiate attractive deal terms as we have postulated will impact our forecasts.
- **Bronchitol US adoption will affect our valuation:** Bronchitol and Aridol, (PXS' currently marketed products) account for the majority of our current valuation for PXS. US Bronchitol sales are the key driver for revenue and the segment achieving profitability. Therefore if adoption of Bronchitol in the US is slower than our forecast, it will adversely affect our forecasts and valuation.
- **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 the myelofibrosis space which PXS is targeting has other companies engaged in drug development which are more advanced than PXS' asset PXS-5505. There is no guarantee that clinical trial results of PXS-5505, even if they hit the endpoints of the studies, will be viewed as clinically meaningful by clinicians' vis-à-vis current SOC and other approved drugs by then on the market. Even if the drug does get approved on successful pivotal studies, commercial adoption might still be hampered by the cost of the combination (as we assume an add-on therapy positioning). Also we believe the drug has disease modifying potential and if that does not pan out in trials in a meaningful way, it again would impact the market share and pricing assumptions that we have currently postulated.
- **Funding risk:** PXS has proforma cash of ~A$29m and debt related to finance lease of A$7.7m, which we believe provides it with cash runway into 2HCY22. Restructuring initiatives and further licensing of bronchitol territories may further extend this cash runway. However, at this stage we have assumed that PXS will need to raise a modest amount of capital prior to PXS-5505 Phase 1c/2a trial results due in 2HCY22 to strengthen its balance sheet ahead of results and a larger capital raise in CY23 at a higher price following positive results to fund a subsequent Phase 2b combination trial in myelofibrosis. These funding rounds could be more dilutive for shareholders than we have currently postulated. We also note that a partnering deal for PXS' LOXL-2 has been guided to by PXS for 1HCY21. We do not include LOXL-2 in our model, however upfront from a deal if partnered could potentially also extend PXS' current cash runway.

Pharmaxis Ltd.
as at 7 January 2021

Recommendation	Buy, Speculative
Price	$0.093
Valuation	$0.14

Table 6 - Financial summary

Pharmaxis Ltd (PXS) — **Share price (A$)** **$0.093**
As at 7 January 2021 — **Market cap (A$m)** **36.9**

Profit and Loss

Y/e June 30 (A$m)	2019A	2020A	2021E	2022E	2023E
Product Sales Revenues	5.7	7.0	9.3	13.2	15.2
Other Revenue (commercial)	0.0	0.0	14.3	0.0	0.0
Other Income	6.5	5.6	1.8	3.7	3.7
Total Revenue	**12.2**	**12.7**	**25.3**	**16.9**	**18.9**
EBITDA	**-15.7**	**-12.1**	**-0.5**	**-7.4**	**-5.9**
Depreciation & Amortisation	-2.6	-3.2	-3.2	-3.2	-3.2
EBIT	**-18.3**	**-15.3**	**-3.7**	**-10.6**	**-9.1**
Net interest & Other Income/(Expense)	-0.7	1.9	-0.3	-0.2	-0.1
Pre-tax profit	**-19.0**	**-13.4**	**-4.1**	**-10.8**	**-9.2**
Tax	0.0	0.0	0.0	0.0	0.0
Net profit (loss) normalised	**-19.0**	**-13.4**	**-4.1**	**-10.8**	**-9.2**
Abnormal items	-1.1	-0.6	-0.6	-1.0	-1.0
Reported Net profit (loss)	**-20.1**	**-13.9**	**-4.7**	**-11.8**	**-10.1**

Cashflow

Y/e June 30 (A$m)	2019A	2020A	2021E	2022E	2023E
Reported NPAT	-20.1	-13.9	-4.7	-11.8	-10.1
Non-cash items	5.6	2.2	4.2	4.5	4.3
Net change in Working capital	-5.4	-1.6	4.9	-3.3	-0.1
Operating cashflow	**-19.8**	**-13.3**	**4.5**	**-10.6**	**-5.9**
Capex	-0.6	-0.3	-0.2	-0.2	-0.4
Investments	0.0	0.0	0.0	0.0	0.0
Investments in intangible assets	-0.4	-0.3	-0.3	-0.3	-0.4
Other investing cash flow	0.0	0.0	0.0	0.0	0.0
Investing cashflow	**-1.0**	**-0.6**	**-0.5**	**-0.5**	**-0.8**
Change in borrowings	-1.6	-2.2	-2.3	-2.0	-2.5
Equity issued	22.7	0.0	0.0	4.8	19.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	-0.3	-0.3	-0.7	-0.8	-1.1
Financing cashflow	**20.8**	**-2.5**	**-3.0**	**1.9**	**15.4**
Net change in cash	**0.1**	**-16.4**	**1.0**	**-9.2**	**8.7**
Cash at end of period*	31.1	14.8	15.7	6.5	15.2
* Includes effect of exchange rate fluctuations on cash balance					
Free cash flow (op. CF less capex and intangibles)	**-20.8**	**-13.9**	**4.0**	**-11.1**	**-6.7**

