BELL POTTER

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

30 July 2019

Analyst
Tanushree Jain 612 8224 2849

Authorisation
John Hester 612 8224 2871

Pharmaxis Ltd. (PXS)

Key catalysts coming up in FY20

Recommendation
Buy (unchanged)
Price
$0.225
Valuation
$0.57 (previously $0.54)
Risk
Speculative

GICS Sector
Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**153.3%**
Dividend yield	**0.0%**
Total expected return	**153.3%**
Company Data & Ratios	
Enterprise value	**$64.8m**
Market cap	**$88.7m**
Issued capital	**394.3m**
Free float	**98.7%**
Avg. daily val. (52wk)	**$71,243**
12 month price range	**$0.225- $0.335**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.25	0.30	0.31
Absolute (%)	-8.00	-23.33	-25.81
Rel market (%)	-10.56	-31.40	-34.79

Absolute Price

SOURCE: IRESS

Key highlights from FY19 unaudited results

Revenue was ahead of BPe, driven by R&D tax rebate and higher Aridol and Bronchitol sales. Variance from BPe was driven by an order from US for aridol and Russia for bronchitol. Overall FY19 Bronchitol and Aridol sales were ~7% below pcp, with increase in Aridol sales (driven by US) offset by lower Bronchitol sales (reduced orders from Chiesi for EU). PXS expects this segment to become profitable from 2020 following US approval of Bronchitol. Excluding the US$10m milestone receivable in FY20 from Chiesi for Bronchitol, we forecast this segment to break even in FY22 on our risk-adjusted revenue forecasts for US. Proforma cash of $37m ($31.1m cash plus $6m R&D rebate), provide ~22 months runway ahead of boost expected through licensing deal for LOXL-2 and milestone from Chiesi.

LOXL-2 partnering process extended to end CY19

PXS has revised its guidance for timeline of conclusion of the LOXL-2 partnering process to before end of CY19 (vs. previous guidance of mid CY19). The company does not expect to provide any updates prior to conclusion of the process citing the confidential nature of these discussions. PXS hinted that changing market conditions and the fact that multiple therapeutic indications are under discussion have tended to extend these discussions. We continue to believe that the LOXL-2 asset being one of the true anti-fibrotic mechanisms in play has good partnering potential. We continue to model a risk adjusted deal for LOXL-2 asset in 2HCY19 (4QCY19 vs 3QCY19).

Valuation lifted to $0.57, Retain Buy (speculative)

Revisions to our model resulted in a large decrease in our NPAT forecast for FY20 which was offset by a large decrease in our Net loss forecast for FY21, driven primarily by revised timeline for a deal and related Phase 2A initiation milestone for LOXL-2 asset. Short term earning changes, rolling forward of our DCF model and revised currency estimates have led to a modest increase in our valuation for PXS to A$0.57/sh (was A$0.54/sh). We retain Buy (Spec). **Key Catalysts:** a) Completion of commercial process for LOXL-2 in 4QCY19; b) Results from Phase 2A NASH trial run by partner Boehringer Ingelheim in 4QCY19 and c) FDA approval decision on Bronchitol in 1QCY20, with potential US$10m milestone from Chiesi in 2QCY20.

Earnings Forecast

Year end 30th June	2018A	2019E	2020E	2021E	2022E
Revenue (A$m)	50.2	12.2	32.0	20.2	16.1
EBITDA (A$m)	11.5	-15.7	5.6	-6.2	-7.7
NPAT (reported) (A$m)	6.4	-20.1	2.8	-8.8	-10.5
NPAT (normalised) (A$m)	7.6	-19.0	4.0	-7.5	-9.1
EPS (reported) (cps)	2.0	-5.3	0.7	-2.2	-2.7
EPS (adjusted) (cps)	2.4	-5.1	1.0	-1.9	-2.3
EPS growth (%)	NM	N/A	NM	N/A	N/A
PER (x)	9.4	N/A	22.4	N/A	N/A
EV/EBITDA (x)	5.6	-4.1	11.6	-10.5	-8.4
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 (%)	68.5%	NM	21.1%	NM	NM

