BELL POTTER

Speculative
See Key Risks on Page 10 & Biotechnology Risk Warning on Page 12
Speculative securities may not be suitable for Retail clients

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Pharmaxis Ltd. (PXS)

1H21 results - EBITDA miss, NPAT beat

Recommendation
Buy (unchanged)
Price
$0.088
Valuation
$0.14 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

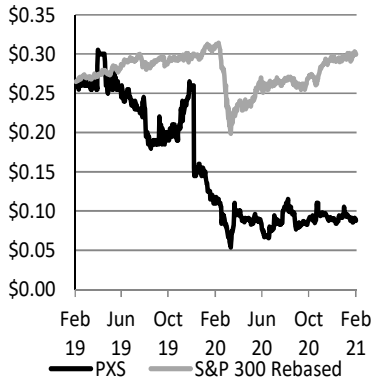
Expected Return	
Capital growth	**59.1%**
Dividend yield	**0.0%**
Total expected return	**59.1%**

Company Data & Ratios	
Enterprise value	**$24.0m**
Market cap	**$35.0m**
Issued capital	**397.2m**
Free float	**98.7%**
Avg. daily val. (52wk)	**$215,425**
12 month price range	**$0.053- $0.17**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.10	0.10	0.11
Absolute (%)	-10.20	-9.28	-20.00
Rel market (%)	-11.88	-17.48	-17.56

Absolute Price



SOURCE: IRESS

Mannitol business now EBITDA positive

Mannitol (Bronchitol + Aridol) product sales for 1H21 were in-line with BPe, with variance in overall revenue driven by a lower matched grant received from the govt. through its BTB program for pre-clinical asset PXS-4699. Mannitol product sales were 5% down over pcp, with COVID impacting Aridol sales. However, we note that sales have recovered in 2Q21 vs. 1Q21 and we expect a stronger 2HFY21. We est. FY21 mannitol sales to grow ~9% over pcp. First US revenue for bronchitol is expected in 2HFY21, with launch by Chiesi in 2QCY21. The Mannitol business reported a positive EBITDA of $6.7m in the half vs. loss in pcp, driven by a A$10m Chiesi milestone payment. With the imminent US launch of bronchitol and ~A$4m milestone expected shortly, we expect the segment to continue to be profitable henceforth. In FY22 we expect mannitol product sales to almost double over FY20 to $13.5m. Opex was 3% higher than BPe, with higher manufacturing purchases and pharmacovigilance costs, partially offset by lower drug development costs. Normalised NPAT of $0.5m vs. our net loss forecast was driven by a non-cash FX gain. Proforma cash of $22.2m, provide cash runway through FY22 and importantly fund the Phase 1c/2a trial of PXS' lead asset PXS-5505 targeted at myelofibrosis (market >US$1bn) to next inflexion point.

Retain Buy (speculative) and Valuation of $0.14

Revisions to our model led to ~23% increase in our FY21 Net loss forecast, which was driven primarily by lower revenue and modestly higher opex. FY21 revenues decreased due to a combination of lower bronchitol sales (assuming COVID-19 pushes an order for UK out to FY22 and timing for royalty component on in-market sales by Chiesi for US likely moving to 1QFY22 given launch is expected in 4QFY21) and lower AUD conversion of the US$3M milestone from Chiesi due shortly. There was no change to our FY23 net loss forecast and changes to our FY22 net loss forecast was not material. Earning changes were offset by adjusting our DCF for time creep. Our valuation for PXS remains unchanged at A$0.14/sh. We retain Buy (spec.). Our PXS valuation continues to be weighted towards the mannitol business, with modest value ascribed to its drug development business. **Key catalysts:** a) US$3m milestone from Chiesi in 1QCY21 and b) interim data from Phase 1c/2a myelofibrosis trial in 2HCY21 and top-line results in 2HCY22.

