BELL POTTER

Speculative

See Key Risks on Page 9 & Biotechnology Risk Warning on Page 11

Speculative securities may not be suitable for Retail clients

25 November 2019

Analyst
Tanushree Jain 612 8224 2849
John Hester 612 8224 2871

Authorisation
TS Lim 612 8224 2810

Pharmaxis Ltd. (PXS)

Approaching key inflexion points

Recommendation
Buy (unchanged)
Price
$0.235
Valuation
$0.59 (previously $0.57)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**151.1%**
Dividend yield	**0.0%**
Total expected return	**151.1%**
Company Data & Ratios	
Enterprise value	**$72.8m**
Market cap	**$92.7m**
Issued capital	**394.7m**
Free float	**98.7%**
Avg. daily val. (52wk)	**$65,775**
12 month price range	**$0.18- $0.305**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.20	0.20	0.25
Absolute (%)	15.38	12.50	-10.00
Rel market (%)	14.59	8.72	-27.93

Key catalysts approaching in 4QCY19 for lead assets

Results from Phase 2A NASH trial for partnered asset BI 1467335 with Boehringer Ingelheim (BI) is due before the end of CY19 and will be a key catalyst for the stock. The results will be accompanied by a commercial assessment from BI with a potential decision to move it or not into Phase 2b trials. A decision by BI to progress it to Phase 2b trials will de-risk the asset and could add over 10 cents to our current valuation.

PXS is targeting completion of commercial process for LOXL-2 asset before the end of CY19. Additional studies using PXS' proprietary assay to measure LOX enzyme in serum and tissue have reinforced the drugs best in class position (able to penetrate fibrotic tissue and be available in high concentration to successfully inhibit LOXL-2 at all times) and re-energised ongoing partnering process in PXS' view. We continue to model a deal of US$700m (incl. US$50m upfront) albeit on a risk adjusted basis.

Further value inflexion points in CY20

Chiesi has received FDA sign off on design of Human Factor Study for bronchitol, which improves chance of a positive outcome, however FDA approval decision is now expected in 2QCY20 (was 1QCY20). Upfront of US$10m on launch of bronchitol in US is now expected in 3QCY20, with segment becoming profitable from FY21. Commercial assessment and results from Phase 2A Diabetic Retinopathy trial with BI 1467335 also being run by partner BI are expected in 3QCY20 (vs. 1HCY20).

Valuation lifted to $0.59, 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 shifting timeline for first sales from US and milestone from Chiesi for Bronchitol from FY20 to FY21, partially offset by a lift in the probability of success assigned to it to 90% (was 85%). We now forecast a Net Loss in FY20 and a Net Profit in FY21. Our FY22 Net loss forecast increased by 10%, driven by increased depreciation costs due to increase in PPE resulting from the adoption of a new accounting standard. Short term earning changes were offset by adjusting our DCF model for time creep. Our valuation for PXS increased modestly to A$0.59/sh (was A$0.57/sh). We retain Buy (Spec).

Absolute Price

SOURCE: IRESS

Earnings Forecast

Year end 30th June	2018A	2019A	2020E	2021E	2022E
Revenue (A$m)	50.2	12.2	20.7	32.4	16.3
EBITDA (A$m)	11.5	-15.7	-4.3	4.6	-7.4
NPAT (reported) (A$m)	6.4	-20.1	-9.3	0.6	-11.5
NPAT (normalised) (A$m)	7.6	-19.0	-8.1	1.9	-10.1
EPS (reported) (cps)	2.0	-5.1	-2.4	0.2	-2.9
EPS (adjusted) (cps)	2.4	-4.8	-2.1	0.5	-2.6
EPS growth (%)	NM	N/A	N/A	NM	N/A
PER (x)	9.9	N/A	N/A	48.7	N/A
EV/EBITDA (x)	6.3	-4.6	-16.9	15.9	-9.8
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	NM	22.2%	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

1QFY20 – Key highlights

PXS has provided an update on it's various programs for 1QFY20. Key highlights are as follows:

