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# Pharmaxis Ltd. (PXS)

## FDA Issues CRL on Bronchitol - approval now expected in early 2020

**Recommendation**  
**Buy** (unchanged)  
**Price**  
**\$0.24**  
**Valuation**  
**\$0.54** (unchanged)  
**Risk**  
**Speculative**

**GICS Sector**  
**Pharmaceuticals & Biotechnology**

**Expected Return**

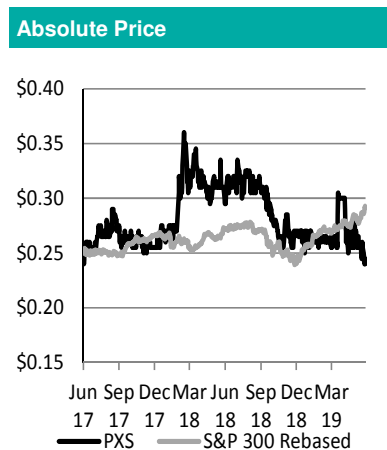
Capital growth	<b>125.0%</b>
Dividend yield	<b>0.0%</b>
Total expected return	<b>125.0%</b>

**Company Data & Ratios**

Enterprise value	<b>\$67.0m</b>
Market cap	<b>\$94.6m</b>
Issued capital	<b>394.3m</b>
Free float	<b>98.7%</b>
Avg. daily val. (52wk)	<b>\$74,708</b>
12 month price range	<b>\$0.23- \$0.347</b>

**Price Performance**

	(1m)	(3m)	(12m)
Price (A\$)	0.26	0.26	0.31
Absolute (%)	-5.88	-7.69	-22.58
Rel market (%)	-8.63	-15.20	-31.43



SOURCE: IRESS

### FDA issues Complete Response Letter on Bronchitol

The US FDA has issued a Complete Response Letter (CRL) for Bronchitol which details outstanding matters which Chiesi/PXS need to address before the drug can be approved for treating adults with cystic fibrosis. The key matter to address is revision of the product packaging and user instructions and then conducting a Human factor Study (HFS) to demonstrate that the revised instructions enable healthcare professionals to properly administer the mannitol tolerance test (MTT). Chiesi will fund the HFS study and is targeting for completion of this study and submission of the same to the FDA by end of CY19. PXS expects FDA approval decision in 1QCY20. Milestone from Chiesi of US\$10m is triggered as soon as PXS ships the product, which at this stage is expected in 2QCY20. Our FY20 est. remain unchanged, with milestone from Chiesi now expected in 2HFY20 (vs. 1HFY20). Recall, that an FDA Advisory Committee voted 9-7 in favour of approving Bronchitol in May'19 based on its risk-benefit profile. Following the vote, we had indicated that we expected FDA to likely approve the product but would still have to focus on getting the label right to highlight risks (such as bronchospasm). As such we are not surprised by FDA asking for revisions to the packaging and user instructions, however the need to repeat a HFS study, has likely led to a CRL which has pushed approval to 1QCY20 (vs. 3QCY19). Due to risk of bronchospasm, patients have to pass the MTT before they can start Bronchitol treatment, which was a feature of all Bronchitol clinical trials and is common practice for its use in Ex-US markets. We see limited risk with the HFS as it is only testing effectiveness of user instructions and not the safety or efficacy of Bronchitol.

### Retain Buy (speculative) and Valuation of \$0.54

Revisions to our model resulted in a large increase in our FY19 Net loss forecast, offset by a large increase in our FY20 NPAT forecast, driven by revised timeline for a deal and related upfront for LOXL-2 asset. Our valuation of \$0.54/sh is unchanged. We retain Buy (Spec). Key Catalysts: a) Completion of commercial process and licensing deal for LOXL-2 asset in 2HCY19; b) Results from Phase 2A NASH trial run by partner Boehringer Ingelheim in Sep/Oct'19 (trial is fully recruited) and c) FDA approval decision on Bronchitol in 1QCY20, with potential milestone from Chiesi in 2QCY20.

