BELL POTTER

Speculative
See Key Risks on Page 12 & Biotechnology Risk Warning on Page 14
Speculative securities may not be suitable for Retail clients

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Analyst
Tanushree Jain 612 8224 2849

Authorisation
John Hester 612 8224 2871

Pharmaxis Ltd. (PXS)

1HFY19 - Strong cash position and approaching key inflexion points

Recommendation
Buy (unchanged)
Price
$0.26
Valuation
$0.47 (previously $0.52)
Risk
Speculative

GICS Sector
Pharmaceuticals & Biotechnology

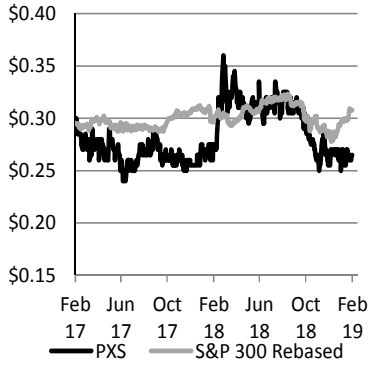
Expected Return	
Capital growth	**80.8%**
Dividend yield	**0.0%**
Total expected return	**80.8%**

Company Data & Ratios	
Enterprise value	**$68.2m**
Market cap	**$102.5m**
Issued capital	**394.3m**
Free float	**98.7%**
Avg. daily val. (52wk)	**$59,244**
12 month price range	**$0.2475- $0.37**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.27	0.27	0.27
Absolute (%)	0.00	0.00	0.00
Rel market (%)	-4.95	-2.17	-3.56

Absolute Price



SOURCE: IRESS

Key highlights from 1HFY19

PXS' LOXL-2 asset is one step closer to partnering. PXS strengthened its balance sheet with a $24m capital raise which should assist its partnering negotiations. Other pipeline asset LOX is expected to move into the clinic this quarter. Results from Phase 2A NASH trial for partnered asset with Boehringer Ingelheim (BI) is expected in 1HCY19 and will be a key catalyst, while the results from the Phase 2A DR trial is delayed to 1HCY20. Sales for Aridol were up in the half driven by the US where it was relaunched in Dec'18 while sales for Bronchitol were down over pcp due to no order from partner Chiesi for Western Europe in the half. Bronchitol obtained national reimbursement in Russia and PXS' US partner Chiesi resubmitted NDA for approval to FDA in the half. Net cash position of $34.3m provides ~2 years runway, ahead of boost expected through a licensing deal for LOXL-2 program.

LOXL-2 program targeted for partnering in 1HCY19

Successful completion of Phase 1 trials with both the LOXL-2 assets and 3-month toxicology studies have now made them Phase 2 ready. PXS is already engaged with multiple companies in discussions around partnering, with several of them well advanced in their confidential due diligence. With the clinical data and the expanded pre-clinical data package in hand, PXS is now well equipped to move into serious partnering negotiations. We expect a deal for LOXL-2 to be finalised in 1HCY19, in line with the targeted timeline announced by PXS management.

Valuation reduced to $0.47, Retain Buy (speculative)

Revisions to our model have resulted in an increase in our Net loss forecasts for FY19 by 7% and for FY20 by 34%, driven by higher opex, partially offset by an increase in our revenue forecasts (driven by higher risk-adjusted LOXL-2 related upfront and milestone following lift of probability of success to 22.0% vs. 20.0%). Our valuation for PXS has reduced to $0.47/sh (was $0.52/sh), driven primarily by the dilutive effect of the recent capital raising, near term earning changes and longer term impact of shift in launch and approval timelines for PXS/BI drug BI_1467335 for Diabetic Retinopathy and for LOXL-2 asset for NASH. We retain Buy (Spec).

