BELL POTTER

Speculative
See Key Risks on Page 8 & Biotechnology Risk Warning on Page 10
Speculative securities may not be suitable for Retail clients

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Pharmaxis Ltd. (PXS)

COVID-19 impacting timing for key catalysts

Recommendation
Buy (unchanged)
Price
$0.09
Valuation
$0.19 (previously $0.26)
Risk
Speculative

GICS Sector

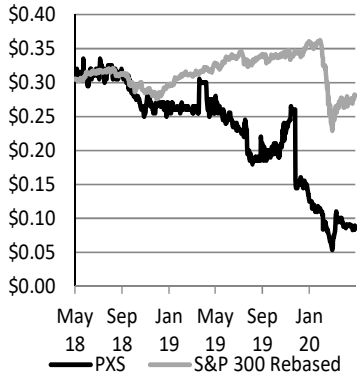
Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**111.1%**
Dividend yield	**0.0%**
Total expected return	**111.1%**
Company Data & Ratios	
Enterprise value	**$23.9m**
Market cap	**$35.6m**
Issued capital	**395.2m**
Free float	**98.7%**
Avg. daily val. (52wk)	**$59,934**
12 month price range	**$0.053- $0.285**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.10	0.12	0.26
Absolute (%)	-8.25	-24.26	-65.10
Rel market (%)	-9.68	-2.23	-52.51

Absolute Price



SOURCE: IRESS

PXS has been in partnering discussions for its LOXL-2 asset since Jan'19, following completion of phase 1 trials. The process has taken much longer than expected with PXS continuing to add to the clinical data package (another small PK study was completed in 1QCY20). **COVID-19 distractions have further slowed down the partnering process for this asset and we now expect a deal in 1HFY21 (was 2HFY20).** PXS notes that multiple parties continue to be interested and expects further development of this product will be partner funded. We also note that Pharmakea (the only other company with a LOXL-2 asset in development), also went through a long partnering process. Pharmakea completed Phase 1 trial in 2017 with its LOXL-2 asset, but only merged with Galecto (another company focused on fibrotic diseases) in Jan'20. Terms of the merger were not disclosed. We believe PXS' LOXL-2 asset has a more favourable PK/PD profile than Pharmakea's asset and is more potent due to dual inhibition of LOXL-2/3. We are optimistic that PXS will find a partner for its asset as well, however the long partnering process which seems to be a common factor seems to reflect the NASH market where a string of keenly awaited trials have been unsuccessful and the overhang from Gilead's failed LOXL-2 antibody. Last week, **FDA acknowledged Chiesi's NDA resubmission for bronchitol, confirming its completeness.** While this is positive, FDA's classification has extended the review time from 2 months to 6 months. Approval is now expected by 1st Nov'20 (vs. BPe mid-CY20). **The US$10m launch milestone from Chiesi is now expected in 1QCY21** (vs. BPe 3QCY20).

Valuation reduced to $0.19, Retain Buy (speculative)

Revisions to our model led to a large increase in our FY20 Net loss forecast which was offset by a large increase in our FY21 NPAT forecast, driven primarily by moving deal timing of LOXL-2 and related upfront to FY21. Changes to our FY22 Net loss forecast was not material. Earning changes, increasing our WACC to 19% (was 17%), partially offset by adjusting our DCF for time creep, has led to a significant decrease in our valuation for PXS to A$0.19/sh (was A$0.26/sh). We retain Buy (Spec). Cash at end of 3QFY20 of $20.3m, provides ~12 months runway. The increase in WACC is to reflect risk around the potential for further timeline slippage for LOXL-2 deal due to COVID-19 distractions, which coupled with the delayed timeline for bronchitol milestone could potentially pressurise the company's balance sheet.

Earnings Forecast

Year end 30th June	2018A	2019A	2020E	2021E	2022E
Revenue (A$m)	50.2	12.2	9.8	39.9	19.2
EBITDA (A$m)	11.5	-15.7	-14.3	14.1	-7.0
NPAT (reported) (A$m)	6.4	-20.1	-22.1	9.7	-11.3
NPAT (normalised) (A$m)	7.6	-19.0	-21.2	10.8	-10.1
EPS (reported) (cps)	2.0	-5.1	-5.5	2.4	-2.8
EPS (adjusted) (cps)	2.4	-4.8	-5.2	2.7	-2.5
EPS growth (%)	NM	N/A	N/A	NM	N/A
PER (x)	3.8	N/A	N/A	3.4	N/A
EV/EBITDA (x)	2.1	-1.5	-1.7	1.7	-3.4
Dividend (¢ps)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
ROE (%)	68.5%	NM	NM	244.7%	NM