- Phase 2A results from NASH trial of BI 1467335 completed by partner Boehringer Ingelheim (BI) is due in 4QCY19. Apart from the results, PXS also expects to get an update following BI's internal review of all data on the drug to date (including Phase 2A trial data, Phase 1 trial data and data from pre-clinical studies) as to whether BI will proceed the drug into Phase 2b trials or not.
- Timelines for the completion and results from the Phase 2A trial in Diabetic Retinopathy of BI 1467335 also being run by partner BI have further slipped. The trial is now expected to report in 2HCY20 (vs. 1HCY20). The trial is over 50% recruited.
- On the LOXL-2 partnering process, discussions continue and no particular update will be provided before conclusion of process due to confidentiality. PXS however did note that it has been conducting some further studies this year using its unique and proprietary assay that are able to measure both the concentration and activity of LOX enzyme (all family members including LOXL-2) in serum and tissue even at low levels. Data from this again highlights PXS LOXL-2 inhibitors being best in class (i.e. able to penetrate fibrotic tissue and be present in high enough concentration to successfully inhibit LOXL-2 at all times). PXS has also run new pre-clinical studies to answer partner questions which further demonstrate the relevance of LOXL-2 in fibrotic disease and superiority of PXS's compounds vs. Gileads failed drug which also targeted LOXL-2. Together these studies have energised the ongoing partnering process in PXS' view.
- Multiple ascending dose study (Phase 1B) for systemic LOX drug PXS-5505 (targeting cancer myelofibrosis or pancreatic cancer) has now commenced and will report results in 1QCY20. IND to start Phase 2 (in either myelofibrosis or pancreatic cancer) is being targeted for filing with the FDA in 2HCY20. Phase 1A data was positive and demonstrated good pharmacokinetic profile and inhibition of LOX family of enzymes.
- Phase 1 studies for other pipeline drug (Topical LOX inhibitor) in healthy volunteers with scarring is expected to start in CY20. Pre-clinical 3-month studies started in 1QFY20.
- Bronchitol is on track for US approval. Chiesi has on feedback from FDA increased the size of its planned Human Factor Study and also incorporated some other changes that FDA recommended. While getting FDA sign off on the study further improves chances of a positive outcome, we understand the timeline for approval has slipped by a month to 2QCY20 (was 1QCY20) and subsequently the upfront US$10m receivable from Chiesi on shipment of the launch order for US is now expected in mid-CY20 i.e. early 3QCY20 (vs. end 2QCY20).
- Bronchitol sales for 1QFY20 were up 36% over pcp. A large order shipped to Chiesi for Western Europe positively impacted 1Q20 revenues. Revenue from Australia also grew over pcp, while Russia and Eastern Europe were down.
- Aridol revenues were modestly up over pcp (2%). While sales in both Australia and Europe were up over pcp, South Korea which tends to be lumpy was down over pcp. There were no orders from US in this quarter or the pcp, which is in line with our expectations given we had two large orders for US in FY19. Launch of Aridol in Canada is expected in 4QCY19.
- PXS ended 1QFY20 with A$23m cash. Proforma cash including A$6.2m R&D tax rebate received in October was A$29.2m. This should provide PXS with ~15 months runway. Milestone from Chiesi and upfront from a LOXL-2 deal expected within the next 12 months should further extend this cash runway.