NOTE: REVENUE INCLUDES R&D TAX INCENTIVE, MILESTONES FROM BI DEAL AND CHIESI DEAL AND FY20/21 REVENUE INCLUDES RISK ADJUSTED UPFRONT AND MILESTONES FROM LICENSING DEAL FOR LOXL-2. SOURCE: BELL POTTER SECURITIES ESTIMATES

FY19 – Result Summary

A summary of the reported FY19 result based on unaudited income statement summary as per PXS' quarterly update is shown in the Table below:

Table 1 – FY19 (unaudited) result summary

	Result vs PCP			Result vs Forecast		Comments
	FY18A	FY19A	% change	FY19E	Variance (%)	
Revenues	**50.2**	**12.2**	**-76%**	**5.5**	**120%**	Revenue higher than our forecast due to higher Bronchitol and Aridol sales and inclusion of R&D tax rebate (where we had none)
Total operating costs	**38.7**	**27.8**	**-28%**	**26.8**	**4%**	Opex 4% higher than our forecast driven primarily by higher clinical trials cost on PXS' pipeline assets
EBITDA	**11.5**	**-15.7**	**NM**	**-21.3**	**-26%**	**EBITDA loss lower than forecast driven by higher revenue**
Depreciation and Amortisation	-3.1	-2.6	-16%	-2.7	-2%	Depreciation expense modestly lower than our forecast
EBIT	**8.4**	**-18.3**	NM	**-23.9**	**-24%**	**Lower EBIT loss with variance reduced from EBITDA line due to lower D&A**
Net Interest Income/(expense)	0.0	0.4	NM	0.2	NM	Higher Interest income
Other Income/(expense)	-0.8	-1.1	-37%	-0.9	NM	Higher Fx loss of $1.1m
Pretax Income (Loss)	7.6	-19.0	NM	-24.6	-23%	
Net Income (Loss) after tax - normalised	**7.6**	**-19.0**	**NM**	**-24.6**	**-23%**	**Lower Net loss with modest decrease in variance from EBIT due to higher interest income**
Diluted EPS/Share (cents)	2.38	-5.06	NM	-6.56	-23%	
Reported Net Income (loss)	**6.4**	**-20.1**	**NM**	**-25.9**	**-23%**	Reported Net loss lower than our forecasts. Includes share based compensation of $1.1m
Reported Diluted EPS/sh (cents)	2.01	-5.35	NM	-6.91	-23%	

NOTE: FY19A EPS/SHARE NUMBERS ARE ESTIMATES SUBJECT TO CHANGES WHEN COMPANY FILES ITS AUDITED FINANCIALS LATER IN AUG'19.

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

The key highlights from the result were:

- **Significant beat in revenue:** Total revenue of $12.2m (down 76% y/y) was significantly ahead of our forecast of $5.5m and was driven by higher Aridol and Bronchitol sales as well as higher other income (which included a $6.0m R&D tax accrual for FY19 where we had none). Aridol sales were higher than our forecast driven primarily by another order for the US market in 4QFY19, where we had not expected any and higher sales in Australia. Bronchitol sales were modestly higher than our forecast driven by an order from Russia in 4QFY19. We had expected an order to be shipped in June to Russia but thought revenue would be recorded in the next period and hence had none in our forecast this year.

  Overall Bronchitol and Aridol product sales of $5.7m in FY19 was ~7% below pcp, with increase in Aridol sales offset by lower Bronchitol sales. The ~55% increase in Aridol sales over pcp was driven by launch in the US market (US sales were ~$1m in FY19 vs. nil in FY18). The ~37% decrease in Bronchitol sales over pcp was driven primarily by lower number of orders from Chiesi for Germany, UK and Italy, partially offset by higher revenue in Australia and orders from Russia in FY19. We note that revenue from Russia was significant (~$0.6m in FY19, however was reduced by a credit note of ~$0.4m related to expired product which was a result of delay in timing of receiving national reimbursement vs. original expectations).

  The significant decrease in overall revenues over pcp was mainly driven by the A$42.1m milestone payment from partner Boehringer Ingelheim (BI) in FY18 on initiation of Phase 2A NASH and Diabetic Retinopathy (DR) trials with BI_1467335, partially offset by the $6m R&D tax rebate booked in FY19.