Balance sheet

Y/e June 30 (A$m)	2019A	2020A	2021E	2022E	2023E
Cash	31.1	14.8	15.7	6.5	15.2
Current receivables	7.2	6.9	1.7	5.0	5.1
Inventories	2.1	2.6	3.0	3.1	3.2
Other current assets	0.1	0.2	0.2	0.2	0.2
Current assets	**40.6**	**24.5**	**20.6**	**14.8**	**23.7**
PPE	10.3	8.9	6.0	3.2	0.5
Non-current receivables	1.1	1.1	1.1	1.1	1.1
Intangible assets	0.8	0.9	1.1	1.3	1.6
Other non-current assets	0.0	0.0	0.0	0.0	0.0
Non-current assets	**12.1**	**10.9**	**8.2**	**5.6**	**3.2**
Total assets	**52.7**	**35.4**	**28.9**	**20.4**	**26.9**
Payables	4.8	3.5	3.5	3.5	3.5
Debt	7.2	8.2	6.3	4.6	2.3
Provisions	1.1	1.2	1.3	1.4	1.5
Financial liabilities (Novaquest financing agreement)	23.6	21.2	20.5	19.7	18.5
Deferred Lease Incentive	1.1	0.0	0.0	0.0	0.0
Other liabilities	0.0	0.0	0.0	0.0	0.0
Total liabilities	**37.9**	**34.0**	**31.5**	**29.1**	**25.8**
Net Assets	**14.8**	**1.4**	**-2.7**	**-8.7**	**1.1**
Shareholders' equity	367.3	367.3	367.3	372.1	391.1
Reserves	21.8	22.3	22.9	23.8	24.8
Retained earnings/(losses)	-374.2	-388.2	-392.8	-404.6	-414.8
Total shareholders equity	**14.8**	**1.4**	**-2.7**	**-8.7**	**1.1**

Valuation data

Y/e June 30	2019A	2020A	2021E	2022E	2023E
Net profit -normalised (A$m)	-19.0	-13.4	-4.1	-10.8	-9.2
EPS - normalised (c)	-4.8	-3.3	-1.0	-2.5	-1.7
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
P/E ratio (x)	N/A	N/A	N/A	N/A	N/A
FCFPS (c)	-5.3	-3.5	1.0	-2.5	-1.1
Price/FCF (x)	-1.8	-2.7	9.3	-3.7	-8.5
DPS (c)	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
EV/EBITDA	-1.3	-1.7	-38.5	-2.8	-3.5
EV/EBIT	-1.1	-1.4	-5.5	-2.0	-2.3

Share price now (A$)	$0.093
Valuation (A$):	$0.14
Premium (discount) to price	50.5%
Recommendation:	Buy
Risk Rating	Speculative

Profitability ratios

Y/e June 30	2019A	2020A	2021E	2022E	2023E
EBITDA margin (%)	N/A	N/A	N/A	N/A	N/A
EBIT margin (%)	N/A	N/A	N/A	N/A	N/A
Return on assets (%)	-36.0%	-37.8%	-14.2%	-53.0%	-34.2%
Return on equity (%)	-128.1%	-935.2%	153.7%	123.9%	-851.1%
Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%

Liquidity and leverage ratios

Y/e June 30	2019A	2020A	2021E	2022E	2023E
Net debt (cash) (A$m)	-24.0	-6.6	-9.4	-1.9	-12.9
Net debt/equity (%)	N/A	N/A	N/A	N/A	N/A
Net interest cover (x)	NM	N/A	NM	N/A	N/A
Current ratio (x)	5.0	3.6	2.8	1.8	2.7

Segmentals

Y/e June 30	2019A	2020A	2021E	2022E	2023E
Bronchitol and Aridol					
Product Sales	5.7	7.0	9.3	13.2	15.2
Other revenue (Clinical trial cost reimbursement)	0.0	0.0	14.3	0.0	0.0
Other income	0.0	0.0	0.2	0.0	0.0
Total Revenues	**5.7**	**7.0**	**23.7**	**13.2**	**15.2**
EBITDA	**-5.0**	**-4.0**	**12.3**	**1.4**	**2.7**
New Drug Development					
Product Sales	0.0	0.0	0.0	0.0	0.0
Other revenue (Milestone+license+royalty)	0.0	0.0	0.0	0.0	0.0
Other income (R&D tax incentive etc.)	6.0	5.2	1.1	3.2	3.2
Total Revenues	**6.0**	**5.2**	**1.1**	**3.2**	**3.2**
EBITDA	**-6.8**	**-5.1**	**-9.6**	**-5.5**	**-5.3**
Corporate					
Other income	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**
EBITDA	**-3.9**	**-3.0**	**-3.3**	**-3.3**	**-3.3**
Total Company					
Revenues	**12.2**	**12.7**	**25.3**	**16.9**	**18.9**
EBITDA	**-15.7**	**-12.1**	**-0.5**	**-7.4**	**-5.9**

Interims

Y/e June 30 (A$m)	2H19A	1H20A	2H20A	1H21E	2H21E
Revenue	9.7	3.8	8.9	13.9	11.4
EBITDA	-5.8	-8.0	-4.1	1.4	-2.0
Depreciation & Amortisation	-1.3	-1.6	-1.6	-1.7	-1.5
EBIT	**-7.2**	**-9.6**	**-5.7**	**-0.3**	**-3.4**
Net interest & Other Expense	0.1	-0.2	2.1	-0.2	-0.2
Pre-tax profit	-7.1	-9.8	-3.6	-0.5	-3.6
Tax	0.0	0.0	0.0	0.0	0.0
Net Profit (loss) - normalised	**-7.1**	**-9.8**	**-3.6**	**-0.5**	**-3.6**
Net Profit (loss) - reported	-7.5	-10.3	-3.6	-0.8	-3.9

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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