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

- We have shifted our launch timelines for the PXS/Boehringer Ingelheim (BI) drug BI_1467335 from FY27 to FY28, following the revised timelines for completion of ongoing Phase 2A trial in Diabetic Retinopathy (DR) to 2QCY20 (vs. previous 1QCY20). We now expect results from this trial (including commercial assessment from BI) in 2HCY20. Accordingly we have also moved the timelines for receipt of future milestones from Boehringer Ingelheim.
- Chiesi has increased the size of its planned Human Factor Study (HFS) and incorporated other changes based on feedback from FDA. While getting FDA sign off on the study further improves chances of a positive outcome, we understand the timeline for approval has slipped by a month to 2QCY20 (was 1QCY20) and subsequently the upfront US$10m receivable from Chiesi on shipment of the launch order for US is now expected in mid-CY20 i.e. early 3QCY20 (vs. end 2QCY20). We have shifted the milestone from FY20 to FY21. We have also increased the probability of success assigned to US Bronchitol revenues and the milestone to 90% (was 85%).
- We also now assume first revenues from US for bronchitol (on shipping product to Chiesi) in FY21 (vs. FY20), which has reduced our product sales for bronchitol for 2HFY20 and FY20 overall. We have also increased our bronchitol sales forecast for 1H based on the large order from Chiesi received for Western Europe in 1QFY20. We now expect bronchitol sales to be evenly spread between both the halves.
- We now include a R&D tax rebate of $0.6m for FY20 (with $0.3m recorded in 1QFY20).
- We have modestly increased our drug development costs for FY20 by ~$0.3m (related to the LOX assets), based on the slightly higher than expected cost reported for 1QFY20.
- We have decreased our clinical trial costs for FY20 and increased it for FY21 by ~$1.5m each. This was driven by timing of the planned Phase 1 and 1c/2 trials for the LOX systemic and topical assets. Pre-clinical studies for the topical LOX asset were started in 1QFY20, with Phase 1 planned for CY20. We believe it will start in 2HCY20. The multiple ascending dose (MAD) study for the systemic LOX asset also started in 1QFY20 and is due to report results in 1QCY20. IND filing for 1c/2 study is targeted for 2HCY20.
- PXS has adopted the new AASB 16 leases accounting standard from 1st July 2019, which has led to a $2.6m increase in property, plant and Equipment (PPE) and the corresponding liability in lease (related to its French's Forest facility) for FY20. The increase in PPE has also led to an increase in our forward depreciation forecasts.
- We have modestly reduced our capex estimate for FY20 based on lower than expected expense for 1QFY20.
- Our operating cash flow forecasts for FY20 have reduced due to higher receivables and lower payables reported for 1QFY20, impacting our working capital movement.
- We have updated our model for issue and exercise of options/performance rights.
- We have adjusted our DCF model for time creep.

We value PXS at $0.59/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 shifting timeline for first sales from US and milestone from Chiesi for Bronchitol from FY20 to FY21, partially offset by a lift in the probability of success assigned to it to 90% (was 85%). We now forecast a Net Loss in FY20 and a Net Profit in FY21. Our Net loss forecast for FY22 increased by 10%, driven by increased depreciation costs due to increase in PPE resulting from the adoption of a new accounting standard. Short term earning changes were offset by adjusting our DCF model for time creep. Our valuation for PXS increased modestly to A$0.59/sh (was A$0.57/sh). **We retain Buy (Spec) on PXS.**

Table 1 - Key Changes to our FY20-22 Forecasts

	FY2020E			FY2021E			FY2022E		
	Old	New	Change (%)	Old	New	Change (%)	Old	New	Change (%)
Revenues	32.0	20.7	-35%	20.1	32.4	61%	16.1	16.3	1%
Interest Income	1.0	0.8	-22%	1.1	0.8	-21%	0.7	0.7	-6%
Operating Costs	26.4	25.0	-5%	26.3	27.8	6%	23.8	23.7	0%
EBITDA	5.6	-4.3	-177%	-6.2	4.6	-174%	-7.7	-7.4	-3%
EBIT	3.3	-7.4	-323%	-8.3	1.5	-118%	-9.6	-10.5	10%
NPAT (adjusted)	4.0	-8.1	-306%	-7.5	1.9	-125%	-9.1	-10.1	11%
Adjusted Diluted EPS	1.0	-2.1	-306%	-1.9	0.5	-125%	-2.3	-2.6	11%
NPAT (reported)	2.8	-9.3	-436%	-8.8	0.6	-107%	-10.4	-11.5	10%
Reported Diluted EPS	0.7	-2.4	-436%	-2.2	0.2	-107%	-2.6	-2.9	10%

ALL AMOUNTS IN AUD IN MILLIONS EXCEPT EPS. SOURCE: BELL POTTER SECURITIES ESTIMATES

Our DCF valuation model is based on a WACC of 16.0% and a terminal growth rate of 1%.