- **Operating expenses were 4% higher than expected:** Total opex of $27.8m (down 28% y/y) were 4% higher than our forecast of $26.8m. This was driven by higher clinical costs related to the LOX Phase 1 trial and modestly higher costs related to the LOXL-2 program. The decrease over pcp was primarily driven by the one-off $9.6m payment in FY18 made to Synairgen pursuant to the change in collaboration terms for the LOXL-2 program and lower clinical trials and drug development costs.

- **EBITDA loss lower than our forecast:** EBITDA loss of $15.7m was significantly lower than our forecast loss of $21.3m and was driven by higher revenue, partially offset by higher opex. The profit in pcp vs. loss in FY19 was driven by the large milestones received from BI in FY18.
- **Underlying and Reported Net Loss lower than our forecast:** Underlying Net loss of $19.0m was lower than our forecast loss of $24.6m and was driven by higher revenue. The variance at the Net loss line was modestly lower than the EBITDA loss line due to lower than expected D&A expense and higher interest income than our forecasts, partially offset by higher Fx loss. Reported Net loss was $20.1m (including $1.1m share based compensation expense), which was also lower than our forecast loss.
- **Strong cash position:** PXS' cash reserves are A$31.1m. Borrowings are just lease liabilities and hence included in our cash burn assumptions. An R&D tax rebate of $6m is expected to be received in 2HCY19. This should provide ~22 months cash runway ahead of further boost expected through a licensing deal for LOXL-2 asset in 2HCY19 and a US$10m milestone payment from Chiesi in 2QCY20, following US approval of Bronchitol (milestone is triggered once product is shipped to Chiesi for sale).

LOXL-2 partnering process extended to end CY19

PXS has revised its guidance for timeline of conclusion of the LOXL-2 partnering process to before end of CY19 (vs. previous guidance of mid CY19). The company does not expect to provide any updates prior to conclusion of the process citing the confidential nature of these discussions. The company hinted that changing market conditions and the fact that multiple therapeutic indications are under discussion have tended to extend the ongoing partnering discussions.

Some keenly awaited trials in NASH have been unsuccessful and in general the industry is potentially cautious and waiting on some more data releases later this year to understand what approaches alone or in combination are likely to work for NASH. Interest is still high and given combination pathway, key players such as Gilead are looking for approaches to combine with their pipeline.

We continue to believe that the LOXL-2 asset being one of the true anti-fibrotic mechanisms in play has good partnering potential, the question would be how a potential deal gets structured to have more risk sharing by both the parties involved. PXS' deal with Boehringer Ingelheim (BI) was a traditional deal with all development responsibility taken over by BI. A LOXL-2 deal may be structured a bit differently to still have more of PXS involvement at least in the earlier stages. At this stage we continue to model a risk adjusted deal (similar in structure to the BI deal for now) in 2HCY19.

Earnings and Valuation Changes

We have reviewed our assumptions for PXS and made adjustments to our forecasts based on its quarterly update and investor presentation filed on the ASX, which have impacted earnings and valuation.

Key changes to our modelling assumptions

- Aridol received regulatory approval from the Canadian regulatory authorities in June'19. Launch is expected in FY20 (in-line with our forecast). Following approval, we have removed the 80% risk-adjustment we had applied to our forecasts for Canada.
- We have reduced our Aridol sales forecast for FY20 and modestly increased it from FY21 onwards. The reduction in FY20 was driven by an unexpected order being received for the US in 4QFY19 from Methapharm. Based on the orders received in FY19, we believe Methapharm was likely building its inventory up on launch and it may not be a reflection of actual in-market sales. We now believe it unlikely that we may get another order in FY20 (as Methapharm works through its inventory) and therefore assume no US sales for Aridol in FY20. From FY21 onwards, we have modestly increased our US sales estimates for Aridol.
- We have reduced our Bronchitol sales forecast for FY20 and modestly increased it from FY21 onwards. The increase from FY21 onwards is driven by modestly higher sales assumptions for both Russia and US markets. For Russia the increase was driven by higher unit sales assumptions (following initial order of 2000 units received in 4QFY19). For US the increase was driven by a revision in our methodology for modelling the US revenue. For FY20 the decrease was driven by the US market. We now break up our risk-adjusted revenue for US into two components (transfer price manufacturing revenue and royalties on net sales of the product). We believe PXS will ship product to Chiesi ahead of US launch of Bronchitol in 4QFY20, however royalties on sales will have a lag and receivable post launch (expected in 1HFY21). Hence, we have removed the royalty component from our FY20 revenue forecasts, assuming only the manufacturing revenue portion gets booked in FY20. For our forward forecasts we assume 50% of the royalty component each year is deferred to the next year. For US we also assume a higher share of revenue for PXS and in parallel have also assumed higher cost on raw material purchases related to the US.
- We now assume that a deal for LOXL-2 asset gets finalised in 4QCY19 (vs. 3QCY19), which is as per management guidance of the partnering process coming to a conclusion before end of CY19. We now assume that a partner will only be able to start a Phase 2A trial in FY21. Hence we have moved our risk-adjusted Phase 2A start milestone to FY21 (was FY20) and forward milestones accordingly. We now expect first sales in 1HFY29 (was 2HFY28) and have moved our related milestones and royalties accordingly.
- Based on our revised revenue forecasts, we now include a R&D tax rebate of $3m in FY22.
- We have decreased our drug development costs for FY20 by ~$0.8m as we had earlier expected the company to be spending on preclinical development of its SSAO/MPO pipeline asset. However, that asset has been missing both from PXS' quarterly update and its investor presentation, implying that PXS is no longer pursuing it. The LOX (systemic and topical) assets have taken precedence and PXS is pursuing development of these pipeline assets.