NOTE: REVENUE INCLUDES R&D TAX INCENTIVE, MILESTONES FROM BI DEAL AND CHIESI DEAL AND FY21/22 REVENUE INCLUDES RISK ADJUSTED UPFRONT AND MILESTONES FROM LICENSING DEAL FOR LOXL-2. SOURCE: BELL POTTER SECURITIES ESTIMATES

Earnings and Valuation Changes

We have reviewed our assumptions for PXS and made adjustments to our forecasts based on its quarterly update and announcement re FDA's decision date on the Bronchitol resubmission filed on the ASX, which have impacted earnings and valuation.

Key changes to our modelling assumptions

- We now assume that a deal for LOXL-2 asset gets finalised in 2HCY20 (vs. 1HCY20). Accordingly we have moved our assumed upfront payment from the deal to 1HFY21 (was 2HFY20). Management is no longer guiding to a timeline for conclusion of the process. We believe COVID-19 has slowed down all non-COVID-19 deal making. We now assume it happens before end of Dec'20. In 1Q20, PXS further built on the data package by completing a small Phase 1 study which tested the effect of food and different dosing regimens on the drugs PK profile. The company has stated that it is pursuing a number of different partnering options with international pharma companies to enable the drug to move into Phase 2 clinical trials. We have also moved the timeline for some of the other milestones accordingly.
- Since we have moved the LOXL-2 deal timing to FY21, we now include an estimated R&D tax rebate of $2.8m in 2HFY20.
- We have increased our Bronchitol sales forecast for FY20 for Australia and Western Europe. Australia Bronchitol sales in 3Q20 was higher than expected and PXS has invoiced more than $1m in distributor orders in 4Q20. We have reduced our Bronchitol sales forecast for FY21, primarily expecting lower sales in US due to launch now expected in 1HCY21 vs. 2HCY20 earlier.
- Due to the COVID-19 pandemic, lung function tests across several markets have been restricted to more severe cases. As a result PXS has seen a significant decrease in Aridol sales across all markets since mid-March. We expect FY20 and FY21 Aridol revenues to be impacted and therefore have reduced our forward Aridol sales forecasts across all markets.
- Changes to our opex forecast for FY20 was not material. We have reduced our opex forecast for FY21 by ~6% driven by reducing drug development costs for projects other than already disclosed by management and also reducing manufacturing purchases cost for Bronchitol to reflect lower US sales forecast for FY21. We have increased our opex forecast for FY22 by ~12% driven by higher clinical trials cost (related to an assumed Phase 2 myelofibrosis trial), partially offset by lower drug development costs for projects other than already disclosed by management.
- Our FY20 Net loss estimate was impacted by a $3.3m Fx loss reported by PXS for 3QFY20.
- We have reduced our interest income forward forecasts based on the lower cash balances and lower interest rates.
- We have reduced our forward capex forecasts based on the lower than expected spend in the first nine months of FY20.
- We have updated our model for the exercise and expiry of performance rights over the last 2-3 months.
- We have increased the WACC we use in our DCF valuation from 17% to 19% to account for the increased risk in the company's situation. The LOXL-2 deal timelines continue to drag and there is still risk around our revised timing of 2HCY20 given that we expect COVID-19 distractions are slowing down deal making for anything non COVID-19 related and due to no concrete guidance from management. The delay in

timeline for FDA decision on Bronchitol and delay in timeline for receipt of potential US$10m milestone from Chiesi to 1QCY21 (vs. BPe 3QCY20) will pressurise the company's balance sheet especially if the LOXL-2 deal takes longer to be done than what we have forecasted. The company may need to raise capital at dilutive terms, especially since the size and cost of a potential Phase 2 trial in myelofibrosis expected to start in 4QCY20 with PXS' oral pan-LOX inhibitor PXS-5505 is unclear.

- We have adjusted our DCF model for time creep.