Table 2 - Summary of Valuation

Forecasts	Base case
Enterprise value from DCF (AUDm)	226.1
Add: Proforma Cash incl. R&D tax rebate (AUDm)	29.4
Less: Current Debt	9.4
Equity value (AUDm)	246.1
Total diluted shares (million)	414.6
Value per share (AUD)	**$0.59**
Current Share price (AUD)	$0.24
Expected Capital Growth	151.1%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 3 - PXS Sum-of-parts DCF Valuation Summary

Asset	Probability adjusted NPV (A$m)	Value per share (A$)	% Mix	Probability of success/Risk adjustment	Current Phase
Bronchitol and Aridol	$20	**$0.05**	8.2%	Aridol - Canada (100%), Bronchitol - US (85%)	Marketed (Ex-Canada) and for Bronchitol (Ex-US and Canada)
New Drug Development	$242	**$0.58**	98.5%	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**	-14.8%	NA	NA
Proforma Cash	$29	**$0.07**	11.9%	NA	NA
Reported Debt	($9)	**-$0.02**	-3.8%	NA	NA
Equity Value	**$246.1**	**$0.59**	**100.0%**		

SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 4 – PXS- Key assumptions used in New Drug Development segment

Asset	Indication	Stage	Partnering Status	First Fiscal Year of sales (Est.)	Peak Market share	Peak Global Sales (US$m)	Probability of success
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	2028	10.0%	$813	23.5%
LOXL-2	NASH - F3/F4 fibrosis stage	Phase 1 complete	Partnering process ongoing	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 5 – Deal Assumptions for Key Drug Development Pipeline Assets

Asset	Indication	Stage at Licensing	Licensee	Fiscal Year Timing of deal (Est.)	Total Deal Value in USDm (upfront plus milestones)	Upfront (USDm)	Other developmental & regulatory Milestones (USDm)	Commercial Milestones Est (USDm)	Royalty Rate (%)	PXS's share
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 FY21) 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 initiated a Phase 1 trial in healthy volunteers with its LOX systemic asset PXS-5505 in Feb'19. The SAD (single ascending dose) part of this study was completed in June'19 and the company has just initiated the second MAD (multiple ascending dose) in 1QFY20, results from which are expected in 1QCY20. Phase 1A data was positive showing good PK profile and inhibition of all LOX family of enzymes. PXS has also generated positive results from its LOX systemic asset in myelofibrosis and pancreatic cancer in preclinical models and has completed 3 month toxicology studies in parallel with the ongoing Phase 1 trial in healthy volunteers. Longer term tox studies (6 months) are also being carried out in parallel for the compound. IND to start Phase 2 (in either myelofibrosis or pancreatic cancer) is being targeted for filing with the FDA in 2HCY20.

  Preclinical development is continuing for the topical asset (3 month tox studies were initiated in 1QFY20). PXS expects to start a Phase 1 trial in healthy volunteers with scarring in CY20 (BPe 2HCY20).

  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 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 a 90% 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 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 is also focusing on developing its earlier stage LOX pipeline asset (systemic and topical), with pre-clinical and Phase 1 trials ongoing for these assets. 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 and the segment achieve profitability.

INVESTMENT STRATEGY

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

$0.59 valuation: We value PXS using a risk adjusted DCF at $0.59. The valuation is approximately a 151.1% premium to the previous closing share price of $0.235/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 2HCY20. 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' proforma cash at end of 1QFY20 of ~A$29.0m (along with A$6m in R&D tax rebate received in Oct'19) in our view, provides ~15 months cash runway, with flexibility to defer some expenses on other pipeline programs to further extend this runway. A US$10m Milestone from Chiesi for Bronchitol in 3QCY20 and upfront from a LOXL-2 deal later in 4QCY19 should further extend this cash runway. The company has a modest debt (related to finance lease) of A$9.4m. PXS is now focused on accelerating the development of its earlier stage LOX systemic and topical assets for myelofibrosis/pancreatic cancer and scarring. PXS' strong cash position should also allow the company to consider Phase 2A/2B development for its LOX assets (to potentially enhance their 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 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 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 2QCY20. 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 proforma cash of A$29.4m and debt related to finance lease of A$9.4m. Although PXS has a high cash balance currently, which should provide ~15 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 US$10m milestone from Chiesi. There is no guarantee that PXS will be able to secure additional financing if and when required.

