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Pharmaxis Ltd. (PXS)

Good clinical and partnering progress on LOXL-2 asset

Recommendation
Buy (unchanged)
Price
\$0.275
Valuation
\$0.56 (unchanged)
Risk
Speculative

GICS Sector
Pharmaceuticals & Biotechnology

Expected Return

Capital growth	103.6%
Dividend yield	0.0%
Total expected return	103.6%

Company Data & Ratios

Enterprise value	\$53.4m
Market cap	\$87.9m
Issued capital	319.7m
Free float	98.1%
Avg. daily val. (52wk)	\$97,184
12 month price range	\$0.227- \$0.315

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.26	0.27	0.28
Absolute (%)	5.88	0.00	-1.82
Rel market (%)	6.65	-2.21	-8.48

Absolute Price



SOURCE: IRESS

1H18 result well ahead of our forecast

Underlying NPAT of \$6.5m (up 162% y/y) was well ahead of our forecast of \$5.2m and was driven by higher revenue and lower opex. Revenue of \$31.1m (up 378% y/y) was 2% ahead of our forecast of \$30.5m and was driven by higher bronchitol sales and other income. The significant increase in revenues over pcp was driven by the A\$26.9m milestone payment from partner Boehringer Ingelheim (BI) received in Sep'17. Opex were 3% lower than our forecast, driven by lower clinical costs, offset by higher drug development expense related to LOX and SSAO/MPO assets. Cash of \$43.3m provides ~2 years runway, ahead of boost expected through a licensing deal for LOXL-2 asset in 2HCY18.

Good clinical and partnering progress on LOXL-2 asset

In its quarterly update, PXS reported that it recently met up with 8 of 12 companies interested in the LOXL-2 program in US. Encouragingly, PXS also confirmed that it has entered 'confidential due diligence' with several of these. This highlights the serious interest from these parties and also their willingness to allocate greater resources to the process. PXS is following a similar process of partnering as it did previously for its SSAO/VAP-1 inhibitor ahead of deal with BI in 2015. Hence, we expect a deal for LOXL-2 should follow close behind results from the ongoing Phase 1 trials expected in mid-CY18, if not earlier. Furthermore, PXS reported that early data from these Phase 1 trials have provided evidence of target engagement through significant enzyme inhibition, which improves the likelihood of success of these trials.

Retain Buy (speculative) and Valuation of \$0.56

Revisions to our model have resulted in a decrease in our NPAT forecasts for FY18 by -10%, driven by the increase in development costs for the LOX and SSAO/MPO assets, partially offset by reduced clinical trial costs. Our net loss forecasts for FY19 and FY20 have decreased by -5% and -6% respectively, driven by higher risk-adjusted LOXL-2 related upfront and milestone revenues following lift of probability of success assigned to it to 17.5% (vs. 14.5%), partially offset by reduced bronchitol sales. Our valuation for PXS remains unchanged at A\$0.56/sh. We retain Buy (Spec).

Earnings Forecast

Year end 30th June	2016A	2017A	2018E	2019E	2020E
Revenue (A\$m)	17.8	17.3	50.2	17.2	15.0
EBITDA (A\$m)	-14.8	-15.2	11.1	-7.3	-5.2
NPAT (reported) (A\$m)	-16.5	-18.3	7.1	-11.6	-9.7
NPAT (normalised) (A\$m)	-15.3	-17.4	8.3	-10.4	-8.5
EPS (reported) (cps)	-5.2	-5.7	2.2	-3.6	-3.0
EPS (adjusted) (cps)	-4.8	-5.5	2.6	-3.2	-2.7
EPS growth (%)	N/A	N/A	NM	N/A	N/A
PER (x)	N/A	N/A	10.6	N/A	N/A
EV/EBITDA (x)	-3.6	-3.5	4.8	-7.3	-10.2
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 (%)	-73.0%	-494.3%	70.2%	NM	121.3%