**Earnings Forecast**

Year end 30th June	2017A	2018A	2019E	2020E	2021E
Revenue (A\$m)	17.3	50.2	5.5	41.4	10.7
EBITDA (A\$m)	-15.2	11.5	-21.3	15.9	-14.2
NPAT (reported) (A\$m)	-18.3	6.4	-25.9	12.3	-17.8
NPAT (normalised) (A\$m)	-17.4	7.6	-24.6	13.6	-16.4
EPS (reported) (cps)	-5.7	2.0	-6.9	3.1	-4.5
EPS (adjusted) (cps)	-5.5	2.4	-6.6	3.5	-4.2
EPS growth (%)	N/A	NM	N/A	NM	N/A
PER (x)	N/A	10.1	N/A	7.0	N/A
EV/EBITDA (x)	-4.4	5.8	-3.1	4.2	-4.7
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 (%)	NM	68.5%	NM	59.7%	NM

NOTE: REVENUE INCLUDES R&D TAX INCENTIVE. MILESTONES FROM BI DEAL AND CHIESI DEAL AND FY20 REVENUE INCLUDES RISK ADJUSTED UPFRONT AND MILESTONES FROM LICENSING DEAL FOR LOXL-2. SOURCE: BELL POTTER SECURITIES ESTIMATES

# Earnings and Valuation Changes

We have reviewed our assumptions for PXS and made adjustments to our forecasts based on the ASX announcement on Bronchitol, which have impacted earnings and valuation.

## Key changes to our modelling assumptions

- We now expect the milestone from Chiesi on launch of Bronchitol in the US market in 2HFY20 (was 1HFY20).
- We now assume that a deal for LOXL-2 asset gets finalised in 3QCY19 (vs. 2QCY19), which is still as per management guidance of mid-CY19. Accordingly we have moved the risk adjusted upfront related to the deal from FY19 to FY20.

Revisions to our model resulted in a large increase in our Net loss forecast for FY19 which was offset by a large increase in our NPAT forecast for FY20, driven by revised timeline for a deal and related upfront for LOXL-2 asset. No change to our FY21 forecast. Our valuation for PXS remains unchanged at A\$0.54/sh. **We retain Buy (Spec) on PXS.**

**We value PXS at \$0.54/sh**

**Table 1 - Key Changes to our FY19-21 Forecasts**

	FY2019E			FY2020E			FY2021E		
	Old	New	Change (%)	Old	New	Change (%)	Old	New	Change (%)
Revenues	18.0	5.5	-69%	28.9	41.4	43%	10.7	10.7	0%
Interest Income	0.9	0.7	-17%	1.0	0.9	-15%	0.8	0.8	-1%
Operating Costs	26.8	26.8	0%	25.5	25.5	0%	24.8	24.8	0%
EBITDA	-8.8	-21.3	142%	3.4	15.9	365%	-14.2	-14.2	0%
EBIT	-11.5	-23.9	109%	0.7	13.2	1823%	-17.0	-17.0	0%
NPAT (adjusted)	-12.0	-24.6	105%	1.3	13.6	946%	-16.4	-16.4	0%
Adjusted Diluted EPS	-3.2	-6.6	105%	0.3	3.5	946%	-4.2	-4.2	0%
NPAT (reported)	-13.3	-25.9	95%	0.0	12.3	NM	-17.8	-17.8	0%
Reported Diluted EPS	-3.5	-6.9	95%	0.0	3.1	NM	-4.5	-4.5	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 2 - Summary of Valuation**

Forecasts	Base case
Enterprise value from DCF (AUDm)	193.0
Add: Reported Cash (AUDm)	35.1
Less: Current Debt	7.5
Equity value (AUDm)	220.7
Total diluted shares (million)	411.1
<b>Value per share (AUD)</b>	<b>\$0.54</b>
Current Share price (AUD)	\$0.24
Expected Capital Growth	125.0%