- We have increased our clinical trial costs for FY20 and FY21 by ~$1m each, allowing for a bit more cost for a potential Phase 1c/2 study in myelofibrosis and/or pancreatic patients with the LOX systemic asset expected to start in 1HCY20.
- We have updated our model with revised BPe USD/AUD and EUR/AUD currency assumptions for FY20-22.
- We have rolled forward our DCF model.

We value PXS at $0.57/sh

Revisions to our model resulted in a large decrease in our NPAT forecast for FY20 which was offset by a large decrease in our Net loss forecast for FY21, driven primarily by revised timeline for a deal and related Phase 2A initiation milestone for LOXL-2 asset. Short term earning changes, rolling forward of our DCF model and revised currency estimates have led to a modest increase in our valuation for PXS to A$0.57/sh (was A$0.54/sh). **We retain Buy (Spec) on PXS.**

Table 2 - Key Changes to our FY20-21 Forecasts

	FY2020E			FY2021E		
	Old	New	Change (%)	Old	New	Change (%)
Revenues	42.3	32.0	-24%	10.7	20.2	89%
Interest Income	0.9	1.0	21%	0.8	1.1	28%
Operating Costs	25.5	26.4	3%	24.8	26.3	6%
EBITDA	16.8	5.6	-67%	-14.2	-6.2	-56%
EBIT	14.1	3.3	-76%	-17.0	-8.3	-51%
NPAT (adjusted)	14.5	4.0	-73%	-16.4	-7.5	-54%
Adjusted Diluted EPS	3.7	1.0	-73%	-4.2	-1.9	-54%
NPAT (reported)	13.2	2.8	-79%	-17.8	-8.8	-50%
Reported Diluted EPS	3.4	0.7	-79%	-4.5	-2.2	-50%

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)	211.7
Add: Reported Cash (AUDm)	31.1
Less: Current Debt	7.2
Equity value (AUDm)	235.7
Total diluted shares (million)	411.0
Value per share (AUD)	**$0.57**
Current Share price (AUD)	$0.23
Expected Capital Growth	153.3%

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	$19	**$0.05**	8.1%	Aridol - Canada (100%), Bronchitol - US (85%)	Marketed (Ex-Canada) and for Bronchitol (Ex-US and Canada)
New Drug Development	$229	**$0.56**	97.1%	BI_1467335 (NASH, DR - 23.5%), LOXL-2 (NASH -22.0%)	BI_1467335 (Phase 2A) and LOXL-2 (Phase 1 complete)
Corporate/Non-Allocated	($36)	**-$0.09**	-15.3%	NA	NA
Reported Cash	$31	**$0.08**	13.2%	NA	NA
Reported Debt	($7)	**-$0.02**	-3.0%	NA	NA
Equity Value	**$235.7**	**$0.57**	**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
BI_1467335	NASH - F2/F3 fibrosis stage	Phase 2A	Boehringer Ingelheim	2027	5% (US), (3.5% ROW)	$1,962	23.5%
BI_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	2029	5% (US), (3.5% ROW)	$1,448	22.0%