Earnings Forecast

Year end 30th June	2019A	2020A	2021E	2022E	2023E
Revenue (A$m)	12.2	12.7	23.1	17.6	18.6
EBITDA (A$m)	-15.7	-12.1	-3.2	-7.1	-5.9
NPAT (reported) (A$m)	-20.1	-13.9	-5.7	-11.5	-10.1
NPAT (normalised) (A$m)	-19.0	-13.4	-5.1	-10.5	-9.1
EPS (reported) (cps)	-5.1	-3.4	-1.4	-2.6	-1.9
EPS (adjusted) (cps)	-4.8	-3.3	-1.3	-2.4	-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)	-1.5	-2.0	-7.5	-3.4	-4.1
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%	138.7%	111.2%	NM

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

1H21 – Result Summary

A summary of the reported 1H21 result is shown in the Table below:

Table 1 – 1H21 result summary

	Result vs PCP			Result vs Forecast		Comments
	1H20A	1H21A	% change	1H21E	Variance (%)	
Revenues	**3.8**	**13.7**	**260%**	**13.9**	**-2%**	Revenue 2% lower than our forecast due to lower grant from BTB for DMD drug
Total operating costs	**11.8**	**12.9**	**10%**	**12.5**	**3%**	Opex 3% higher than our forecast driven primarily by higher manufacturing purchases, higher pharmacovigilance costs, partially offset by lower drug development costs
EBITDA	**-8.0**	**0.7**	**-109%**	**1.4**	**-50%**	**EBITDA lower than forecast driven by both lower revenue and higher opex**
Depreciation and Amortisation	-1.6	-1.6	-2%	-1.7	-9%	D&A modestly lower than our forecast
EBIT	**-9.6**	**-0.9**	-91%	**-0.3**	**178%**	**Higher EBIT loss**
Net Interest Income/(expense)	-0.1	-0.2	181%	-0.2	17%	Modestly lower Interest income
Other Income/(expense)	-0.1	1.5	NM	0.0	NM	Fx gain of $1.5m, where we had none in our forecast
Pretax Income (Loss)	-9.8	0.5	-105%	-0.5	-192%	
Net Income (Loss) after tax - normalised	**-9.8**	**0.5**	**-105%**	**-0.5**	**-192%**	**Net Profit vs. our Net loss estimate, with variance from EBIT due to non-cash items (FX gain)**
Diluted EPS/Share (cents)	-2.41	0.11	-105%	-0.12	-191%	
Reported Net Income (loss)	**-10.3**	**0.05**	**-100%**	**-0.8**	**-106%**	Reported Net Profit vs. our Net loss estimate. Includes share based compensation of $0.41m
Reported Diluted EPS/sh (cents)	-2.55	0.01	-100%	-0.19	-106%	

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

The key highlights from the result were:

- **Revenue 2% lower than forecast:** Total revenue of $13.7m (up 260% y/y) was modestly lower than our forecast of $13.9m, due to a lower matched grant received from the AU government's Biomedical Translation Bridge (BTB) program for PXS-4699 pre-clinical asset being developed for orphan disorder Duchenne Muscular Dystrophy (DMD). **Mannitol (Bronchitol + Aridol) product sales of $3.1m were in-line with our forecast and ~5% below pcp.** The significant increase in revenues over pcp was driven by milestone revenue of ~$10m received from Chiesi on Bronchitol approval.

  Bronchitol product sales of $2.2m were flat over pcp, with a large order during the half from Russia being offset by no material order from Chiesi for Western Europe (vs. pcp which had reasonable size orders for both markets). **COVID impact saw Aridol sales declining by 18% over pcp to $0.9m,** with material declines in both Australia and Europe. Unit sales for Aridol declined 24% in AU and 51% in EU vs. pcp, however we note that both markets seem to be recovering with 2Q21 sales higher than 1Q21.

  We expect 2H21 product sales for both Bronchitol and Aridol to be up over 1H21. Drivers for Bronchitol will be first US revenues, an order from Chiesi for Western Europe and a smaller order for Russia. Drivers for Aridol will be higher sales in both AU and EU assuming continued recovery in these markets and an order from Metapharm for the US (where there was none in pcp).