NOTE: REVENUE INCLUDES R&D TAX INCENTIVE, MILESTONES FROM BI DEAL AND FY19 AND FY20 REVENUE INCLUDES RISK ADJUSTED UPFRONT AND MILESTONES FROM LICENSING DEAL FOR LOXL-2. SOURCE: BELL POTTER SECURITIES ESTIMATES

1H18 – Result Summary

A summary of the reported 1H18 result based on income statement summary as per PXS' quarterly update is shown in the Table below:

	Result vs PCP			Result vs Forecast		Comments
	1H17A	1H18A	% change	1H18E	Variance (%)	
Revenues	6.5	31.1	378%	30.5	2%	2% beat in revenue, driven by higher bronchitol sales and other income (incl. R&D tax rebate)
Total operating costs	14.9	23.3	56%	24.1	-3%	Opex 3% lower than our forecast driven by lower clinical trial costs for Bronchitol, partially offset by higher drug development expense on PXS' pipeline assets
EBITDA	-8.4	7.8	192%	6.4	21%	EBITDA beat driven by higher revenue and lower opex
Depreciation and Amortisation	-1.5	-1.6	3%	-1.7	-6%	Lower depreciation expense than forecasted
EBIT	-10.0	6.2	162%	4.8	31%	EBIT beat with variance higher than EBITDA line driven by lower D&A
Net Interest Income/(expense)	0.1	0.0	-154%	-0.1	-32%	Higher interest income
Other Income/(expense)	-0.7	0.3	151%	0.5	-28%	Lower Fx gain of \$0.3m
Pretax Income (Loss)	-10.6	6.5	162%	5.2	26%	
Net Income (Loss) after tax - normalised	-10.6	6.5	162%	5.2	26%	NPAT beat with decrease in variance from EBIT due to lower Fx gain
Diluted EPS/Share (cents)	-3.32	2.04	161%	1.62	26%	
Reported Net Income (loss)	-11.0	5.9	154%	4.7	27%	Reported NPAT higher than our forecasts. Includes share based compensation of \$0.61m
Reported Diluted EPS/sh (cents)	-3.47	1.85	153%	1.46	27%	

NOTE: 1H18E FIGURES HAVE BEEN ADJUSTED FOR REVISED TREATMENT OF PAYMENT TO SYNAIIRGEN FROM ABNORMALS TO OPERATING COSTS CONSISTENT WITH TREATMENT BY THE COMPANY. 1H18A EPS/SHARE NUMBERS ARE ESTIMATES SUBJECT TO CHANGES WHEN COMPANY FILES ITS AUDITED FINANCIALS LATER IN FEB'18.

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

The key highlights from the result were:

- 2% beat in revenue:** Total revenue of \$31.1m (up 378% y/y) was 2% ahead of our forecast of \$30.5m and was driven by higher bronchitol sales as well as higher other income (which included a \$0.16m higher R&D tax accrual for FY17). Overall Bronchitol and Aridol product sales of \$2.5m in 1HFY18 grew 45% over pcp, with increase in bronchitol driven by higher sales to Chiesi for Germany, Italy and UK. The significant increase in revenues over pcp was mainly driven by the A\$26.9m milestone payment from partner Boehringer Ingelheim (BI) received in Sep'17 on first patient being dosed in the Phase 2A NASH trial with BI_1467335.
- Operating expenses were 3% lower than expected:** Total opex of \$23.3m (up 56% y/y) were 3% lower than our forecast of \$24.1m. This was driven by lower clinical costs related to the US Bronchitol trial (BPe \$1.4m vs. reported \$0.2m) due to an unexpected credit back from the CRO running that trial. This was offset by higher drug development expense of \$3.4m, related to LOX and SSAO/MPO assets. PXS commenced the toxicity studies for both these assets in 2QFY18 ahead of our expectations. The increase over pcp was driven by the one-off \$9.6m payment made to Synairgen pursuant to the change in collaboration terms for the LOXL-2 program which gave PXS greater commercial control and higher revenue share from a future deal.
- EBITDA ahead of our forecast:** EBITDA of \$7.8m (up 192% y/y) was well ahead of our forecast of \$6.4m and was driven by both higher revenue and lower opex. The profit in 1H18 vs. loss in pcp was driven by the milestone received from BI in Sep'17.
- Underlying and Reported NPAT ahead:** Underlying NPAT of \$6.5m (up 162% y/y) was well ahead of our forecast of \$5.2m and was driven by both higher revenue and lower operating costs. The beat at the NPAT line was higher than the EBITDA line due to lower than expected D&A expense and higher interest income than our forecasts, partially offset by lower Fx gain. Reported NPAT was \$5.9m (including \$0.61m share based compensation expense), which was ahead of our forecasts.
- Strong cash position:** PXS' current cash position on a proforma basis is A\$43.3m (including \$25m cash at end of Dec'17, \$15m milestone payment received from BI in Jan'18 and \$3.26m R&D tax rebate received in Jan'18). This should provide ~2 years cash runway ahead of further boost expected through a licensing deal for LOXL-2 asset in 2HCY18.