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	\$22	\$0.05	10.1%	Aridol - Canada (80%), Bronchitol - US (85%)	Marketed (Ex-Canada) and for Bronchitol (Ex-US and Canada)
New Drug Development	\$203	\$0.49	92.2%	BI_1467335 (NASH, DR - 23.5%), LOXL-2 (NASH -22.0%)	BI_1467335 (Phase 2A) and LOXL-2 (Phase 1 complete)
Corporate/Non-Allocated	(\$33)	-\$0.08	-14.8%	NA	NA
Reported Cash	\$35	\$0.09	15.9%	NA	NA
Reported Debt	(\$7)	-\$0.02	-3.4%	NA	NA
<b>Equity Value</b>	<b>\$220.7</b>	<b>\$0.54</b>	<b>100.0%</b>		

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
BL_1467335	NASH - F2/F3 fibrosis stage	Phase 2A	Boehringer Ingelheim	2027	5% (US), (3.5% ROW)	\$1,962	23.5%
BL_1467335	Diabetic Retinopathy (DR)	Phase 2A	Boehringer Ingelheim	2027	10.0%	\$813	23.5%
LOXL-2	NASH - F3/F4 fibrosis stage	Phase 1 complete	Will look to partner	2028	5% (US), (3.5% ROW)	\$1,448	22.0%

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

Table 5 – Deal Assumptions for Key Drug Development Pipeline Assets

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's share
BL_1467335	NASH and Diabetic Retinopathy	Phase 1	Boehringer Ingelheim	2015	645	33	462	150	11.0%	100.0%
LOXL-2	NASH and a second indication (potentially IPF)	Phase 1 complete	TBC	2020	700	50	470	180	11.0%	83.0%

NOTE: ROYALTIES ARE LIKELY TO BE TIERED. WE ASSUME A FLAT RATE FOR NOW. FOR LOXL-2 DEAL PXS AND ITS PARTNER SYNARGEN WILL SHARE THE DEAL VALUE IN 83:17 RATIO. THE BI DEAL VALUE INCLUDES OUR ESTIMATES ABOUT POTENTIAL UNDISCLOSED COMMERCIAL MILESTONES WHICH ARE PART OF THE DEAL AND HENCE MAY BE CONSERVATIVE. THE BI DEAL IS IN EUROS, WE HAVE CONVERTED IT TO USD AT CURRENT EXCHANGE RATES. SOURCE: BELL POTTER SECURITIES ESTIMATES

## Upside Risk to our valuation

- Clinical success will allow for increased probability of success:** We currently assign a 23.5% probability of success (of reaching the market) to BL\_1467335, given that it's currently in a Phase 2A trial, for both NASH and DR. We envisage that completion of the trials with positive results and subsequent advancement of BL\_1467335 into Phase 2B trials (BPe CY20) will allow us to assign a higher probability of success and therefore will lead to material upgrades in our numbers.

Similarly, we currently assign a 22.0% probability of success (of reaching the market) to LOXL-2 in NASH, following the successful completion of its Phase 1 trial. We envisage that subsequent advancement of LOXL-2 into Phase 2A trials will allow us to assign a higher POS and therefore will lead to material upgrades in our numbers.
- Conservative assumptions for BI\_1467335 in absence of Phase 2 clinical data:** Our market penetration & pricing assumptions, are all based on the premise that BI\_1467335 will be behind a few years to other NASH approaches such as Allergan's CCR2/CCR5 antagonist and Gilead's selonsertib. Our base assumption at this stage is that BI\_1467335 shows at least equivalent efficacy to these assets, with a better safety profile, with the advantage potentially to be used both as a monotherapy and in combination, in the moderate-severe fibrosis stage NASH population, with one or more approved assets by that stage. In the absence of Phase 2 clinical data we are conservative in our assumptions at this stage.
- Conservative assumptions for LOXL-2 to start with in absence of Phase 2 clinical data:** Our market penetration & pricing assumptions and deal size assumptions, are all based on the premise that LOXL-2 will be behind several years to other drugs targeting NASH to get to market. At that stage we expect the drug is more likely than not to be used as an add on therapy with existing standard of care by then to improve efficacy, likely in the more severe end of the fibrosis stage spectrum of NASH. However, given the scarcity of anti-fibrotic assets in development for NASH, we expect both partnering interest and deal size for the LOXL-2 asset with its novel mechanism of action (MoA) to be in line with other high value deals in this space recently. In the absence of Phase 2 clinical data from LOXL-2 we are conservative in our assumptions at this stage including our assumptions for the deal size. Following positive Phase 1 data and the fact that multiple pharma parties seem to be interested, there exists a potential for a deal to emerge with a value higher than our current forecast.
- We do not model royalty revenue from a second indication (likely IPF) for LOXL-2 presently:** At this stage in our valuation, we do not include a market revenue model for LOXL-2 for Idiopathic Pulmonary Fibrosis (IPF) as a potential secondary indication and therefore do not model royalty revenue as a percentage of net sales from this indication to PXS. Confirmation of IPF as a second indication by PXS' future partner and progress of this into Phase 2 clinical trials is likely to considerably 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 LOXL-2 deal included in our model:** At this stage we do not model PXS' share of the assumed US\$180m sales milestones from a potential LOXL-2 deal in our model. We intend to include it in our model once a LOXL-2 deal is inked by PXS, in which case it's likely to be a source of upside to our valuation.
- **No value assigned for other early stage pipeline assets:** We also do not include any value for PXS' early stage assets namely SSAO/MPO inhibitor and LOX inhibitor. PXS has initiated a Phase 1 trial in healthy volunteers with its LOX systemic asset in Feb'19.