- **Operating expenses were 3% higher than expected:** Total opex of $12.9m (up 10% y/y) were 3% higher than our forecast of $12.5m. This was driven primarily by higher manufacturing purchases (net of inventory), higher pharmacovigilance costs due to externalising its management and additional resource brought on due to a routine audit of PXS' EU pharmacovigilance during the half, partially offset by lower drug development costs. Drug development costs were lower due to timing with some of the costs for its DMD drug PXS-4699 moving to 2HFY21 and FY22. The increase over pcp was also primarily driven by higher manufacturing purchases and pharmacovigilance costs including additional resourcing, combined with higher clinical trial costs which were however partially offset by lower drug development costs.

- **EBITDA profit lower than our forecast:** EBITDA profit of $0.7m (vs. $8m loss in pcp) was lower than our $1.4m forecast and was driven by both lower revenue (due to lower

grant income) and higher opex. The EBITDA profit vs. loss in pcp was driven by higher revenue due to ~$10m milestone from Chiesi on bronchitol approval for US market.

We note that the Mannitol business reported a positive EBITDA of $6.7m in 1HFY21 vs. EBITDA loss of $2.3m in pcp, which was driven by the Chiesi milestone payment. With the launch of bronchitol expected in US in 2QCY21 and another A$4m in milestone expected from Chiesi shortly, **the segment is now expected to continue to be EBITDA positive for FY21 and beyond.**

- **Underlying and Reported Net profit vs. our loss forecast:** Underlying Net profit of $0.5m (vs. $9.8m loss in pcp) compared to our Net loss forecast of $0.5m was primarily driven by a non-cash Fx gain of $1.5m, where we had none in our forecast. Reported Net Profit was $46k (after including $0.41m share based compensation expense).

  On an overall company level, we note that we don't expect PXS to be either EBITDA positive or be profitable for several years out, given costs on the drug development business side will increase moving forward with imminent start of the Phase 1c/2A clinical trial for myelofibrosis with PXS' lead drug candidate PXS-5505.

- **Cash runway through FY22:** PXS ended 1HFY21 with cash reserves of A$18.2m (modestly below BPe $19.3m), having been bolstered by a $5m R&D tax rebate received in Oct'20 and a ~$10m milestone from Chiesi on Bronchitol approval by the FDA. In addition a ~A$4m (US$3m) milestone has been triggered from Chiesi and expected to be received later this quarter. This was triggered on PXS exporting its first shipment of Bronchitol to the US earlier this week. **In our view, proforma cash of ~A$22.2m, provides PXS with cash runway through FY22.** 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$7.3m.

Earnings and Valuation Changes

We have reviewed our assumptions for PXS and made adjustments to our forecasts based on its 1HFY21 results filed on the ASX, which have impacted earnings and valuation.

Key changes to our modelling assumptions

- Pre-clinical development of PXS' drug PXS-4699 targeted at Duchenne Muscular Dystrophy is being funded partially through a $1m matched Australian Govt. grant through their Biomedical Translation Bridge (BTB) program. The grant requires matched spend by PXS on the program. Given the lower than expected spend and grant money received in 1HFY21, we have moved $0.35m of the grant money and the related spend of ~$0.7m to FY22 (from FY21). This has modestly reduced both our other income forecasts and drug development costs for FY21, while increasing them for FY22.
- PXS is expected to get US$3m milestone from Chiesi shortly. Due to Fx rate revision since our last report, the conversion into AUD has reduced to ~$4m, which has modestly reduced our FY21 revenue forecast.
- We have modestly increased our Aridol sales forecast for FY21 and have reduced it for Bronchitol. The increase in Aridol sales was driven by South Korea, where 1HFY21 reported sales of $0.35m was equal to FY20 revenue. Aridol sales in South Korea were materially impacted with COVID-19 in FY20 and the 1HFY21 results suggest a faster recovery than what we had envisaged. The reduction in Bronchitol sales were driven by UK (with the pandemic impact we assume an order for UK will likely be in FY22 now vs/ FY21), US (assuming that the royalty component on in market sales will be received by PXS in 1QFY22 vs. 4QFY21, given launch by Chiesi is not expected till 4QFY21), partially offset by higher revenue for Russia (with sales in 1HFY21 stronger than expected). Our Bronchitol sales forecast has modestly increased for FY22 and reduced for FY23, driven by UK (assuming a slightly larger order now in FY22 and a slightly lower order in FY23).
- We have increased our opex forecasts for FY21 and FY22 by 2% to account for the higher than expected manufacturing purchases (net of inventory) and safety, medical and regulatory affairs (pharmacovigilance cost and extra resourcing for audit) in 1HFY21, which was partially offset by lower drug development costs.
- We have modestly reduced our forward depreciation forecasts for FY21 and beyond to account for the lower than expected cost reported for 1HFY21.
- We have included the $1.5m non cash Fx gain reported in 1HFY21 for our FY21 forecasts, assuming no Fx impact in 2HFY21.
- We have updated our model with revised BPe USD/AUD and EUR/AUD currency assumptions for FY21-23.
- We have adjusted our DCF for time creep.