Earnings Forecast

Year end 30th June	2017A	2018A	2019E	2020E	2021E
Revenue (A$m)	17.3	50.2	19.1	16.6	8.6
EBITDA (A$m)	-15.2	11.5	-6.8	-9.1	-13.3
NPAT (reported) (A$m)	-18.3	6.4	-11.7	-12.9	-17.4
NPAT (normalised) (A$m)	-17.4	7.6	-10.4	-11.6	-16.1
EPS (reported) (cps)	-5.7	2.0	-3.1	-3.3	-4.4
EPS (adjusted) (cps)	-5.5	2.4	-2.8	-2.9	-4.1
EPS growth (%)	N/A	NM	N/A	N/A	N/A
PER (x)	N/A	10.9	N/A	N/A	N/A
EV/EBITDA (x)	-4.5	5.9	-10.0	-7.5	-5.1
Dividend (¢ps)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
ROE (%)	-494.3%	68.5%	-44.5%	NM	372.5%

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

DISCLOSURE: BELL POTTER SECURITIES ACTED AS JOINT LEAD MANAGER IN THE AUGUST 2018 PLACEMENT AND RECEIVED FEES FOR THAT SERVICE.

1HFY19– Key highlights

Key operational highlights for 1HFY19 are as follows:

- **PXS raised $24m via placement of 73.9m shares @$0.325/sh.** The placement was done at a small premium of 3.1% to the last close before the placement. This was its first capital raise since 2011 and not only did it strengthen the company's balance sheet but also strengthened its register with well-regarded specialist investors such as Arix Bioscience. It also saw Mr. Edward Rayner (investment director at Arix Bioscience) join the PXS Board as a NED (non-executive director). We believe the capital raise was timely and should assist the company in its partnering negotiations on the LOXL-2 program and to accelerate the development of its other pipeline assets.
- **PXS reported positive results from Phase 1 trials for both of its LOXL-2 assets.** There were no dose limiting toxicities (DLTs) or safety concerns observed at any of the dose levels tested across both the stages in each of the two trials. This was a 'first-in-human' study and as such we are highly encouraged with the establishment of a clean safety profile for both the LOXL-2 assets, which considerably de-risks the LOXL-2 program. Importantly, PXS also reported that both the drugs have achieved significant (over 80% for one compound and 85% for the other) and long lasting (over 24 hours) inhibition of LOXL-2 that is dose dependent. We are highly encouraged by this dose dependent, significant and long-lasting inhibition of LOXL-2 enzyme, which provides compelling evidence of target engagement and in our view, positions PXS as having the best-in-class LOXL-2 asset, which should enhance its partnering prospects.
- **PXs successfully cleared 3-month (~13 weeks) toxicology studies for the LOXL-2 assets for both compounds in two different animal species.** This expanded its pre-clinical package, further de-risked the program and made it Phase 2 ready for a potential partner.
- **PXS is targeting partnering the LOXL-2 program in 1HCY19.** Given, the LOXL-2 asset is one of the very few pure anti-fibrotic mechanism in clinical development, partnering interest for the asset is high. Several companies are conducting confidential due diligence on the program and are in process of completing their scientific review, following which PXS will move into commercial partnering discussions including terms, deal structure etc.
- **PXS also progressed its early stage pipeline behind its LOXL-2 program.** With its LOX inhibitor program, PXS 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). In 1HFY19, its LOX inhibitor (oral formulation), successfully completed pre-clinical toxicology studies (and has shown promise in both myelofibrosis and pancreatic cancer in vivo models) and is now ready to move into the clinic. PXS intends to move into a Phase 1 trial in healthy volunteers with its LOX oral asset in 1QCY19, for which an ethics submission has already been made. Preclinical development is also continuing for the topical asset.
- **Boehringer Ingelheim updated timelines for completion of the Phase 2A trial ongoing for BI_1467335 for Diabetic Retinopathy (DR).** There is expected to be ~8 month delay in completing the trial due to slower than expected site initiation and recruitment. Results from the DR trial are now expected in 1HCY20 (vs. 2QCY19). This has moved our estimated timelines for receipt of milestones, approval and launch of this drug for the DR indication. We understand that BI is adding additional sites in countries with good recruitment rates to enable timely completion of the trial now.