The LOX inhibitor program is developing a drug which broadly inhibits all the LOX family of enzymes, which has potential anti-fibrotic application in scarring (a topical formulation) and other severe fibrotic indications including some cancers (a systemic formulation). PXS has had positive results from its LOX systemic asset in myelofibrosis and pancreatic cancer and also intends to complete 3 month toxicology studies while running the currently ongoing Phase 1 trial in healthy volunteers. PXS intends to start a clinical study in pancreatic cancer patients in early CY20. Preclinical development is continuing for the topical asset, with PXS targeting early 2020 to start a Phase 1 trial in healthy volunteers with scarring.

The SSAO/MPO program is developing a dual inhibitor of both SSAO and myeloperoxidase (MPO), which has potential anti-inflammatory application in both respiratory and cardiovascular disease. Preclinical development is continuing for this asset, however it has moved down the priority list behind the LOX topical asset.

PXS believes that the above two assets 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 these two assets into Phase 2 trials in future is likely to be a source of upside to our valuation.

- **We model limited markets for Bronchitol and risk adjust the US opportunity:** For Bronchitol, we model the existing markets of Australia, Western Europe including Italy, Eastern Europe and Russia and now also model US, following the recent positive recommendation in support of approval by the FDA advisory committee. PXS' US partner Chiesi is responsible for its commercialisation. Should Bronchitol get approved and launch in US, PXS will receive a US\$10m milestone from Chiesi, additional US\$15m sales milestones and a mid to high teen percentage of royalties on net sales. At this stage we assign US sales and the launch milestone from Chiesi an 85% probability of success, given FDA approval is yet to be granted. FDA approval and launch of Bronchitol in the US therefore will be an upside to our valuation for PXS. We also do not model the US\$15m sales milestone receivable from Chiesi on meeting certain undisclosed sales thresholds at this stage, which would represent an upside.
- **We model limited markets for Aridol:** For Aridol, we model the existing markets of Australia, Europe and South Korea and now also model US where the company relaunched Aridol in Dec'18 following FDA approval of its manufacturing facility. We also model revenue from Canada (assigning it an 80% probability of success), given Aridol is not approved in Canada as yet. Filing for approval in Canada was made in June 2018, with approval expected by mid-CY19. We assume FY20 launch in Canada.
- **Small contribution from Bronchitol and Aridol segment in our valuation:** With the addition of the US opportunity for Bronchitol in our model, we now expect the Bronchitol and Aridol segment to transition to profitability over the next 1-2 years. Excluding the US opportunity, we believe Russia for Bronchitol and Canada for Aridol may surprise us on the upside, however at this stage we choose to be conservative till we see increasing traction in Russia for Bronchitol after obtaining wider reimbursement and launch in Canada for Aridol.