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

- Consistent with the company, we also now treat the payment of \$9.58m to Synairgen for change in LOXL-2 collaboration terms as an operating costs part of the corporate segment vs. our previous allocation of it to unallocated cost as a one-off item.
- We have slightly reduced Bronchitol sales from Russia starting FY18 and onwards as we expect the ongoing national reimbursement process to take some more time than we previously expected. For FY18, this was mostly offset by higher other income in 1H18.
- We have increased the probability of success assigned to LOXL-2 from 14.5% to 17.5%, following update by company that they have seen early data from the ongoing Phase 1 trials indicating target engagement i.e. significant LOXL-2 enzyme inhibition. The subsequent increase in our risk adjusted upfront and milestone revenue from the LOXL-2 deal for FY19 and FY20, have offset our reduced Bronchitol sales forecast.
- We have increased our drug development costs for FY18 significantly based on the higher than expected 1H18 number. Given that PXS has initiated preclinical toxicology studies for the pipeline assets LOX and SSAO/MPO assets in 2QFY18, we expect the bulk of the expenditure related to these in 2HFY18. PXS has already spent \$1.6m on these programs in 1HFY18. We have also slightly increased the drug development expense related to LOXL-2 for FY18, given the slightly higher spend of \$1.6m on it in 1H18.
- We have reduced our clinical trial costs for FY18 based on the lower clinical cost related to Bronchitol in 1H18. We have also moved some of the clinical cost for LOXL-2 from 2HFY18 to 1HFY19 (~\$0.5m), given that the trial is expected to complete mid-year.

**We value PXS at
\$0.56/sh**

The net result is a decrease in our NPAT forecasts for FY18 by -10% driven by the increase in development costs for the LOX and SSAO/MPO assets, partially offset by reduced clinical trial costs. Our net loss forecasts for FY19 and FY20 have decreased by -5% and -6% respectively, driven by higher risk-adjusted LOXL-2 related upfront and milestone revenues following lift of probability of success assigned to it to 17.5% (vs. 14.5%), partially offset by reduced bronchitol sales. Our valuation for PXS remains unchanged at A\$0.56/sh. **We retain our Buy (Speculative) recommendation.**

Table 2 - Key Changes to our FY18-20 Forecasts

	FY2018E			FY2019E			FY2020E		
	Old	New	Change (%)	Old	New	Change (%)	Old	New	Change (%)
Revenues	50.3	50.2	0%	15.8	17.2	9%	14.1	15.0	6%
Interest Income	0.6	0.6	1%	0.6	0.6	4%	0.4	0.4	10%
Operating Costs	38.4	39.1	2%	23.6	24.4	3%	19.9	20.2	2%
EBITDA	11.8	11.1	-6%	-7.8	-7.3	-7%	-5.8	-5.2	-9%
EBIT	8.7	7.9	-9%	-11.0	-10.5	-5%	-9.0	-8.5	-6%
NPAT (adjusted)	9.2	8.3	-10%	-10.9	-10.4	-5%	-9.1	-8.5	-6%
Adjusted Diluted EPS	2.9	2.6	-10%	-3.4	-3.2	-5%	-2.8	-2.7	-6%
NPAT (reported)	8.2	7.1	-13%	-11.9	-11.6	-3%	-10.1	-9.7	-4%
Reported Diluted EPS	2.6	2.2	-13%	-3.7	-3.6	-3%	-3.2	-3.0	-4%