- **Aridol was relaunched in the US in December 2018,** following approval by the US FDA of PXS' manufacturing facility in Sydney, which will be used to supply product to the US market. Methapharm is PXS' exclusive distributor in the US and first sales to them for the US were $0.7m in 2QFY19. We expect Aridol sales to increase moving forward with the addition of the US market.
- For Bronchitol, PXS' US partner Chiesi is responsible for commercialisation in the US. **Chiesi has resubmitted a New Drug Application (NDA) with the US FDA for Bronchitol in Dec' 2018.** 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. PXS expects the FDA review process to take between 6-12 months to conclude. We do not model the US market for Bronchitol as yet.
- **PXS also gained national reimbursement for Bronchitol in Russia.** The drug has now been added to Russia's Essential Drugs list (effective 1st Jan, 2019).

1H19 – Result Summary

A summary of the reported 1H19 result based on income statement summary as per PXS' 1H19 report is shown in the Table below:

Table 1 – 1H19 result summary

	Result vs PCP			Comments
	1H18A	1H19A	% change	
Revenues	**31.1**	**2.5**	**-92%**	Product sales were ~9% below pcp. PCP had BI milestone payment and R&D tax incentive with nil in this half
Total operating costs	**23.3**	**12.3**	**-47%**	Opex lower than pcp driven by lower clinical trials and drug development cost and pcp had one off expense of $9.6m related to change in Synairgen collaboration agreement
EBITDA	**7.8**	**-9.8**	**-226%**	**EBITDA loss vs. profit in pcp driven by lower revenue partially offset by lower opex**
Depreciation and Amortisation	-1.6	-1.3	-17%	Depreciation expense lower than pcp
EBIT	**6.2**	**-11.1**	-278%	
Net Interest Income/(expense)	0.0	0.2	504%	Net Interest income higher due to higher cash balance following capital raise
Other Income/(expense)	0.3	-1.0	-393%	Fx loss of $1m vs. gain in pcp of $0.3m
Pretax Income (Loss)	6.5	-11.9	-283%	
Net Income (Loss) after tax - normalised	**6.5**	**-11.9**	**-283%**	**NPAT loss with increase in variance from EBIT due to Fx loss**
Diluted EPS/Share (cents)	2.02	-3.18	-257%	
Reported Net Income (loss)	**5.9**	**-12.6**	**-313%**	Reported NPAT includes share based compensation of $0.7m vs. $0.6m in pcp
Reported Diluted EPS/sh (cents)	1.84	-3.36	-283%	

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

The key highlights from the result were:

- **Sales for Bronchitol in 1HFY19 of $0.6m were significantly below pcp ($1.5m) driven primarily by weak Western Europe sales as there was no order from PXS' partner Chiesi in the half.** Low Western Europe sales were partially offset by strong growth in Australia over pcp, as a result of the widened government reimbursement. There was also no order from Russia in this half. Given the recent achievement of national reimbursement in Russia, the company expects an order in 3QFY19. The company also expects to receive an order from Chiesi for Western Europe in 3QFY19.
- **Sales of Aridol of $1.6m in 1HFY19 significantly increased over pcp ($1m) due to first order of $0.7m for the US market in 2QFY19,** partially offset by lower sales to South Korea. Sales in both Australia and EU markets showed slight increases as expected.
- **We note that overall the increase in Aridol sales was offset by reduced Bronchitol sales in the half, with the total segment sales falling modestly below pcp ($2.2m vs. $2.5m in pcp).** We expect this trend to continue in 2HFY19, leading to full year FY19 sales being mostly flat over pcp according to our estimates.
- **Current cash reserves are A$42.0m, borrowings were A$7.7m, which leaves PXS with a net cash position of A$34.3m.** This provides ~2 years runway, with further boost expected through a licensing deal for LOXL-2 asset in 1HCY19.

Earnings and Valuation Changes

We have reviewed our assumptions for PXS and made adjustments to our forecasts based on news flow over the last 6 months including its FY18 results, positive results from Phase 1 trials for LOXL-2 and its 1H19 results filed on the ASX, which have impacted earnings and valuation.