## 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 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 drugs while not first-in-class, have the potential to be best-in-class and be useful in other fibrotic diseases and we forecast both to be blockbusters (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 by 2020. 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 also has two marketed respiratory products Bronchitol and Aridol which we view as non-core, however they represent an existing albeit small revenue stream for PXS with potential upside should US approval come through.

### INVESTMENT STRATEGY

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

**\$0.54 valuation:** We value PXS using a risk adjusted DCF at \$0.54. The valuation is approximately a 125.0% premium to the current share price of \$0.24/sh.

**Lead assets targeting NASH have blockbuster potential:** Pharmaxis' lead assets Phase 2 SSAO/VAP-1 inhibitor BI\_1467335 and Phase 1 LOXL-2 inhibitor are both targeting Non-alcoholic Steatohepatitis (NASH), a multibillion dollar market, estimated to grow to be ~US\$20bn-US\$35bn. We model US\$1.96bn peak worldwide sales (pre risk adjustment) for BI\_1467335 in NASH and US\$1.45bn for LOXL-2 in NASH.

**NASH represents significant commercial opportunity:** NASH is a large market, growing rapidly with an increasing obese population. It is estimated that NASH will surpass Hepatitis C Virus (HCV) as the leading cause of liver transplants by 2020. 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. There have been a number of high value deals in this space recently and active companies are looking to license or acquire to build a portfolio of assets targeting different stages of NASH. Average deal sizes are around US\$860m, however some deals recently have been over \$1bn.

**PXS emerging as a key player in NASH:** Drugs targeting NASH in development 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 has two assets which fall under two different categories. BI\_1467335 is an anti-inflammatory agent and LOXL-2 asset is an anti-fibrotic agent and therefore should complement each other and other drugs in advanced development. There are very few drugs in development in these 2 categories and as far as we are aware both these drugs are currently the only one in their class being actively developed for NASH.

**Drugs not first-in-class but potentially best-in-class:** PXS' SSAO/VAP-1 and LOXL-2 inhibitor are not the first in their class. However based on pre-clinical data for both and Phase 1 data for the SSAO drug, we believe the drugs possess a more favourable PK/PD

profile which could make them 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 beyond NASH:** Both the lead drugs have potential to be used across fibrotic diseases with the SSAO inhibitor in a phase 2 trial for Diabetic Retinopathy (DR) and LOXL-2 being explored in Pulmonary 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.

**Value inflexion points approaching:** Results from phase 2A trials for the SSAO/VAP-1 drug partnered with BI in NASH is expected in 2H2019 and in Diabetic Retinopathy in 1H2020. LOXL-2 has successfully completed Phase 1 trials and longer term toxicology studies and PXS is now in discussions to potentially partner it, with a multi-million dollar licensing deal expected in 2H2019.

**Strong cash position:** PXS' current cash reserves of A\$35.1m, in our view, provides ~1.5 years cash runway, with flexibility to defer some expenses on other pipeline programs to further extend this runway. The company has a modest debt (related to finance lease) of \$7.5m. PXS is unlikely to require any capital raisings in the medium term, given it has recently raised capital and strengthened its balance sheet. We believe the company is well placed to look at capital management initiatives such as a share buyback or special dividend to return some surplus capital to its shareholders after they finalise a deal for LOXL-2 later this year. PXS' strong cash position should also help its ongoing negotiations for the LOXL-2 asset. It will also allow it to pursue some asset acquisitions to further enrich its drug development pipeline and also allow the company to consider Phase 2A/2B development for some of its pipeline assets to add more value before partnering them out.



# 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 near 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 the development of the product PXS' ability to generate revenue from that asset will diminish/or fail totally.
- **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 now affect our valuation:** While we look at Bronchitol and Aridol, PXS' currently marketed products as non-core assets and attribute minimal value to it, our inclusion of Bronchitol's US opportunity now makes our valuation vulnerable to FDA's decision on Bronchitol. FDA has issued a CRL detailing matters which Chiesi still need to address prior to approval. 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). PXS expect approval in 1QCY20. We currently assign an 85% probability of success to US sales of Bronchitol and risk adjust the potential US\$10m milestone receivable from Chiesi on launch.
- **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 BI drug or the LOXL-2 drug, 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 in LOXL-2's case where 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 may impact PXS' funding position in the long term. PXS has A\$35.1m in cash and debt related to finance lease of A\$7.5m, amounting to a net cash position of A\$27.7m. Although PXS has a high cash balance currently, which should provide ~1.5 years cash runway, the company may need to raise additional capital for funding its requirements beyond that should there be delays in partnering its LOXL-2 asset. There is no guarantee that PXS will be able to secure additional financing if and when required.