NOTE: FY2018E FIGURES HAVE BEEN ADJUSTED FOR REVISED TREATMENT OF PAYMENT TO SYNAIRGEN FROM ABNORMALS TO OPERATING COSTS CONSISTENT WITH TREATMENT BY THE COMPANY. 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)	150.8
Add: Reported Cash incl BI milestone and R&D tax rebate (AUDm)	43.3
Less: Current Debt	8.8
Equity value (AUDm)	185.3
Total diluted shares (million)	333.5
Value per share (AUD)	\$0.56
Current Share price (AUD)	\$0.28
Expected Capital Growth	103.6%

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	(\$14)	-\$0.04	-7.4%	Aridol - Canada (60%)	Marketed (Ex -US and Canada)
New Drug Development	\$204	\$0.61	110.1%	BI_1467335 (NASH, DR - 23.5%), LOXL-2 (NASH -17.5%)	BI_1467335 (Phase 2A) and LOXL-2 (Phase 1)
Corporate/Non-Allocated	(\$39)	-\$0.12	-21.3%	NA	NA
Reported Cash	\$43	\$0.13	23.4%	NA	NA
Reported Debt	(\$9)	-\$0.03	-4.7%	NA	NA
Equity Value	\$185.3	\$0.56	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	2026	5% (US), (3.5% ROW)	\$1,962	23.5%
BI_1467335	Diabetic Retinopathy (DR)	Phase 2A	Boehringer Ingelheim	2026	10.0%	\$813	23.5%
LOXL-2	NASH - F3/F4 fibrosis stage	Phase 1	Will look to partner	2028	5% (US), (3.5% ROW)	\$1,448	17.5%

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	2019	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 trial with positive results and subsequent advancement of BI_1467335 into Phase 2B trials (BPe 1HCY19) 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 17.5% probability of success (of reaching the market) to LOXL-2 in NASH, given that it's currently in a Phase 1 trial with some early data indicating target engagement. We envisage that completion of Phase 1 with positive

results and subsequent advancement of LOXL-2 into Phase 2A trials will allow us to assign a higher probability of success and therefore will lead to material upgrades in our numbers.

- **Timing assumption for licensing deal for LOXL-2:** We currently assume a licensing deal for LOXL-2 in 2H CY18, on completion of its Phase 1 trial. If it gets licensed prior to our estimates, it will be an upside to our valuation.
- **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 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 clinical data from LOXL-2 we are conservative in our assumptions at this stage including our assumptions for the deal size. Positive Phase 1 data and interest by multiple pharma parties could lead to a deal 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' other early stage assets namely SSAO/MPO inhibitor and LOX inhibitor. Formal toxicology studies for these two assets have now commenced, with the view to moving to the clinic (Phase 1 human trials) in FY19.

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. PXS is currently focused on fully profiling the drugs under development and identifying the appropriate indications to pursue.

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 (likely oral

formulation). PXS is currently focused on formulation for the scarring application and is also exploring other severe fibrotic indications where this may also have application.

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 the clinic in future is likely to be a source of upside to our valuation.