Key changes to our modelling assumptions

- We have increased the probability of success assigned to LOXL-2 from 20.0% to 22.0%, following the successful completion of and positive results from the LOXL-2 Phase 1 program as well as ongoing longer term toxicology studies. The compound is Phase 2 ready now and in our view has a stronger partnering prospect. This has led to an increase in our risk adjusted upfront and milestone revenue from the LOXL-2 deal for FY19 and FY20.
- We have shifted our approval timelines for the LOXL-2 asset from FY27 to FY28 in the US and similarly for EU and Japan, given we now assume a partnering deal for the asset takes place in 2HFY19 (was 1HFY19). Accordingly we have also moved the timelines for receipt of future milestones from a future partner.
- We have shifted our approval timelines for the PXS/BI drug BI_1467335 for Diabetic Retinopathy (DR) from FY26 to FY27, following the revised timelines for completion of ongoing Phase 2A trial in DR to 1HCY20 (vs. previous 1HCY19). We now expect results from this trial in 1QCY20. Accordingly we have also moved the timelines for receipt of future milestones from Boehringer Ingelheim.
- We have reduced the launch year penetration for LOXL-2 asset for NASH and the PXS/BI drug BI_1467335 for Diabetic Retinopathy, given that we now assume launch in the second half of our assumed launch financial year vs. first half earlier.
- We have updated our model for the recent $24m capital raise via placement of 73.9m shares @$0.325/sh.
- We have also updated our model for the options and performance rights granted and exercised during FY19.
- For FY19 and FY20 we have increased our drug development costs for the pipeline assets primarily LOX program (systemic and topical), based on the lower expense related to these in FY18 and higher expense in 1HFY19. We believe costs have been deferred from FY18 to FY19 and FY20. Our FY19 drug development costs have also increased due to spend on LOXL-2 asset (where we had not expected any spend in FY19 earlier).
- For FY19 we have reduced our clinical trial costs given an unexpected refund on the Bronchitol pivotal trial completed in FY17 by the CRO of 0.6m in 1HFY19 and excluding costs of Phase 1 trials for the SSAO/MPO asset, which we now believe is still a couple of years away from entering the clinic. For FY20 we earlier did not forecast any clinical trial expense. We now believe PXS could potentially move the topical asset from its LOX program into the clinic in FY20 and potentially also start another Phase 1b/2A trial for the LOX systemic asset in FY20.
- We have reduced our Bronchitol sales forecasts for FY19 onwards driven primarily by lower sales expectations from Western Europe given there was no order from Chiesi in 1QFY19 or 2QFY19. We have also slightly increased our sales expectations for Bronchitol in Australia driven by widened government reimbursement, however it was not enough to offset the reduced Western Europe sales expectations.

- For Aridol, we have increased the risk adjustment to sales from Canada from 60% to 80% now that PXS has filed its application for marketing approval to the Canadian authorities.
- Aridol was relaunched in the US in December 2018, following FDA approval of PXS' manufacturing facility in Sydney. We now include US Aridol sales in our forecasts from FY19 onwards, which have led to an increase in our Aridol sales forecasts. This was partially offset by slightly reduced forward forecasts for Aridol sales from South Korea based on 2QFY19 numbers.
- We have reduced our forward D&A forecasts based on lower than expected depreciation expense in 1HFY19.
- For FY19 we have recorded a FX loss of 1.0m as reported in 1HFY19.
- We have modestly increased our share based payment expense forecasts for FY19 and onwards.
- We have updated our model with revised BPe USD/AUD and EUR/AUD currency assumptions for FY19-21.
- We have rolled forward our DCF model.

We value PXS at $0.47/sh

The net result is an increase in our Net loss forecasts for FY19 by 7% and for FY20 by 34%, driven by higher opex related to the New Drug Development segment and a FX loss for FY19, partially offset by an increase in our revenue forecasts, driven by higher risk-adjusted LOXL-2 related upfront and milestone revenues following lift of probability of success assigned to it to 22.0% (vs. 20.0%). Our valuation for PXS has reduced to A$0.47/sh (was A$0.52/sh), driven primarily by the dilutive effect of the recent capital raising, the near term earning changes and the longer term impact of the shift in launch timelines and approval milestones for PXS/BI drug BI_1467335 for Diabetic Retinopathy and for LOXL-2 asset for NASH. **We retain our Buy (Speculative) recommendation.**