**Table 6 - Financial summary**

Pharmaxis Ltd (PXS)						Share price (A\$)	\$0.240				
As at 24 June 2019						Market cap (A\$)	94.6				
<b>Profit and Loss</b>						<b>Valuation data</b>					
<b>Y/e June 30 (A\$m)</b>	<b>2017A</b>	<b>2018A</b>	<b>2019E</b>	<b>2020E</b>	<b>2021E</b>	<b>Y/e June 30</b>	<b>2017A</b>	<b>2018A</b>	<b>2019E</b>	<b>2020E</b>	<b>2021E</b>
Product Sales Revenues	4.8	6.1	5.0	8.2	10.0	Net profit - normalised (A\$m)	-17.4	7.6	-24.6	13.6	-16.4
Other Revenue (commercial)	8.6	43.5	0.0	32.6	0.0	EPS - normalised (c)	-5.5	2.4	-6.6	3.5	-4.2
Other Income	3.9	0.7	0.5	0.7	0.7	EPS growth (%)	N/A	NM	N/A	NM	N/A
<b>Total Revenue</b>	<b>17.3</b>	<b>50.2</b>	<b>5.5</b>	<b>41.4</b>	<b>10.7</b>	P/E ratio (x)	N/A	10.1	N/A	7.0	N/A
<b>EBITDA</b>	<b>-15.2</b>	<b>11.5</b>	<b>-21.3</b>	<b>15.9</b>	<b>-14.2</b>	FCFPS (c)	-5.0	3.5	-5.8	4.0	-3.7
Depreciation & Amortisation	-3.1	-3.1	-2.7	-2.7	-2.8	Price/FCF (x)	-4.8	6.8	-4.2	6.1	-6.5
<b>EBIT</b>	<b>-18.3</b>	<b>8.4</b>	<b>-23.9</b>	<b>13.2</b>	<b>-17.0</b>	DPS (c)	0.0	0.0	0.0	0.0	0.0
Net interest & Other Income/(Expense)	0.9	-0.8	-0.6	0.5	0.5	Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Pre-tax profit</b>	<b>-17.4</b>	<b>7.6</b>	<b>-24.6</b>	<b>13.6</b>	<b>-16.4</b>	Franking (%)	N/A	N/A	N/A	N/A	N/A
Tax	0.0	0.0	0.0	0.0	0.0	EV/EBITDA	-4.4	5.8	-3.1	4.2	-4.7
<b>Net profit (loss) normalised</b>	<b>-17.4</b>	<b>7.6</b>	<b>-24.6</b>	<b>13.6</b>	<b>-16.4</b>	EV/EBIT	-3.7	8.0	-2.8	5.1	-3.9
Abnormal items	-0.9	-1.2	-1.3	-1.3	-1.3						
<b>Reported Net profit (loss)</b>	<b>-18.3</b>	<b>6.4</b>	<b>-25.9</b>	<b>12.3</b>	<b>-17.8</b>						
<b>Cashflow</b>						<b>Share price now (A\$)</b> \$0.240					
<b>Y/e June 30 (A\$m)</b>	<b>2017A</b>	<b>2018A</b>	<b>2019E</b>	<b>2020E</b>	<b>2021E</b>	<b>Valuation (A\$):</b>	\$0.54				
Reported NPAT	-18.3	6.4	-25.9	12.3	-17.8	Premium (discount) to price	125.0%				
Non-cash items	3.7	5.6	5.4	4.5	4.4	<b>Recommendation:</b>	Buy				
Net change in Working capital	-0.6	0.1	-1.1	0.0	0.0	<b>Risk Rating</b>	Speculative				
<b>Operating cashflow</b>	<b>-15.3</b>	<b>12.2</b>	<b>-21.6</b>	<b>16.8</b>	<b>-13.3</b>	<b>Profitability ratios</b>					
Capex	-0.3	-0.8	-0.8	-0.8	-0.8	<b>Y/e June 30</b>	<b>2017A</b>	<b>2018A</b>	<b>2019E</b>	<b>2020E</b>	<b>2021E</b>