- **We model limited markets for Bronchitol and do not model US market as yet:** For Bronchitol, we model the existing markets of Australia, Western Europe including Italy, Eastern Europe and Russia. We do not model the US market for Bronchitol as yet. PXS' US partner Chiesi is responsible for completing and finalising a New Drug Application (NDA) with the US FDA and subsequent commercialisation of it. 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. FDA approval and launch of Bronchitol in the US therefore will be an upside to our valuation for PXS.
- **We model limited markets for Aridol and do not model US market as yet:** For Aridol, we model the existing markets of Australia, Europe and South Korea. We also model revenue from Canada (assigning it a 60% probability of success), given Aridol is not approved in Canada as yet, and filing for approval is expected in 1H CY8. We note we assume a FY20 launch in Canada, however PXS believes it might launch earlier than that, in which case it may be an upside to our estimates. We do not model the US market for Aridol as yet. PXS has appointed a distributor for the US and plans to launch subsequent to FDA approval of its Sydney manufacturing facility in FY19.
- **Limited contribution from Bronchitol and Aridol segment in our valuation:** We note that PXS believes the Bronchitol and Aridol segment could transition to profitability over the next 1-2 years, irrespective of any US approval. On our estimates we expect the EBITDA loss from the segment to significantly come down from the FY16/FY17 levels starting FY18, however we do not see the segment becoming profitable out to several more years, continuing instead to make a modest loss, albeit declining each year as product sales pick up. 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 on obtaining 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:

\$0.56 valuation: We value PXS using a risk adjusted DCF at \$0.56. The valuation is approximately a 103.6% premium to the current share price of \$0.275/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 both phase 2A trials for the SSAO/VAP-1 drug partnered with BI are expected in 2HCY18. LOXL-2 is in Phase 1, with results due in mid-CY18, with a multi-million dollar licensing deal expected in 2HCY18.

Strong cash position: PXS' current cash position on a proforma basis is A\$43.3m (including \$25m cash at end of Dec'17, \$15m milestone payment received from BI in Jan'18 and \$3.26m R&D tax rebate received in Jan'18). In our view, this provides at least 2 years cash runway. PXS is unlikely to require any capital raisings in the medium term and 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 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 LOXL-2 fail to reach their endpoints, which would in turn impact its 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 may have sentiment impact, although won't affect our valuation:** The revenue driver in our model for PXS is its 'New Drug Development segment' which includes the partnered BI_1467335 drug for the indication NASH and Diabetic Retinopathy and its currently unpartnered asset LOXL-2 also targeting NASH and other fibrotic indications. While we look at Bronchitol and Aridol, PXS' currently marketed products as non-core assets and attribute minimal value to it, with no value in our model for Bronchitol's potential US approval and launch, we believe PXS is vulnerable to partner Chiesi's success/failure in obtaining US regulatory approval for Bronchitol, which could impact sentiment around the company.
- **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\$43.3m in proforma cash and debt related to finance lease of A\$8.8m, amounting to a net cash position of A\$34.5m. Although PXS has a high cash balance currently, which should provide cash runway into CY20, 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 7 - Financial summary