We value PXS at $0.19/sh

Revisions to our model led to a large increase in our Net loss forecast for FY20 which was offset by a large increase in our NPAT forecast for FY21, driven primarily by moving deal timing of LOXL-2 and related upfront payment to 1HFY21 (was 2HFY20), partially offset by a reduction in our opex forecasts. Changes to our Net loss forecast for FY22 was not material. Earning changes, longer term impact of moving deal timing of LOXL-2 and consequently start of a potential Phase 2 trial and increasing our WACC to 19% (was 17%), partially offset by adjusting our DCF model for time creep, has led to a significant decrease in our valuation for PXS to A$0.19/sh (was A$0.26/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	20.5	9.8	-52%	32.7	39.9	22%	16.3	19.2	17%
Interest Income	0.6	0.4	-35%	0.6	0.4	-31%	0.5	0.4	-14%
Operating Costs	24.5	24.1	-1%	27.5	25.9	-6%	23.4	26.2	12%
EBITDA	-4.0	-14.3	260%	5.2	14.1	170%	-7.1	-7.0	-1%
EBIT	-7.2	-17.5	143%	2.0	10.9	449%	-10.3	-10.2	-1%
NPAT (adjusted)	-8.0	-21.2	164%	2.1	10.8	414%	-10.1	-10.1	0%
Adjusted Diluted EPS	-2.0	-5.2	164%	0.5	2.7	414%	-2.5	-2.5	0%
NPAT (reported)	-9.2	-22.1	140%	0.8	9.7	NM	-11.5	-11.3	-2%
Reported Diluted EPS	-2.3	-5.5	141%	0.2	2.4	NM	-2.8	-2.8	-2%

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

Our DCF valuation model is based on a WACC of 19.0% and a terminal growth rate of 1%.

Table 2 - Summary of Valuation

Forecasts	Base case
Enterprise value from DCF (AUDm)	66.9
Add: Current Cash (AUDm)	20.3
Less: Current Debt	8.6
Equity value (AUDm)	78.5
Total diluted shares (million)	413.9
Value per share (AUD)	**$0.19**
Current Share price (AUD)	$0.09
Expected Capital Growth	111.1%

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	$15	**$0.04**	19.5%	Bronchitol - US (90%)	Marketed for Aridol, Marketed for Bronchitol (Ex-US and Canada)
New Drug Development	$82	**$0.20**	103.9%	BI_1467335 (DR - 23.5%), LOXL-2 (NASH -22.0%)	BI_1467335 for DR (Phase 2A) and LOXL-2 (Phase 1 complete)
Corporate/Non-Allocated	($30)	**-$0.07**	-38.3%	NA	NA
Reported Cash	$20	**$0.05**	25.8%	NA	NA
Reported Debt	($9)	**-$0.02**	-10.9%	NA	NA
Equity Value	**$78.5**	**$0.19**	**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	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 LOXL-2 (expected to be partnered in 2HCY20)

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
LOXL-2	NASH and a second indication (potentially IPF)	Phase 1 complete	TBC	2021	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. 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 DR. We envisage that completion of the trial 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 following a partnering deal for it, will allow us to assign a higher POS and therefore will lead to material upgrades in our numbers.

- **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.
- **Conservative assumptions for BI_1467335 for DR in absence of Phase 2 clinical data:** Our market penetration & pricing assumptions, are all based on the premise that BI 1467335 will offer a new mechanism of action and a new oral delivery route to treat patients with nonproliferative Diabetic Retinopathy, where currently anti-VEGF drugs with multibillion dollar sales and delivery via intra-ocular injections are the main stay, with laser treatments the second choice of treatment. Our base assumption at this stage is that BI_1467335 is likely to be used at an earlier stage of the disease and will be priced at a discount to the annual cost of anti-VEGF treatment. We note that the price and market share will ultimately be dictated by efficacy. In the absence of Phase 2 clinical data we are conservative in our assumptions at this stage.

- **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 completed the second MAD (multiple ascending dose) part of the study in 1QCY20. Phase 1 data was positive showing good PK profile and dose related strong 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 and 6 month toxicology studies in parallel with the ongoing Phase 1 trial in healthy volunteers. IND to start Phase 2 (in myelofibrosis, a bone marrow cancer) is being targeted for filing with the FDA later in 3QCY20, with the view to initiate a 6-month Phase 2 study before the end of CY20. Company expects to obtain orphan drug designation from the FDA for myelofibrosis, prior to initiating Phase 2 trials. They estimate that the myelofibrosis market is valued in excess of US$1bn per annum.

  Preclinical development is continuing for the topical asset PXS-6302 (3 month tox studies were initiated in 3QCY19 and is expected to report in 2QCY20). Earlier PXS had guided to starting a Phase 1 trial in healthy volunteers with scarring in CY20. The company has not confirmed this in the latest quarterly, instead suggesting that investigator initiated studies to assess the drug in burn related scars are being discussed with an Australian hospitals' burn unit.