We value PXS at $0.14/sh

Revisions to our model led to ~23% increase in our FY21 Net loss forecast, which was driven primarily by lower revenue and modestly higher opex. FY21 revenues decreased due to a combination of lower bronchitol sales (assuming COVID-19 pushes an order for UK out to FY22 and timing for royalty component on in-market sales by Chiesi for US likely moving to 1QFY22 given launch is expected in 4QFY21) and lower AUD conversion of the US$3M milestone from Chiesi due shortly. There was no change to our FY23 net loss forecast and changes to our FY22 net loss forecast was not material. Earning changes were offset by adjusting our DCF for time creep. **Our valuation for PXS remains unchanged at A$0.14/sh**. **We retain Buy (Speculative) on PXS**.

Table 2 - Changes to our FY21-23 Forecasts

	FY2021E			FY2022E			FY2023E		
	Old	New	Change (%)	Old	New	Change (%)	Old	New	Change (%)
Revenues	25.3	23.1	-9%	16.9	17.6	4%	18.9	18.6	-1%
Interest Income	0.1	0.1	-6%	0.1	0.1	-15%	0.1	0.1	-16%
Operating Costs	25.9	26.3	2%	24.3	24.7	1%	24.8	24.5	-1%
EBITDA	-0.5	-3.2	495%	-7.4	-7.1	-4%	-5.9	-5.9	0%
EBIT	-3.7	-6.3	69%	-10.6	-10.2	-4%	-9.1	-9.0	-1%
NPAT (adjusted)	-4.1	-5.1	25%	-10.8	-10.5	-3%	-9.2	-9.1	-1%
Adjusted Diluted EPS	-1.0	-1.3	25%	-2.5	-2.4	-3%	-1.7	-1.7	-1%
NPAT (reported)	-4.7	-5.7	23%	-11.8	-11.5	-3%	-10.1	-10.1	0%
Reported Diluted EPS	-1.1	-1.4	23%	-2.7	-2.6	-3%	-1.9	-1.9	0%

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 3 - Summary of Valuation

Forecasts	Base case
Enterprise value from DCF (AUDm)	42.5
Add: Proforma cash incl. US$3m receivable from Chiesi (AUDm)	22.2
Less: Current Debt (related to finance lease on manufacturing/office premises)	7.3
Equity value (AUDm)	57.5
Total diluted shares (million)	416.2
Value per share (AUD)	**$0.14**
Current Share price (AUD)	$0.088
Expected Capital Growth	59.1%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 4 - 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	$53	**$0.13**	91.9%	Bronchitol - (100%)	Marketed for Aridol, Marketed for Bronchitol (Ex-US and Canada), US to be launched in 1HCY21
New Drug Development	$11	**$0.03**	18.4%	PXS-5505 (MF -22.0%)	PXS-5505 (Phase 1c/2a to start in 1QCY21)
Corporate/Non-Allocated	($21)	**-$0.05**	-36.4%	NA	NA
Proforma Cash (incl Chiesi milestone)	$22	**$0.05**	38.7%	NA	NA
Reported Debt	($7)	**-$0.02**	-12.6%	NA	NA
Equity Value	**$57.5**	**$0.14**	**100.0%**		

SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 5 – 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 6 – 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. LOXL-2 has been found to be important in kidney fibrosis, NASH and idiopathic pulmonary fibrosis (IPF).
- **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 1HCY21. 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 do not include any value for PXS-4728 SSAO inhibitor:** This asset was earlier partnered with Boehringer Ingelheim (BI). BI's decision to return the drug to PXS and discontinue its development for NASH and Diabetic Retinopathy was due to its off

target inhibition of MAOB in the brain and the potential drug interactions that could flow from that. PXS now has the asset back and is conducting a review of the extensive data generated by BI over a 5 year period to determine potential utility of the drug in an indication where potential drug interactions will be of less concern. They believe neurodegenerative diseases where the joint inhibition of SSAO and MAOB enzymes would be neuroprotective could likely be a potential opportunity to pursue. They expect to complete their review, including discussions with KOL's and relevant pharma companies in 1HCY21. Should this asset move to future clinical trials in a new indication, it would represent a source of upside to our forecasts.

- **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 59.1% premium to the previous closing share price of $0.088/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 $13.5m. We also expect EBITDA to grow over the next 5 years to generate ~$12.0m 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 1HCY21. 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 through FY22: PXS' had cash at end of 1HFY21 of ~A$18.2m, which along with the ~A$4m milestone from Chiesi for Bronchitol expected shortly, leads to proforma cash of ~A$22.2m. In our view, this provides PXS cash runway through FY22. 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$7.3m.

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$22.2m and debt related to finance lease of A$7.3m, which we believe provides it with cash runway through FY22. 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 conclusion of partnering discussions 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 13 February 2021

Recommendation	Buy, Speculative
Price	$0.088
Valuation	$0.14

Table 7 - Financial summary

Pharmaxis Ltd (PXS) — **Share price (A$)** **$0.088**
As at 13 February 2021 — **Market cap (A$m)** **35.0**

Profit and Loss

Y/e June 30 (A$m)	2019A	2020A	2021E	2022E	2023E
Product Sales Revenues	5.7	7.0	7.7	13.5	14.9
Other Revenue (commercial)	0.0	0.0	14.0	0.0	0.0
Other Income	6.5	5.6	1.5	4.1	3.7
Total Revenue	**12.2**	**12.7**	**23.1**	**17.6**	**18.6**
EBITDA	**-15.7**	**-12.1**	**-3.2**	**-7.1**	**-5.9**
Depreciation & Amortisation	-2.6	-3.2	-3.1	-3.1	-3.1
EBIT	**-18.3**	**-15.3**	**-6.3**	**-10.2**	**-9.0**
Net interest & Other Income/(Expense)	-0.7	1.9	1.2	-0.2	-0.1
Pre-tax profit	**-19.0**	**-13.4**	**-5.1**	**-10.5**	**-9.1**
Tax	0.0	0.0	0.0	0.0	0.0
Net profit (loss) normalised	**-19.0**	**-13.4**	**-5.1**	**-10.5**	**-9.1**
Abnormal items	-1.1	-0.6	-0.6	-1.0	-1.0
Reported Net profit (loss)	**-20.1**	**-13.9**	**-5.7**	**-11.5**	**-10.1**

Cashflow

Y/e June 30 (A$m)	2019A	2020A	2021E	2022E	2023E
Reported NPAT	-20.1	-13.9	-5.7	-11.5	-10.1
Non-cash items	5.6	2.2	2.6	4.4	4.3
Net change in Working capital	-5.4	-1.6	5.6	-3.4	-0.1
Operating cashflow	**-19.8**	**-13.3**	**2.5**	**-10.4**	**-5.9**
Capex	-0.6	-0.3	-0.3	-0.3	-0.5
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**	**-0.6**	**-0.6**	**-0.9**
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	-0.4	-0.8	-1.1
Financing cashflow	**20.8**	**-2.5**	**-2.7**	**1.9**	**15.4**
Net change in cash	**0.1**	**-16.4**	**-0.7**	**-9.1**	**8.6**
Cash at end of period*	31.1	14.8	14.0	5.0	13.6
* Includes effect of exchange rate fluctuations on cash balance					
Free cash flow (op. CF less capex and intangibles)	**-20.8**	**-13.9**	**1.9**	**-11.0**	**-6.8**