Table 2 - Key Changes to our FY19-20 Forecasts

	FY2019E			FY2020E		
	Old	New	Change (%)	Old	New	Change (%)
Revenues	18.2	19.1	5%	15.8	16.6	5%
Interest Income	0.6	0.9	55%	0.4	0.9	139%
Operating Costs	24.8	25.9	5%	21.2	25.6	21%
EBITDA	-6.6	-6.8	4%	-5.4	-9.1	68%
EBIT	-9.8	-9.8	0%	-8.6	-12.1	40%
NPAT (adjusted)	-9.7	-10.4	7%	-8.7	-11.6	34%
Adjusted Diluted EPS	-3.0	-2.8	-8%	-2.7	-2.9	9%
NPAT (reported)	-10.9	-11.7	8%	-9.9	-12.9	31%
Reported Diluted EPS	-3.4	-3.1	-8%	-3.1	-3.3	6%

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)	158.3
Add: Reported Cash (AUDm)	42.0
Less: Current Debt	7.7
Equity value (AUDm)	192.6
Total diluted shares (million)	411.3
Value per share (AUD)	**$0.47**
Current Share price (AUD)	$0.26
Expected Capital Growth	80.8%

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)	**-$0.03**	-7.1%	Aridol - Canada (80%)	Marketed (Ex-Canada) and for Bronchitol (Ex-US and Canada)
New Drug Development	$202	**$0.49**	105.1%	BI_1467335 (NASH, DR - 23.5%), LOXL-2 (NASH -22.0%)	BI_1467335 (Phase 2A) and LOXL-2 (Phase 1 complete)
Corporate/Non-Allocated	($30)	**-$0.07**	-15.7%	NA	NA
Reported Cash	$42	**$0.10**	21.8%	NA	NA
Reported Debt	($8)	**-$0.02**	-4.0%	NA	NA
Equity Value	**$192.6**	**$0.47**	**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	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 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 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 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 2QCY19, given the recent completion of its Phase 1 trial and long term toxicology studies. 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 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' other early stage assets namely SSAO/MPO inhibitor and LOX inhibitor. PXS intends to move into a Phase 1 trial in healthy volunteers with its LOX systemic asset in 1QCY19.

  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 it's ready to get into the clinic. Preclinical development is continuing for the topical asset.

  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.

  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 1B/2 trials 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 its commercialisation. Chiesi has resubmitted a New Drug Application (NDA) with the US FDA for Bronchitol in Dec' 2018. 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:** 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 an FY20 launch in Canada.
- **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. We have already seen the EBITDA loss from the segment come down significantly in FY18 from the FY16/FY17 levels. On our estimates we continue to see the EBITDA loss from the segment decreasing further. 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 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:

$0.47 valuation: We value PXS using a risk adjusted DCF at $0.47. The valuation is approximately an 80.8% premium to the current share price of $0.26/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 1HCY19 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 a multi-million dollar licensing deal expected in 1HCY19.

Strong cash position: PXS' current cash reserves of A$42.0m, in our view, provides ~2 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 $7.7m. 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 any of 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 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$42.0m in cash and debt related to finance lease of A$7.7m, amounting to a net cash position of A$34.3m. Although PXS has a high cash balance currently, which should provide ~2 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.

Pharmaxis Ltd.
as at 15 February 2019

Recommendation	Buy, Speculative
Price	$0.26
Valuation	$0.47

Table 7 - Financial summary

Pharmaxis Ltd (PXS) — **Share price (A$) $0.260**
As at 15 February 2019 — **Market cap (A$m 102.5**

Profit and Loss

Y/e June 30 (A$m)	2017A	2018A	2019E	2020E	2021E
Product Sales Revenues	4.8	6.1	6.1	7.1	7.9
Other Revenue (commercial)	8.6	43.5	12.5	8.8	0.0
Other Income	3.9	0.7	0.5	0.7	0.7
Total Revenue	**17.3**	**50.2**	**19.1**	**16.6**	**8.6**
EBITDA	**-15.2**	**11.5**	**-6.8**	**-9.1**	**-13.3**
Depreciation & Amortisation	-3.1	-3.1	-3.0	-3.0	-3.1
EBIT	**-18.3**	**8.4**	**-9.8**	**-12.1**	**-16.4**
Net interest & Other Income/(Expense)	0.9	-0.8	-0.6	0.5	0.3
Pre-tax profit	**-17.4**	**7.6**	**-10.4**	**-11.6**	**-16.1**
Tax	0.0	0.0	0.0	0.0	0.0
Net profit (loss) normalised	**-17.4**	**7.6**	**-10.4**	**-11.6**	**-16.1**
Abnormal items	-0.9	-1.2	-1.3	-1.3	-1.3
Reported Net profit (loss)	**-18.3**	**6.4**	**-11.7**	**-12.9**	**-17.4**