  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 and PXS has now supplied its first (launch) order to Methapharm for Canada in 2QFY20.
- **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 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.

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 is targeting Diabetic Retinopathy an area of unmet need and a large market, 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 LOXL-2 drug while not first-in-class, has evidence that it is best-in-class and can be useful in other fibrotic diseases and we forecast it to be a blockbuster (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 pipeline (LOX assets) targeting scarring and myelofibrosis (est. >$1bn market). 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:

$0.19 valuation: We value PXS using a risk adjusted DCF at $0.19. The valuation is approximately a 111.1% premium to the previous closing share price of $0.09/sh.

Turnaround prospects are strong in FY21: PXS had a disappointing set back in 4QCY19 which caused a significant fall in its stock price, when partner Boehringer Ingelheim (BI) decided to discontinue further development of the partnered SSAO/VAP-1 drug BI_1467335 for NASH. However, we believe at current price levels PXS represents a compelling 'Buy' given its strong turnaround prospects in FY21. Key inflexion points which could drive this turnaround include: a) Results from phase 2A trials for BI_1467335 partnered with BI in Diabetic Retinopathy (DR) and BI's commercial decision regarding further development of the asset for DR is expected in 2HCY20; b) LOXL-2 asset has successfully completed Phase 1 trials and longer term toxicology studies, as well as added to the data package with further supporting studies providing evidence around its utility in fibrotic disease but also its best in class characteristics. The company has been in partnering discussions for a while (Since Jan'19) which have taken longer than the company initially expected. The discussions and due diligence by interested parties are ongoing and we now expect a conclusion of the partnering process in 2HCY20; and c) Also in 4QCY20 we expect FDA approval decision on bronchitol, which is expected to be followed by a US$10m milestone from PXS' partner Chiesi in 1QCY21.

LOXL-2 targeting NASH has blockbuster potential: Pharmaxis' Phase 1 LOXL-2 asset is targeting Non-alcoholic Steatohepatitis (NASH), a multibillion dollar market, estimated to grow to be ~US$20bn-US$35bn. We model US$1.45bn peak worldwide sales (pre risk adjustment) 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' LOXL-2 asset is an anti-fibrotic agent and therefore should complement other drugs in advanced development. There are very few drugs in development in this category and as far as we are aware it is the only one in its class being actively developed for NASH.

Drugs not first-in-class but potentially best-in-class: PXS' LOXL-2 inhibitors are not the first in their class. However based on pre-clinical data and Phase 1 data, we believe the drugs possess a more favourable PK/PD profile which position them as 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 into broader fibrotic diseases: Both the lead drugs have potential to be used across fibrotic diseases with both SSAO and LOXL-2 enzymes upregulated in other areas such as lung and kidney, implying a broader utility in treating other diseases such as pulmonary fibrosis (IPF) and kidney 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. Although, the company had a disappointing set back in 4QCY19 with BI choosing to not pursue NASH for the partnered asset anymore, the deal has delivered to date €57m (A$83m) in upfronts and milestones to PXS and BI is still continuing to develop the asset at this stage for Diabetic Retinopathy. Should BI continue to proceed with further development for DR, PXS stands to receive €177m in Phase 3 initiation, filing and approval milestones. Commercial milestones on reaching sales thresholds and royalties on net sales post approval are also part of the deal as it currently stands.

Early stage pipeline assets represent future value: PXS' LOX (systemic) drug is targeting the bone marrow cancer myelofibrosis with an estimated market value of over $1bn per year. Phase 1 trial is now complete and PXS will proceed with filing for orphan drug designation and IND for a Phase 2 trial later in 3QCY20, targeting start of a phase 2 trial before end CY20. Ongoing pre-clinical studies for the topical LOX asset targeting scarring is expected to complete in 2QCY20. We do not assign any value to these assets currently, however they represent future upside on progression into mid stage trials.