Pharmaxis Ltd (PXS)						Share price (A\$) \$0.275															
As at 1 February 2018						Market cap (A\$) 87.9															
Profit and Loss						Valuation data															
Y/e June 30 (A\$m)	2016A	2017A	2018E	2019E	2020E	Y/e June 30	2016A	2017A	2018E	2019E	2020E										
Product Sales Revenues	6.1	4.8	6.2	6.9	7.4	Net profit - normalised (A\$m)	-15.3	-17.4	8.3	-10.4	-8.5										
Other Revenue (commercial)	8.2	8.6	43.3	9.7	7.0	EPS - normalised (c)	-4.8	-5.5	2.6	-3.2	-2.7										
Other Income	3.5	3.9	0.8	0.6	0.6	EPS growth (%)	N/A	N/A	NM	N/A	N/A										
Total Revenue	17.8	17.3	50.2	17.2	15.0	P/E ratio (x)	N/A	N/A	10.6	N/A	N/A										
EBITDA	-14.8	-15.2	11.1	-7.3	-5.2	FCFPS (c)	-4.2	-5.0	3.4	-2.5	-1.9										
Depreciation & Amortisation	-3.0	-3.1	-3.1	-3.2	-3.2	Price/FCF (x)	-6.5	-5.5	8.1	-11.2	-14.6										
EBIT	-17.9	-18.3	7.9	-10.5	-8.5	DPS (c)	0.0	0.0	0.0	0.0	0.0										
Net interest & Other Income/(Expense)	2.6	0.9	0.4	0.1	0.0	Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%										
Pre-tax profit	-15.3	-17.4	8.3	-10.4	-8.5	Franking (%)	N/A	N/A	N/A	N/A	N/A										
Tax	0.0	0.0	0.0	0.0	0.0	EV/EBITDA	-3.6	-3.5	4.8	-7.3	-10.2										
Net profit (loss) normalised	-15.3	-17.4	8.3	-10.4	-8.5	EV/EBIT	-3.0	-2.9	6.7	-5.1	-6.3										
Abnormal items	-1.2	-0.9	-1.2	-1.2	-1.2																
Reported Net profit (loss)	-16.5	-18.3	7.1	-11.6	-9.7																
Cashflow						<table border="1"> <tr> <td>Share price now (A\$)</td> <td>\$0.275</td> </tr> <tr> <td>Valuation (A\$):</td> <td>\$0.56</td> </tr> <tr> <td>Premium (discount) to price</td> <td>103.6%</td> </tr> <tr> <td>Recommendation:</td> <td>Buy</td> </tr> <tr> <td>Risk Rating</td> <td>Speculative</td> </tr> </table>						Share price now (A\$)	\$0.275	Valuation (A\$):	\$0.56	Premium (discount) to price	103.6%	Recommendation:	Buy	Risk Rating	Speculative
Share price now (A\$)	\$0.275																				
Valuation (A\$):	\$0.56																				
Premium (discount) to price	103.6%																				
Recommendation:	Buy																				
Risk Rating	Speculative																				
Y/e June 30 (A\$m)	2016A	2017A	2018E	2019E	2020E	Profitability ratios															
Reported NPAT	-16.5	-18.3	7.1	-11.6	-9.7	Y/e June 30	2016A	2017A	2018E	2019E	2020E										
Non-cash items	2.6	3.7	4.6	4.9	4.8	EBITDA margin (%)	N/A	N/A	22.1%	N/A	N/A										
Net change in Working capital	1.8	-0.6	0.3	0.0	0.0	EBIT margin (%)	N/A	N/A	15.8%	N/A	N/A										
Operating cashflow	-12.0	-15.3	12.0	-6.7	-4.9	Return on assets (%)	-23.3%	-38.3%	16.9%	-27.7%	-31.2%										
Capex	-1.4	-0.3	-0.8	-0.8	-0.8	Return on equity (%)	-73.0%	-494.3%	70.2%	NM	121.3%										
Investments	0.0	0.0	0.0	0.0	0.0	Dividend cover (x)	N/A	N/A	N/A	N/A	N/A										
Investments in intangible assets	0.0	-0.4	-0.4	-0.4	-0.4	Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%										
Other investing cash flow	0.0	0.0	0.0	0.0	0.0	Liquidity and leverage ratios															
Investing cashflow	-1.4	-0.7	-1.1	-1.2	-1.2	Y/e June 30	2016A	2017A	2018E	2019E	2020E										
Change in borrowings	-1.4	-1.5	-1.6	-1.6	-1.7	Net debt (cash) (A\$m)	-29.1	-12.3	-22.2	-13.5	-6.7										