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

Table 6 – 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
BI_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 SYNAIRGEN 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 BI_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 BI_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.
- **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 2 LOX inhibitors (systemic and Topical). 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 initiated a Phase 1 trial in healthy volunteers with its LOX systemic asset in Feb'19. The SAD (single ascending dose) part of this study was completed in June'19 and the company will conduct the second MAD (multiple ascending dose) in 2HCY19. PXS has had positive results from its LOX systemic asset in myelofibrosis and pancreatic cancer in preclinical models and has completed 3 month toxicology studies while running the currently ongoing Phase 1 trial in healthy volunteers. Longer term tox studies (6 months) are also being carried out in parallel for the compound. PXS intends to start a clinical study in myelofibrosis and/or pancreatic cancer patients in 1HCY20. Preclinical development is continuing for the topical asset, with PXS targeting early 2020 to start a Phase 1 trial in healthy volunteers with scarring.

  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 and CRL received from the FDA. 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, although the likelihood based on the CRL is high. 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, given Aridol received approval in June 2019. PXS expects launch in 2HCY19 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:

$0.57 valuation: We value PXS using a risk adjusted DCF at $0.57. The valuation is approximately a 153.3% premium to the current share price of $0.225/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 4QCY19 and in Diabetic Retinopathy in 1HCY20. LOXL-2 has successfully completed Phase 1 trials and longer term toxicology studies and PXS is now in discussions to potentially partner it, with conclusion of the partnering process expected before end of CY19.

Strong cash position: PXS' current cash reserves of A$31.1m (along with A$6m in R&D tax rebate expected in 2HCY19) in our view, provides ~22 months 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 A$7.2m. 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 and receive a US$10m milestone from Chiesi for Bronchitol in 2QCY20. 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$31.1m in cash and debt related to finance lease of A$7.2m. A$6m R&D tax rebate is expected in 2HCY19. Although PXS has a high cash balance currently, which should provide ~22 months 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 or in receiving the milestone from Chiesi. There is no guarantee that PXS will be able to secure additional financing if and when required.

Pharmaxis Ltd.
as at 30 July 2019

Recommendation	Buy, Speculative
Price	$0.225
Valuation	$0.57

Table 7 - Financial summary

Pharmaxis Ltd (PXS) — **Share price (A$) $0.225**
As at 30 July 2019 — **Market cap (A$m 88.7**

Profit and Loss

Y/e June 30 (A$m)	2018A	2019E	2020E	2021E	2022E
Product Sales Revenues	6.1	5.7	7.0	10.5	12.6
Other Revenue (commercial)	43.5	0.0	24.4	9.1	0.0
Other Income	0.7	6.5	0.5	0.5	3.5
Total Revenue	**50.2**	**12.2**	**32.0**	**20.2**	**16.1**
EBITDA	**11.5**	**-15.7**	**5.6**	**-6.2**	**-7.7**
Depreciation & Amortisation	-3.1	-2.6	-2.3	-2.1	-1.9
EBIT	**8.4**	**-18.3**	**3.3**	**-8.3**	**-9.6**
Net interest & Other Income/(Expense)	-0.8	-0.7	0.6	0.7	0.5
Pre-tax profit	**7.6**	**-19.0**	**4.0**	**-7.5**	**-9.1**
Tax	0.0	0.0	0.0	0.0	0.0
Net profit (loss) normalised	**7.6**	**-19.0**	**4.0**	**-7.5**	**-9.1**
Abnormal items	-1.2	-1.1	-1.2	-1.3	-1.4
Reported Net profit (loss)	**6.4**	**-20.1**	**2.8**	**-8.8**	**-10.5**