Strong cash position: PXS' had cash at end of 3QFY20 of ~A$20.3m, which along with the ~$2.8m R&D rebate expected for FY20, in our view, provides PXS ~12 months cash runway. A US$10m Milestone from Chiesi for Bronchitol in 1QCY21 and upfront from a LOXL-2 deal in 2HCY20 should further extend this cash runway. The company has a modest debt (related to finance lease) of A$8.6m. PXS is now focused on accelerating the development of its earlier stage LOX systemic and topical assets for myelofibrosis and scarring. PXS' expects to move these LOX assets through Phase 2A/2B development (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 medium 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 for DR (as it has already done for NASH) PXS' ability to generate revenue from this 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. Chiesi has recently resubmitted its NDA addressing the matters detailed in the CRL issued by the FDA in June'19. 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 4QCY20. We currently assign a 90% probability of success to US sales of Bronchitol.
- **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 LOXL-2 drugs, 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 since in LOXL-2's case 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 is likely to impact PXS' funding position in the short term. PXS has cash of A$20.3m and debt related to finance lease of A$8.6m. This along with the expected R&D rebate for FY20 should provide ~12 months cash runway. However with the US$10m milestone from Chiesi now expected only in 1QCY21, PXS may need to raise additional capital to fund a Phase 2 myelofibrosis trial during this period 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 22 May 2020

Recommendation	Buy, Speculative
Price	$0.09
Valuation	$0.19

Table 6 - Financial summary

Pharmaxis Ltd (PXS) — **Share price (A$)** **$0.090**
As at 22 May 2020 — **Market cap (A$m)** **35.6**

Profit and Loss

Y/e June 30 (A$m)	2018A	2019A	2020E	2021E	2022E
Product Sales Revenues	6.1	5.7	6.3	8.1	12.1
Other Revenue (commercial)	43.5	0.0	0.0	31.3	3.5
Other Income	0.7	6.5	3.5	0.5	3.5
Total Revenue	**50.2**	**12.2**	**9.8**	**39.9**	**19.2**
EBITDA	**11.5**	**-15.7**	**-14.3**	**14.1**	**-7.0**
Depreciation & Amortisation	-3.1	-2.6	-3.2	-3.2	-3.2
EBIT	**8.4**	**-18.3**	**-17.5**	**10.9**	**-10.2**
Net interest & Other Income/(Expense)	-0.8	-0.7	-3.7	-0.1	0.1
Pre-tax profit	**7.6**	**-19.0**	**-21.2**	**10.8**	**-10.1**
Tax	0.0	0.0	0.0	0.0	0.0
Net profit (loss) normalised	**7.6**	**-19.0**	**-21.2**	**10.8**	**-10.1**
Abnormal items	-1.2	-1.1	-1.0	-1.1	-1.2
Reported Net profit (loss)	**6.4**	**-20.1**	**-22.1**	**9.7**	**-11.3**

Cashflow

Y/e June 30 (A$m)	2018A	2019A	2020E	2021E	2022E
Reported NPAT	6.4	-20.1	-22.1	9.7	-11.3
Non-cash items	5.6	5.6	8.2	4.7	4.7
Net change in Working capital	0.1	-5.4	1.1	3.8	-3.0
Operating cashflow	**12.2**	**-19.8**	**-12.8**	**18.3**	**-9.6**
Capex	-0.8	-0.6	-0.3	-0.5	-0.5
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**	**-0.7**	**-0.9**	**-0.9**
Change in borrowings	-1.5	-1.6	-2.2	-2.2	-2.4
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	-0.6	-0.9
Financing cashflow	**-1.8**	**20.8**	**-2.5**	**-2.8**	**-3.3**
Net change in cash	**9.6**	**0.1**	**-16.0**	**14.7**	**-13.7**
Cash at end of period*	31.1	31.1	15.1	29.8	16.0
* Includes effect of exchange rate fluctuations on cash balance					
Free cash flow (op. CF less capex and intangibles)	**11.3**	**-20.8**	**-13.5**	**17.4**	**-10.4**

Balance sheet

Y/e June 30 (A$m)	2018A	2019A	2020E	2021E	2022E
Cash	31.1	31.1	15.1	29.8	16.0
Current receivables	2.4	7.2	4.3	1.5	4.5
Inventories	2.4	2.1	2.2	2.3	2.4
Other current assets	0.1	0.1	0.1	0.1	0.1
Current assets	**36.0**	**40.6**	**21.8**	**33.8**	**23.1**
PPE	12.5	10.3	9.3	6.4	3.5
Non-current receivables	1.2	1.1	1.3	1.3	1.3
Intangible assets	0.4	0.8	1.0	1.3	1.6
Other non-current assets	0.0	0.0	0.0	0.0	0.0
Non-current assets	**14.1**	**12.1**	**11.7**	**9.1**	**6.5**
Total assets	**50.1**	**52.7**	**33.4**	**42.8**	**29.6**
Payables	5.6	4.8	2.8	3.8	3.8
Debt	8.3	7.2	8.2	6.4	4.3
Provisions	1.0	1.1	1.2	1.3	1.4
Financial liabilities (Novaquest financing agreement)	22.8	23.6	26.7	26.2	25.3
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**	**39.8**	**38.4**	**35.3**
Net Assets	**11.1**	**14.8**	**-6.4**	**4.4**	**-5.7**
Shareholders' equity	344.6	367.3	367.3	367.3	367.3
Reserves	20.7	21.8	22.7	23.8	24.9
Retained earnings/(losses)	-354.2	-374.2	-396.4	-386.6	-397.9
Total shareholders equity	**11.1**	**14.8**	**-6.4**	**4.4**	**-5.7**