Equity issued	0.0	0.0	0.0	0.0	0.0	Net debt/equity (%)	N/A	N/A	N/A	N/A	N/A										
Dividends paid	0.0	0.0	0.0	0.0	0.0	Net interest cover (x)	N/A	N/A	N/A	N/A	N/A										
Other financing cash flow	-0.3	-0.2	-0.4	-0.4	-0.4	Current ratio (x)	4.2	2.7	4.3	3.0	2.0										
Financing cashflow	-1.7	-1.7	-1.9	-2.0	-2.0	Segmentals															
Net change in cash	-15.1	-17.7	9.0	-9.8	-8.0	Y/e June 30	2016A	2017A	2018E	2019E	2020E										
Cash at end of period*	39.2	21.5	30.5	20.7	12.6	Bronchitol and Aridol															
<small>* Includes effect of exchange rate fluctuations on cash balance</small>						Product Sales	6.1	4.8	6.2	6.9	7.4										
Free cash flow (op. CF less capex and intangibles)	-13.4	-16.0	10.9	-7.8	-6.0	Other revenue (Clinical trial cost reimbursement)	8.2	8.6	1.2	0.0	0.0										
Balance sheet						Other income	0.6	0.1	0.2	0.0	0.0										
Y/e June 30 (A\$m)	2016A	2017A	2018E	2019E	2020E	Total Revenues	14.9	13.5	7.5	6.9	7.4										
Cash	39.2	21.5	30.5	20.7	12.6	EBITDA	-8.2	-7.1	-2.7	-3.2	-2.9										
Current receivables	4.8	4.4	1.4	1.5	1.6	New Drug Development															
Inventories	2.2	2.6	2.7	2.8	2.9	Product Sales	0.0	0.0	0.0	0.0	0.0										
Other current assets	0.1	0.1	0.1	0.1	0.1	Other revenue (Milestone+license+royalty)	0.0	0.0	42.1	9.7	7.0										
Current assets	46.4	28.6	34.7	25.1	17.3	Other income (R&D tax incentive etc.)	2.6	3.4	0.2	0.2	0.2										
PPE	17.8	14.9	12.3	9.7	7.0	Total Revenues	2.6	3.4	42.2	9.8	7.1										
Non-current receivables	1.3	1.4	1.5	1.5	1.5	EBITDA	-2.6	-4.1	27.4	0.1	1.8										
Intangible assets	0.1	0.5	0.8	1.2	1.5	Corporate															
Other non-current assets	0.0	0.0	0.0	0.0	0.0	Other income	0.3	0.3	0.5	0.5	0.5										
Non-current assets	19.2	16.8	14.6	12.4	10.0	EBITDA	-4.0	-4.0	-13.6	-4.2	-4.2										
Total assets	65.7	45.4	49.3	37.5	27.3	Total Company															
Payables	5.0	6.8	5.3	5.4	5.5	Revenues	17.8	17.3	50.2	17.2	15.0										
Debt	10.1	9.3	8.3	7.1	5.9	EBITDA	-14.8	-15.2	11.1	-7.3	-5.2										
Provisions	0.8	0.9	1.0	1.1	1.2	Interims															
Financial liabilities (Novaquest financing agreement)	23.2	22.1	21.5	21.1	20.8	Y/e June 30 (A\$m)	2H16A	1H17A	2H17A	1H18A	2H18E										
Deferred Lease Incentive	1.9	1.6	1.4	1.1	0.9	Revenue	9.1	6.5	10.8	31.1	19.1										
Other liabilities	3.7	1.1	0.0	0.0	0.0	EBITDA	-6.8	-8.4	-6.8	7.8	3.3										
Total liabilities	44.7	41.9	37.5	36.0	34.3	Depreciation & Amortisation	-1.5	-1.5	-1.5	-1.6	-1.6										
Net Assets	20.9	3.5	11.9	1.5	-7.0	EBIT	-8.3	-10.0	-8.3	6.2	1.7										
Shareholders' equity	344.6	344.6	344.6	344.6	344.6	Net interest & Other Expense	3.6	-0.6	1.5	0.3	0.1										
Reserves	18.6	19.5	20.7	21.9	23.1	Pre-tax profit	-4.7	-10.6	-6.8	6.5	1.8										
Retained earnings/(losses)	-342.3	-360.6	-353.5	-365.0	-374.7	Tax	0.0	0.0	0.0	0.0	0.0										
Total shareholders equity	20.9	3.5	11.9	1.5	-7.0	Net Profit (loss) - normalised	-4.7	-10.6	-6.8	6.5	1.8										
						Net Profit (loss) - reported	-5.3	-11.0	-7.3	5.9	1.2										

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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