Cashflow

Y/e June 30 (A$m)	2017A	2018A	2019E	2020E	2021E
Reported NPAT	-18.3	6.4	-11.7	-12.9	-17.4
Non-cash items	3.7	5.6	5.8	4.7	4.7
Net change in Working capital	-0.6	0.1	-1.3	0.0	0.0
Operating cashflow	**-15.3**	**12.2**	**-7.2**	**-8.2**	**-12.7**
Capex	-0.3	-0.8	-0.6	-0.6	-0.6
Investments	0.0	0.0	0.0	0.0	0.0
Investments in intangible assets	-0.4	0.0	-0.3	-0.3	-0.3
Other investing cash flow	0.0	0.0	0.0	0.0	0.0
Investing cashflow	**-0.7**	**-0.9**	**-1.0**	**-1.0**	**-1.0**
Change in borrowings	-1.5	-1.5	-1.6	-1.7	-1.7
Equity issued	0.0	0.0	22.7	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	-0.2	-0.2	-0.3	-0.3	-0.4
Financing cashflow	**-1.7**	**-1.8**	**20.8**	**-2.0**	**-2.1**
Net change in cash	**-17.7**	**9.6**	**12.6**	**-11.1**	**-15.8**
Cash at end of period*	21.5	31.1	43.7	32.6	16.8
* Includes effect of exchange rate fluctuations on cash balance					
Free cash flow (op. CF less capex and intangibles)	**-16.0**	**11.3**	**-8.2**	**-9.1**	**-13.7**

Balance sheet

Y/e June 30 (A$m)	2017A	2018A	2019E	2020E	2021E
Cash	21.5	31.1	43.7	32.6	16.8
Current receivables	4.4	2.4	2.5	2.6	2.7
Inventories	2.6	2.4	2.7	2.8	2.9
Other current assets	0.1	0.1	0.1	0.1	0.1
Current assets	**28.6**	**36.0**	**49.0**	**38.1**	**22.5**
PPE	14.9	12.5	10.0	7.5	5.0
Non-current receivables	1.4	1.2	1.2	1.2	1.2
Intangible assets	0.5	0.4	0.7	0.9	1.1
Other non-current assets	0.0	0.0	0.0	0.0	0.0
Non-current assets	**16.8**	**14.1**	**11.9**	**9.6**	**7.2**
Total assets	**45.4**	**50.1**	**60.9**	**47.7**	**29.8**
Payables	6.8	5.6	4.6	4.7	4.8
Debt	9.3	8.3	7.2	5.9	4.5
Provisions	0.9	1.0	1.1	1.2	1.3
Financial liabilities (Novaquest financing agreement)	22.1	22.8	23.5	23.2	22.8
Deferred Lease Incentive	1.6	1.4	1.1	0.9	0.7
Other liabilities	1.1	0.0	0.0	0.0	0.0
Total liabilities	**41.9**	**39.0**	**37.5**	**35.9**	**34.1**
Net Assets	**3.5**	**11.1**	**23.4**	**11.8**	**-4.3**
Shareholders' equity	344.6	344.6	367.3	367.3	367.3
Reserves	19.5	20.7	22.0	23.3	24.6
Retained earnings/(losses)	-360.6	-354.2	-365.9	-378.8	-396.3
Total shareholders equity	**3.5**	**11.1**	**23.4**	**11.8**	**-4.3**

Valuation data

Y/e June 30	2017A	2018A	2019E	2020E	2021E
Net profit -normalised (A$m)	-17.4	7.6	-10.4	-11.6	-16.1
EPS - normalised (c)	-5.5	2.4	-2.8	-2.9	-4.1
EPS growth (%)	N/A	NM	N/A	N/A	N/A
P/E ratio (x)	N/A	10.9	N/A	N/A	N/A
FCFPS (c)	-5.0	3.5	-2.1	-2.3	-3.5
Price/FCF (x)	-5.2	7.3	-12.5	-11.2	-7.5
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-4.5	5.9	-10.0	-7.5	-5.1
EV/EBIT	-3.7	8.1	-7.0	-5.7	-4.2