Valuation data

Y/e June 30	2018A	2019A	2020E	2021E	2022E
Net profit -normalised (A$m)	7.6	-19.0	-21.2	10.8	-10.1
EPS - normalised (c)	2.4	-4.8	-5.2	2.7	-2.5
EPS growth (%)	NM	N/A	N/A	NM	N/A
P/E ratio (x)	3.8	N/A	N/A	3.4	N/A
FCFPS (c)	3.5	-5.3	-3.4	4.4	-2.6
Price/FCF (x)	2.5	-1.7	-2.6	2.0	-3.4
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	2.1	-1.5	-1.7	1.7	-3.4
EV/EBIT	2.8	-1.3	-1.4	2.2	-2.3

Share price now (A$)	$0.090
Valuation (A$):	$0.19
Premium (discount) to price	111.1%
Recommendation:	Buy
Risk Rating	Speculative

Profitability ratios

Y/e June 30	2018A	2019A	2020E	2021E	2022E
EBITDA margin (%)	22.9%	N/A	N/A	35.2%	N/A
EBIT margin (%)	16.7%	N/A	N/A	27.2%	N/A
Return on assets (%)	15.2%	-36.0%	-63.4%	25.2%	-34.2%
Return on equity (%)	68.5%	NM	NM	244.7%	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	-6.9	-23.3	-11.7
Net debt/equity (%)	N/A	N/A	N/A	N/A	N/A
Net interest cover (x)	NM	N/A	NM	-23.4	N/A
Current ratio (x)	4.4	5.0	3.2	4.2	2.8

Segmentals

Y/e June 30	2018A	2019A	2020E	2021E	2022E
Bronchitol and Aridol					
Product Sales	6.1	5.7	6.3	8.1	12.1
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**	**6.4**	**20.7**	**12.2**
EBITDA	**-3.8**	**-5.0**	**-4.5**	**8.8**	**0.1**
New Drug Development					
Product Sales	0.0	0.0	0.0	0.0	0.0
Other revenue (Milestone+license+royalty)	42.1	0.0	0.0	18.8	3.5
Other income (R&D tax incentive etc.)	0.2	6.0	3.1	0.0	3.0
Total Revenues	**42.3**	**6.0**	**3.1**	**18.8**	**6.5**
EBITDA	**28.8**	**-6.8**	**-6.5**	**8.7**	**-3.6**
Corporate					
Other income	**0.5**	**0.5**	**0.4**	**0.5**	**0.5**
EBITDA	**-13.5**	**-3.9**	**-3.4**	**-3.4**	**-3.4**
Total Company					
Revenues	**50.2**	**12.2**	**9.8**	**39.9**	**19.2**
EBITDA	**11.5**	**-15.7**	**-14.3**	**14.1**	**-7.0**

Interims

Y/e June 30 (A$m)	2H18A	1H19A	2H19A	1H20A	2H20E
Revenue	19.1	2.5	9.7	3.8	6.0
EBITDA	3.7	-9.8	-5.8	-8.0	-6.3
Depreciation & Amortisation	-1.5	-1.3	-1.3	-1.6	-1.6
EBIT	**2.2**	**-11.1**	**-7.2**	**-9.6**	**-7.9**
Net interest & Other Expense	-1.1	-0.8	0.1	-0.2	-3.5
Pre-tax profit	1.1	-11.9	-7.1	-9.8	-11.4
Tax	0.0	0.0	0.0	0.0	0.0
Net Profit (loss) - normalised	**1.1**	**-11.9**	**-7.1**	**-9.8**	**-11.4**
Net Profit (loss) - reported	0.5	-12.6	-7.5	-10.3	-11.8

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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