Cashflow

Y/e June 30 (A$m)	2018A	2019E	2020E	2021E	2022E
Reported NPAT	6.4	-20.1	2.8	-8.8	-10.5
Non-cash items	5.6	5.3	3.8	3.7	3.5
Net change in Working capital	0.1	-5.1	6.0	-0.1	-3.1
Operating cashflow	**12.2**	**-19.8**	**12.6**	**-5.2**	**-10.1**
Capex	-0.8	-0.6	-0.8	-0.8	-0.8
Investments	0.0	0.0	0.0	0.0	0.0
Investments in intangible assets	0.0	-0.4	-0.4	-0.4	-0.4
Other investing cash flow	0.0	0.0	0.0	0.0	0.0
Investing cashflow	**-0.9**	**-1.0**	**-1.2**	**-1.2**	**-1.2**
Change in borrowings	-1.5	-1.6	-1.7	-1.7	-1.8
Equity issued	0.0	22.7	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	-0.2	-0.3	-0.4	-0.8	-0.8
Financing cashflow	**-1.8**	**20.8**	**-2.1**	**-2.5**	**-2.5**
Net change in cash	**9.6**	**0.1**	**9.3**	**-9.0**	**-13.8**
Cash at end of period*	31.1	31.1	40.5	31.5	17.7
* Includes effect of exchange rate fluctuations on cash balance					
Free cash flow (op. CF less capex and intangibles)	**11.3**	**-20.8**	**11.4**	**-6.4**	**-11.2**

Balance sheet

Y/e June 30 (A$m)	2018A	2019E	2020E	2021E	2022E
Cash	31.1	31.1	40.5	31.5	17.7
Current receivables	2.4	7.1	1.3	1.4	4.5
Inventories	2.4	2.1	2.2	2.3	2.4
Other current assets	0.1	0.1	0.1	0.1	0.1
Current assets	**36.0**	**40.4**	**44.0**	**35.3**	**24.7**
PPE	12.5	10.3	8.6	7.2	5.9
Non-current receivables	1.2	1.2	1.2	1.2	1.2
Intangible assets	0.4	0.8	1.1	1.4	1.7
Other non-current assets	0.0	0.0	0.0	0.0	0.0
Non-current assets	**14.1**	**12.2**	**10.9**	**9.8**	**8.8**
Total assets	**50.1**	**52.7**	**54.9**	**45.0**	**33.5**
Payables	5.6	4.5	4.6	4.6	4.6
Debt	8.3	7.2	5.9	4.5	3.0
Provisions	1.0	1.4	1.5	1.6	1.7
Financial liabilities (Novaquest financing agreement)	22.8	23.6	23.2	22.4	21.6
Deferred Lease Incentive	1.4	1.1	0.9	0.7	0.4
Other liabilities	0.0	0.0	0.0	0.0	0.0
Total liabilities	**39.0**	**37.9**	**36.2**	**33.8**	**31.3**
Net Assets	**11.1**	**14.8**	**18.8**	**11.2**	**2.2**
Shareholders' equity	344.6	367.3	367.3	367.3	367.3
Reserves	20.7	21.8	22.9	24.2	25.6
Retained earnings/(losses)	-354.2	-374.2	-371.5	-380.3	-390.7
Total shareholders equity	**11.1**	**14.8**	**18.8**	**11.2**	**2.2**

Valuation data

Y/e June 30	2018A	2019E	2020E	2021E	2022E
Net profit -normalised (A$m)	7.6	-19.0	4.0	-7.5	-9.1
EPS - normalised (c)	2.4	-5.1	1.0	-1.9	-2.3
EPS growth (%)	NM	N/A	NM	N/A	N/A
P/E ratio (x)	9.4	N/A	22.4	N/A	N/A
FCFPS (c)	3.5	-5.3	2.9	-1.6	-2.8
Price/FCF (x)	6.4	-4.3	7.8	-13.8	-7.9
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	5.6	-4.1	11.6	-10.5	-8.4
EV/EBIT	7.7	-3.5	19.5	-7.8	-6.8

Share price now (A$)	$0.225
Valuation (A$):	$0.57
Premium (discount) to price	153.3%
Recommendation:	Buy
Risk Rating	Speculative

Profitability ratios

Y/e June 30	2018A	2019E	2020E	2021E	2022E
EBITDA margin (%)	22.9%	N/A	17.5%	N/A	N/A
EBIT margin (%)	16.7%	N/A	10.4%	N/A	N/A
Return on assets (%)	15.2%	-36.0%	7.2%	-16.7%	-27.1%
Return on equity (%)	68.5%	NM	21.1%	NM	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	2018A	2019E	2020E	2021E	2022E
Net debt (cash) (A$m)	-22.8	-24.0	-34.5	-27.0	-14.7
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)	4.4	4.8	5.0	3.9	2.6