Pharmaxis Ltd.

as at 25 November 2019

Recommendation	Buy, Speculative
Price	$0.235
Valuation	$0.59

Table 6 - Financial summary

Pharmaxis Ltd (PXS) — **Share price (A$) $0.235**

As at 25 November 2019 — **Market cap (A$m 92.7**

Profit and Loss

Y/e June 30 (A$m)	2018A	2019A	2020E	2021E	2022E
Product Sales Revenues	6.1	5.7	6.5	10.2	12.8
Other Revenue (commercial)	43.5	0.0	13.0	21.6	0.0
Other Income	0.7	6.5	1.1	0.5	3.5
Total Revenue	**50.2**	**12.2**	**20.7**	**32.4**	**16.3**
EBITDA	**11.5**	**-15.7**	**-4.3**	**4.6**	**-7.4**
Depreciation & Amortisation	-3.1	-2.6	-3.1	-3.1	-3.1
EBIT	**8.4**	**-18.3**	**-7.4**	**1.5**	**-10.5**
Net interest & Other Income/(Expense)	-0.8	-0.7	-0.7	0.4	0.4
Pre-tax profit	**7.6**	**-19.0**	**-8.1**	**1.9**	**-10.1**
Tax	0.0	0.0	0.0	0.0	0.0
Net profit (loss) normalised	**7.6**	**-19.0**	**-8.1**	**1.9**	**-10.1**
Abnormal items	-1.2	-1.1	-1.2	-1.3	-1.4
Reported Net profit (loss)	**6.4**	**-20.1**	**-9.3**	**0.6**	**-11.5**

Cashflow

Y/e June 30 (A$m)	2018A	2019A	2020E	2021E	2022E
Reported NPAT	6.4	-20.1	-9.3	0.6	-11.5
Non-cash items	5.6	5.6	5.8	4.8	4.7
Net change in Working capital	0.1	-5.4	2.0	2.4	-3.0
Operating cashflow	**12.2**	**-19.8**	**-1.5**	**7.8**	**-9.7**
Capex	-0.8	-0.6	-0.4	-0.6	-0.6
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**	**-0.8**	**-1.0**	**-1.0**
Change in borrowings	-1.5	-1.6	-2.2	-2.2	-2.3
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	-0.3	-0.8	-0.8
Financing cashflow	**-1.8**	**20.8**	**-2.5**	**-3.0**	**-3.1**
Net change in cash	**9.6**	**0.1**	**-4.8**	**3.8**	**-13.8**
Cash at end of period*	31.1	31.1	26.3	30.2	16.3
* Includes effect of exchange rate fluctuations on cash balance					
Free cash flow (op. CF less capex and intangibles)	**11.3**	**-20.8**	**-2.3**	**6.8**	**-10.7**

Balance sheet

Y/e June 30 (A$m)	2018A	2019A	2020E	2021E	2022E
Cash	31.1	31.1	26.3	30.2	16.3
Current receivables	2.4	7.2	2.7	1.3	4.3
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**	**40.6**	**31.4**	**33.9**	**23.2**
PPE	12.5	10.3	10.0	7.4	4.7
Non-current receivables	1.2	1.1	1.1	1.1	1.1
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**	**12.1**	**12.1**	**9.8**	**7.4**
Total assets	**50.1**	**52.7**	**43.6**	**43.7**	**30.7**
Payables	5.6	4.8	2.3	3.3	3.3
Debt	8.3	7.2	8.1	6.3	4.3
Provisions	1.0	1.1	1.2	1.3	1.4
Financial liabilities (Novaquest financing agreement)	22.8	23.6	24.3	23.6	22.7
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**	**36.9**	**35.2**	**32.2**
Net Assets	**11.1**	**14.8**	**6.7**	**8.6**	**-1.5**
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	-383.6	-382.9	-394.4
Total shareholders equity	**11.1**	**14.8**	**6.7**	**8.6**	**-1.5**