Investments	0.0	0.0	0.0	0.0	0.0	EBITDA margin (%)	N/A	22.9%	N/A	38.4%	N/A
Investments in intangible assets	-0.4	0.0	-0.4	-0.4	-0.4	EBIT margin (%)	N/A	16.7%	N/A	31.8%	N/A
Other investing cash flow	0.0	0.0	0.0	0.0	0.0	Return on assets (%)	-38.3%	15.2%	-52.8%	23.3%	-41.4%
<b>Investing cashflow</b>	<b>-0.7</b>	<b>-0.9</b>	<b>-1.2</b>	<b>-1.2</b>	<b>-1.2</b>	Return on equity (%)	NM	68.5%	NM	59.7%	NM
Change in borrowings	-1.5	-1.5	-1.6	-1.7	-1.7	Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Equity issued	0.0	0.0	22.7	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	<b>Liquidity and leverage ratios</b>					
Other financing cash flow	-0.2	-0.2	-0.2	-0.5	-0.8	<b>Y/e June 30</b>	<b>2017A</b>	<b>2018A</b>	<b>2019E</b>	<b>2020E</b>	<b>2021E</b>
<b>Financing cashflow</b>	<b>-1.7</b>	<b>-1.8</b>	<b>20.9</b>	<b>-2.2</b>	<b>-2.5</b>	Net debt (cash) (A\$m)	-12.3	-22.8	-22.0	-36.7	-21.1
<b>Net change in cash</b>	<b>-17.7</b>	<b>9.6</b>	<b>-1.9</b>	<b>13.4</b>	<b>-17.0</b>	<b>Net debt/equity (%)</b>	N/A	N/A	N/A	N/A	N/A
<b>Cash at end of period*</b>	<b>21.5</b>	<b>31.1</b>	<b>29.2</b>	<b>42.6</b>	<b>25.6</b>	Net interest cover (x)	N/A	NM	N/A	-32.4	N/A
<small>* Includes effect of exchange rate fluctuations on cash balance</small>						Current ratio (x)	2.7	4.4	4.0	5.4	3.4
<b>Free cash flow (op. CF less capex and intangibles)</b>	<b>-16.0</b>	<b>11.3</b>	<b>-22.8</b>	<b>15.6</b>	<b>-14.5</b>	<b>Segmentals</b>					
<b>Balance sheet</b>						<b>Y/e June 30</b>	<b>2017A</b>	<b>2018A</b>	<b>2019E</b>	<b>2020E</b>	<b>2021E</b>
<b>Y/e June 30 (A\$m)</b>	<b>2017A</b>	<b>2018A</b>	<b>2019E</b>	<b>2020E</b>	<b>2021E</b>	<b>Bronchitol and Aridol</b>					
Cash	21.5	31.1	29.2	42.6	25.6	Product Sales	4.8	6.1	5.0	8.2	10.0
Current receivables	4.4	2.4	2.5	2.6	2.7	Other revenue (Clinical trial cost reimbursement)	8.6	1.3	0.0	11.3	0.0
Inventories	2.6	2.4	2.5	2.6	2.7	Other income	0.1	0.0	0.0	0.0	0.0
Other current assets	0.1	0.1	0.1	0.1	0.1	<b>Total Revenues</b>	<b>13.5</b>	<b>7.5</b>	<b>5.1</b>	<b>19.5</b>	<b>10.0</b>
<b>Current assets</b>	<b>28.6</b>	<b>36.0</b>	<b>34.3</b>	<b>47.9</b>	<b>31.1</b>	<b>EBITDA</b>	<b>-7.1</b>	<b>-3.8</b>	<b>-5.3</b>	<b>8.1</b>	<b>-1.7</b>
PPE	14.9	12.5	10.4	8.3	6.1	<b>New Drug Development</b>					