Segmentals

Y/e June 30	2018A	2019E	2020E	2021E	2022E
Bronchitol and Aridol					
Product Sales	6.1	5.7	7.0	10.5	12.6
Other revenue (Clinical trial cost reimbursement)	1.3	0.0	11.3	0.0	0.0
Other income	0.0	0.0	0.0	0.0	0.0
Total Revenues	**7.5**	**5.7**	**18.4**	**10.5**	**12.6**
EBITDA	**-3.8**	**-5.0**	**6.2**	**-1.8**	**0.0**
New Drug Development					
Product Sales	0.0	0.0	0.0	0.0	0.0
Other revenue (Milestone+license+royalty)	42.1	0.0	13.0	9.1	0.0
Other income (R&D tax incentive etc.)	0.2	6.0	0.0	0.0	3.0
Total Revenues	**42.3**	**6.0**	**13.0**	**9.1**	**3.0**
EBITDA	**28.8**	**-6.8**	**3.3**	**-0.5**	**-3.7**
Corporate					
Other income	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**
EBITDA	**-13.5**	**-3.9**	**-3.9**	**-3.9**	**-3.9**
Total Company					
Revenues	**50.2**	**12.2**	**32.0**	**20.2**	**16.1**
EBITDA	**11.5**	**-15.7**	**5.6**	**-6.2**	**-7.7**

Interims

Y/e June 30 (A$m)	2H18A	1H19A	2H19E	1H20E	2H20E
Revenue	19.1	2.5	9.7	16.2	15.7
EBITDA	3.7	-9.8	-5.8	4.0	1.5
Depreciation & Amortisation	-1.5	-1.3	-1.3	-1.3	-0.9
EBIT	**2.2**	**-11.1**	**-7.2**	**2.7**	**0.6**
Net interest & Other Expense	-1.1	-0.8	0.1	0.2	0.4
Pre-tax profit	1.1	-11.9	-7.1	2.9	1.0
Tax	0.0	0.0	0.0	0.0	0.0
Net Profit (loss) - normalised	**1.1**	**-11.9**	**-7.1**	**2.9**	**1.0**
Net Profit (loss) - reported	0.5	-12.6	-7.5	2.4	0.4

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.

Research Team

Staff Member	Title/Sector	Phone	@bellpotter.com.au
TS Lim	Head of Research	612 8224 2810	tslim
Industrials			
Steven Anastasiou	Industrials	613 9235 1952	sanastasiou
James Filius	Industrials	613 9235 1612	jfilius
Sam Haddad	Industrials	612 8224 2819	shaddad
Alex McLean	Industrials	612 8224 2886	amclean
Hamish Murray	Industrials	613 9235 1813	hmurray
Chris Savage	Industrials	612 8224 2835	csavage
Jonathan Snape	Industrials	613 9235 1601	jsnape
Damien Williamson	Industrials	613 9235 1958	dwilliamson
Healthcare/Biotech			
John Hester	Healthcare	612 8224 2871	jhester
Tanushree Jain	Healthcare/Biotech	612 8224 2849	tnjain
Financials			
TS Lim	Banks/Regionals	612 8224 2810	tslim
Lafitani Sotiriou	Diversified Financials/Fintech	613 9235 1668	lsotiriou
Resources			
Peter Arden	Resources	613 9235 1833	parden
David Coates	Resources	612 8224 2887	dcoates
Stuart Howe	Resources	613 9235 1856	showe
Associate			
Joseph House	Associate Analyst	+61 3 9235 1624	jhouse

Bell Potter Securities Limited
ABN 25 006 390 7721
Level 29, 101 Collins Street
Melbourne, Victoria, 3000
Telephone +61 3 9256 8700
www.bellpotter.com.au

Bell Potter Securities (HK) Limited
Room 1701, 17/F
Posperity Tower, 39 Queens Road
Central, Hong Kong, 0000
Telephone +852 3750 8400

Bell Potter Securities (US) LLC
Floor 39
444 Madison Avenue, New York
NY 10022, U.S.A
Telephone +1 917 819 1410

Bell Potter Securities (UK) Limited
16 Berkeley Street
London, England
W1J 8DZ, United Kingdom
Telephone +44 7734 2929