Valuation data

Y/e June 30	2018A	2019A	2020E	2021E	2022E
Net profit -normalised (A$m)	7.6	-19.0	-8.1	1.9	-10.1
EPS - normalised (c)	2.4	-4.8	-2.1	0.5	-2.6
EPS growth (%)	NM	N/A	N/A	NM	N/A
P/E ratio (x)	9.9	N/A	N/A	48.7	N/A
FCFPS (c)	3.5	-5.3	-0.6	1.7	-2.7
Price/FCF (x)	6.6	-4.5	-39.9	13.6	-8.7
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	6.3	-4.6	-16.9	15.9	-9.8
EV/EBIT	8.7	-4.0	-9.8	48.7	-6.9

Share price now (A$)	$0.235
Valuation (A$):	$0.59
Premium (discount) to price	151.1%
Recommendation:	Buy
Risk Rating	Speculative

Profitability ratios

Y/e June 30	2018A	2019A	2020E	2021E	2022E
EBITDA margin (%)	22.9%	N/A	N/A	14.1%	N/A
EBIT margin (%)	16.7%	N/A	N/A	4.6%	N/A
Return on assets (%)	15.2%	-36.0%	-18.7%	4.4%	-32.9%
Return on equity (%)	68.5%	NM	NM	22.2%	NM
Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%

Liquidity and leverage ratios

Y/e June 30	2018A	2019A	2020E	2021E	2022E
Net debt (cash) (A$m)	-22.8	-24.0	-18.2	-23.8	-12.0
Net debt/equity (%)	N/A	N/A	N/A	N/A	N/A
Net interest cover (x)	NM	N/A	NM	-3.6	N/A
Current ratio (x)	4.4	5.0	5.0	4.5	2.9

Segmentals

Y/e June 30	2018A	2019A	2020E	2021E	2022E
Bronchitol and Aridol					
Product Sales	6.1	5.7	6.5	10.2	12.8
Other revenue (Clinical trial cost reimbursement)	1.3	0.0	0.0	12.5	0.0
Other income	0.0	0.0	0.0	0.0	0.0
Total Revenues	**7.5**	**5.7**	**6.5**	**22.8**	**12.8**
EBITDA	**-3.8**	**-5.0**	**-5.5**	**10.5**	**0.2**
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	0.6	0.0	3.0
Total Revenues	**42.3**	**6.0**	**13.6**	**9.1**	**3.0**
EBITDA	**28.8**	**-6.8**	**5.0**	**-2.1**	**-3.8**
Corporate					
Other income	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**
EBITDA	**-13.5**	**-3.9**	**-3.8**	**-3.8**	**-3.8**
Total Company					
Revenues	**50.2**	**12.2**	**20.7**	**32.4**	**16.3**
EBITDA	**11.5**	**-15.7**	**-4.3**	**4.6**	**-7.4**

Interims

Y/e June 30 (A$m)	2H18A	1H19A	2H19A	1H20E	2H20E
Revenue	19.1	2.5	9.7	16.8	3.9
EBITDA	3.7	-9.8	-5.8	3.9	-8.2
Depreciation & Amortisation	-1.5	-1.3	-1.3	-1.5	-1.6
EBIT	**2.2**	**-11.1**	**-7.2**	**2.3**	**-9.7**
Net interest & Other Expense	-1.1	-0.8	0.1	-1.0	0.3
Pre-tax profit	1.1	-11.9	-7.1	1.3	-9.5
Tax	0.0	0.0	0.0	0.0	0.0
Net Profit (loss) - normalised	**1.1**	**-11.9**	**-7.1**	**1.3**	**-9.5**
Net Profit (loss) - reported	0.5	-12.6	-7.5	0.7	-10.1

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