Share price now (A$)	$0.260
Valuation (A$):	$0.47
Premium (discount) to price	80.8%
Recommendation:	Buy
Risk Rating	Speculative

Profitability ratios

Y/e June 30	2017A	2018A	2019E	2020E	2021E
EBITDA margin (%)	N/A	22.9%	N/A	N/A	N/A
EBIT margin (%)	N/A	16.7%	N/A	N/A	N/A
Return on assets (%)	-38.3%	15.2%	-17.1%	-24.3%	-54.2%
Return on equity (%)	-494.3%	68.5%	-44.5%	NM	372.5%
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	2017A	2018A	2019E	2020E	2021E
Net debt (cash) (A$m)	-12.3	-22.8	-36.5	-26.7	-12.3
Net debt/equity (%)	N/A	N/A	N/A	N/A	N/A
Net interest cover (x)	N/A	NM	N/A	N/A	N/A
Current ratio (x)	2.7	4.4	5.8	4.3	2.5

Segmentals

Y/e June 30	2017A	2018A	2019E	2020E	2021E
Bronchitol and Aridol					
Product Sales	4.8	6.1	6.1	7.1	7.9
Other revenue (Clinical trial cost reimbursement)	8.6	1.3	0.0	0.0	0.0
Other income	0.1	0.0	0.0	0.0	0.0
Total Revenues	**13.5**	**7.5**	**6.1**	**7.2**	**8.0**
EBITDA	**-7.1**	**-3.8**	**-3.7**	**-3.5**	**-2.9**
New Drug Development					
Product Sales	0.0	0.0	0.0	0.0	0.0
Other revenue (Milestone+license+royalty)	0.0	42.1	12.5	8.8	0.0
Other income (R&D tax incentive etc.)	3.4	0.2	0.0	0.2	0.2
Total Revenues	**3.4**	**42.3**	**12.5**	**8.9**	**0.2**
EBITDA	**-4.1**	**28.8**	**0.9**	**-1.5**	**-6.3**
Corporate					
Other income	**0.3**	**0.5**	**0.5**	**0.5**	**0.5**
EBITDA	**-4.0**	**-13.5**	**-4.1**	**-4.1**	**-4.1**
Total Company					
Revenues	**17.3**	**50.2**	**19.1**	**16.6**	**8.6**
EBITDA	**-15.2**	**11.5**	**-6.8**	**-9.1**	**-13.3**

Interims

Y/e June 30 (A$m)	2H17A	1H18A	2H18A	1H19A	2H19E
Revenue	10.8	31.1	19.1	2.5	16.6
EBITDA	-6.8	7.8	3.7	-9.8	3.0
Depreciation & Amortisation	-1.5	-1.6	-1.5	-1.3	-1.7
EBIT	**-8.3**	**6.2**	**2.2**	**-11.1**	**1.3**
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	1.5
Tax	0.0	0.0	0.0	0.0	0.0
Net Profit (loss) - normalised	**-6.8**	**6.5**	**1.1**	**-11.9**	**1.5**
Net Profit (loss) - reported	-7.3	5.9	0.5	-12.6	0.9

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

Research Team

Staff Member	Title/Sector	Phone	@bellpotter.com.au
TS Lim	Head of Research	612 8224 2810	tslim
Industrials			
Sam Haddad	Industrials	612 8224 2819	shaddad
Chris Savage	Industrials	612 8224 2835	csavage
Jonathan Snape	Industrials	613 9235 1601	jsnape
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
Analysts			
James Filius	Analyst	613 9235 1612	jfilius
Alexander McLean	Analyst	612 8224 2886	amclean
Damien Williamson	Analyst	613 9235 1958	dwilliamson

Bell Potter Securities Limited
ABN 25 006 390 7721
Level 38, Aurora Place
88 Phillip Street, Sydney 2000
Telephone +61 2 9255 7200
www.bellpotter.com.au