Balance sheet

Y/e June 30 (A$m)	2019A	2020A	2021E	2022E	2023E
Cash	31.1	14.8	14.0	5.0	13.6
Current receivables	7.2	6.9	1.7	5.0	5.1
Inventories	2.1	2.6	2.7	2.9	3.0
Other current assets	0.1	0.2	0.4	0.4	0.4
Current assets	**40.6**	**24.5**	**18.9**	**13.3**	**22.1**
PPE	10.3	8.9	6.2	3.5	1.0
Non-current receivables	1.1	1.1	1.1	1.1	1.1
Intangible assets	0.8	0.9	1.1	1.3	1.5
Other non-current assets	0.0	0.0	0.0	0.0	0.0
Non-current assets	**12.1**	**10.9**	**8.4**	**5.8**	**3.6**
Total assets	**52.7**	**35.4**	**27.2**	**19.1**	**25.7**
Payables	4.8	3.5	4.1	4.1	4.1
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	19.3	18.5	17.3
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**	**30.9**	**28.5**	**25.2**
Net Assets	**14.8**	**1.4**	**-3.7**	**-9.4**	**0.5**
Shareholders' equity	367.3	367.3	367.3	372.1	391.1
Reserves	21.8	22.3	22.9	23.9	24.9
Retained earnings/(losses)	-374.2	-388.2	-393.9	-405.4	-415.5
Total shareholders equity	**14.8**	**1.4**	**-3.7**	**-9.4**	**0.5**

Valuation data

Y/e June 30	2019A	2020A	2021E	2022E	2023E
Net profit -normalised (A$m)	-19.0	-13.4	-5.1	-10.5	-9.1
EPS - normalised (c)	-4.8	-3.3	-1.3	-2.4	-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	0.5	-2.5	-1.1
Price/FCF (x)	-1.7	-2.5	18.2	-3.6	-8.0
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	-1.5	-2.0	-7.5	-3.4	-4.1
EV/EBIT	-1.3	-1.6	-3.8	-2.3	-2.7

Share price now (A$)	$0.088
Valuation (A$):	$0.14
Premium (discount) to price	59.1%
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%	-18.8%	-54.7%	-35.4%
Return on equity (%)	-128.1%	-935.2%	138.7%	111.2%	NM
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	-7.7	-0.3	-11.3
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	2.3	1.5	2.3

Segmentals

Y/e June 30	2019A	2020A	2021E	2022E	2023E
Bronchitol and Aridol					
Product Sales	5.7	7.0	7.7	13.5	14.9
Other revenue (Clinical trial cost reimbursement)	0.0	0.0	14.0	0.0	0.0
Other income	0.0	0.0	0.1	0.0	0.0
Total Revenues	**5.7**	**7.0**	**21.8**	**13.5**	**14.9**
EBITDA	**-5.0**	**-4.0**	**9.7**	**2.1**	**2.8**
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	0.8	3.6	3.2
Total Revenues	**6.0**	**5.2**	**0.8**	**3.6**	**3.2**
EBITDA	**-6.8**	**-5.1**	**-9.7**	**-5.9**	**-5.4**
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**	**23.1**	**17.6**	**18.6**
EBITDA	**-15.7**	**-12.1**	**-3.2**	**-7.1**	**-5.9**

Interims

Y/e June 30 (A$m)	2H19A	1H20A	2H20A	1H21A	2H21E
Revenue	9.7	3.8	8.9	13.7	9.5
EBITDA	-5.8	-8.0	-4.1	0.7	-3.9
Depreciation & Amortisation	-1.3	-1.6	-1.6	-1.6	-1.5
EBIT	**-7.2**	**-9.6**	**-5.7**	**-0.9**	**-5.4**
Net interest & Other Expense	0.1	-0.2	2.1	1.3	-0.1
Pre-tax profit	-7.1	-9.8	-3.6	0.5	-5.6
Tax	0.0	0.0	0.0	0.0	0.0
Net Profit (loss) - normalised	**-7.1**	**-9.8**	**-3.6**	**0.5**	**-5.6**
Net Profit (loss) - reported	-7.5	-10.3	-3.6	0.0	-5.8

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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