Non-current receivables	1.4	1.2	1.2	1.2	1.2	Product Sales	0.0	0.0	0.0	0.0	0.0
Intangible assets	0.5	0.4	0.7	1.0	1.3	Other revenue (Milestone+license+royalty)	0.0	42.1	0.0	21.2	0.0
Other non-current assets	0.0	0.0	0.0	0.0	0.0	Other income (R&D tax incentive etc.)	3.4	0.2	0.0	0.2	0.2
<b>Non-current assets</b>	<b>16.8</b>	<b>14.1</b>	<b>12.4</b>	<b>10.5</b>	<b>8.7</b>	<b>Total Revenues</b>	<b>3.4</b>	<b>42.3</b>	<b>0.0</b>	<b>21.4</b>	<b>0.2</b>
<b>Total assets</b>	<b>45.4</b>	<b>50.1</b>	<b>46.6</b>	<b>58.4</b>	<b>39.8</b>	<b>EBITDA</b>	<b>-4.1</b>	<b>28.8</b>	<b>-11.9</b>	<b>12.0</b>	<b>-8.3</b>
Payables	6.8	5.6	4.6	4.7	4.8	<b>Corporate</b>					
Debt	9.3	8.3	7.2	5.9	4.5	Other income	0.3	0.5	0.5	0.5	0.5
Provisions	0.9	1.0	1.1	1.2	1.3	<b>EBITDA</b>	<b>-4.0</b>	<b>-13.5</b>	<b>-4.1</b>	<b>-4.1</b>	<b>-4.1</b>
Financial liabilities (Novaquest financing agreement)	22.1	22.8	23.4	22.9	22.1	<b>Total Company</b>					
Deferred Lease Incentive	1.6	1.4	1.1	0.9	0.7	Revenues	17.3	50.2	5.5	41.4	10.7
Other liabilities	1.1	0.0	0.0	0.0	0.0	<b>EBITDA</b>	<b>-15.2</b>	<b>11.5</b>	<b>-21.3</b>	<b>15.9</b>	<b>-14.2</b>
<b>Total liabilities</b>	<b>41.9</b>	<b>39.0</b>	<b>37.4</b>	<b>35.6</b>	<b>33.4</b>	<b>Interims</b>					
<b>Net Assets</b>	<b>3.5</b>	<b>11.1</b>	<b>9.2</b>	<b>22.8</b>	<b>6.4</b>	<b>Y/e June 30 (A\$m)</b>	<b>2H17A</b>	<b>1H18A</b>	<b>2H18A</b>	<b>1H19A</b>	<b>2H19E</b>
Shareholders' equity	344.6	344.6	367.3	367.3	367.3	Revenue	10.8	31.1	19.1	2.5	3.0
Reserves	19.5	20.7	22.0	23.3	24.6	<b>EBITDA</b>	<b>-6.8</b>	<b>7.8</b>	<b>3.7</b>	<b>-9.8</b>	<b>-11.5</b>
Retained earnings/(losses)	-360.6	-354.2	-380.1	-367.8	-385.6	Depreciation & Amortisation	-1.5	-1.6	-1.5	-1.3	-1.4
<b>Total shareholders equity</b>	<b>3.5</b>	<b>11.1</b>	<b>9.2</b>	<b>22.8</b>	<b>6.4</b>	<b>EBIT</b>	<b>-8.3</b>	<b>6.2</b>	<b>2.2</b>	<b>-11.1</b>	<b>-12.8</b>
						Net interest & Other Expense	1.5	0.3	-1.1	-0.8	0.2
						Pre-tax profit	-6.8	6.5	1.1	-11.9	-12.7
						Tax	0.0	0.0	0.0	0.0	0.0
						<b>Net Profit (loss) - normalised</b>	<b>-6.8</b>	<b>6.5</b>	<b>1.1</b>	<b>-11.9</b>	<b>-12.7</b>
						Net Profit (loss) - reported	-7.3	5.9	0.5	-12.6	-13.3

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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