BELL POTTER

Speculative
See Key Risks on Page 11 & Biotechnology Risk Warning on Page 13
Speculative securities may not be suitable for Retail clients

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Pharmaxis Ltd. (PXS)

Key catalysts expected in 4QCY20

Bronchitol approaching key inflexion point – FDA approval

FY20 unaudited revenue was ahead of BPe, driven by R&D tax rebate and higher Bronchitol sales. PXS expects this segment to become profitable from FY21 following US approval of Bronchitol. Excluding the US$10m milestone receivable from Chiesi on FDA approval, we forecast this segment to become profitable in FY22 on our risk-adjusted revenue forecasts for US. PXS has successfully negotiated bringing forward part of the milestone due from Chiesi on product shipment to now be triggered by FDA approval on 1st Nov'20 (US$7m now due in 4QCY20 and US$3m in 1QCY21). Cash at end of 4QFY20 of $14.8m (+$4.9m R&D rebate for FY20), gives ~12 months runway.

Turnaround prospects strong in 4QCY20

PXS' current price is largely supported by our valuation for the Bronchitol + Aridol segment, with the market ascribing minimal value to its drug development business. That business is approaching key catalysts in 4QCY20 which could re-rate the stock. These include a) decision by partner Boehringer Ingelheim on further development of BI_1467335 for Diabetic Retinopathy. Market assumes very low probability as dose related safety risk had prompted BI to stop development of the same drug for NASH last year. We believe given the dose restrictions on BI to move this forward, strength of efficacy signal in Phase 2A will be important; b) a partnering deal for LOXL-2 program. This has taken much longer than expected. However, we believe additional data generated by PXS in 1QCY20 has re-energised interest in the asset and partnering negotiations and expect a deal could be finalised before end of 4QCY20 and c) PXS will start a Phase 1/2 trial with its new pan LOX-inhibitor in myelofibrosis in Dec'20. We do not ascribe any value to it as yet, but intend to do so once its closer to phase 2.

Valuation lifted to $0.20, Retain Buy (speculative)

Revisions to our model led to a large decrease in our FY21 NPAT forecast and ~11% decrease in our FY22 Net loss forecast, driven by revised assumptions around the LOXL-2 deal (probability of success, size of upfront and timing of milestones), offset by higher Bronchitol sales and milestone revenue and lower opex est. Earning changes and rolling forward our DCF model have led to a modest lift in our valuation for PXS to A$0.20/sh (was A$0.19/sh). We retain Buy (Spec).

Recommendation
Buy (unchanged)
Price
$0.098
Valuation
$0.20 (previously $0.19)
Risk
Speculative

GICS Sector
Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**104.1%**
Dividend yield	**0.0%**
Total expected return	**104.1%**
Company Data & Ratios	
Enterprise value	**$32.1m**
Market cap	**$38.7m**
Issued capital	**395.2m**
Free float	**98.7%**
Avg. daily val. (52wk)	**$61,767**
12 month price range	**$0.053- $0.285**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.07	0.09	0.23
Absolute (%)	23.19	-3.41	-62.22
Rel market (%)	21.43	-15.47	-50.96

Absolute Price

SOURCE: IRESS

Earnings Forecast

Year end 30th June	2019A	2020E	2021E	2022E	2023E
Revenue (A$m)	12.2	12.7	31.4	20.2	17.7
EBITDA (A$m)	-15.7	-12.1	6.2	-5.7	-4.4
NPAT (reported) (A$m)	-20.1	-13.9	1.9	-10.0	-8.7
NPAT (normalised) (A$m)	-19.0	-13.4	2.8	-8.9	-7.7
EPS (reported) (cps)	-5.1	-3.4	0.5	-2.5	-2.2
EPS (adjusted) (cps)	-4.8	-3.3	0.7	-2.2	-1.9
EPS growth (%)	N/A	N/A	NM	N/A	N/A
PER (x)	N/A	N/A	14.1	N/A	N/A
EV/EBITDA (x)	-2.1	-2.7	5.2	-5.6	-7.3
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 (%)	-128.1%	NM	66.4%	NM	62.2%

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

FY20 – Result Summary

A summary of the reported FY20 result based on unaudited income statement summary as per PXS' quarterly update is shown in the Table below:

Table 1 – FY20 (unaudited) result summary

	Result vs PCP			Result vs Forecast		Comments
	FY19A	FY20A	% change	FY20E	Variance (%)	
Revenues	**12.2**	**12.7**	**4%**	**9.8**	**29%**	Revenue higher than our forecast due to higher Bronchitol sales and higher R&D tax rebate
Total operating costs	**27.8**	**24.7**	**-11%**	**24.1**	**3%**	Opex 3% higher than our forecast driven primarily by higher drug development cost on PXS' pipeline assets and other expenses, partially offset by lower employee costs
EBITDA	**-15.7**	**-12.1**	**-23%**	**-14.3**	**-16%**	**EBITDA loss lower than forecast driven by higher revenue partially offset by higher opex**
Depreciation and Amortisation	-2.6	-3.2	24%	-3.2	0%	D&A in-line
EBIT	**-18.3**	**-15.3**	-16%	**-17.5**	**-13%**	**Lower EBIT loss**
Net Interest Income/(expense)	0.4	-0.2	NM	-0.2	-6%	Lower Interest income
Other Income/(expense)	-1.1	2.2	292%	-3.4	-163%	Fx gain of $2.7m and $2.6m credit on reduction in NovaQuest Financing liability in 4Q, offset loss recorded at March end
Pretax Income (Loss)	-19.0	-13.4	-29%	-21.2	-37%	
Net Income (Loss) after tax - normalised	**-19.0**	**-13.4**	**-29%**	**-21.2**	**-37%**	**Lower Net loss with increase in variance from EBIT due to non-cash items (FX gain and reduction in NovaQuest financing liability)**
Diluted EPS/Share (cents)	-4.84	-3.31	-32%	-5.24	-37%	
Reported Net Income (loss)	**-20.1**	**-13.9**	**-30%**	**-22.1**	**-37%**	Reported Net loss lower than our forecasts. Includes share based compensation of $0.56m
Reported Diluted EPS/sh (cents)	-5.12	-3.45	-33%	-5.47	-37%	

NOTE: FY20A EPS/SHARE NUMBERS ARE ESTIMATES SUBJECT TO CHANGES WHEN COMPANY FILES ITS AUDITED FINANCIALS LATER IN AUG'20.

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

The key highlights from the result were:

- **Significant beat in revenue:** Total revenue of $12.7m (up 4% y/y) was significantly ahead of our forecast of $9.8m and was driven by higher Bronchitol and Aridol segment sales ($7m vs. BPe $6.3m) as well as higher other income (which included a higher R&D tax accrual of $5.2m vs. BPe $3.1m). The 4% increase in overall revenues over pcp was mainly driven by higher Bronchitol sales, partially offset by lower R&D tax rebate booked in FY20. Overall Bronchitol and Aridol product sales of $7.0m in FY20 was up ~24% over pcp, with increase in Bronchitol sales partially offset by lower Aridol sales.

  Aridol sales were largely in-line with BPe, however were down ~43% over pcp with COVID-19 impacting sales across most markets in 2H20 and due to no order for US in FY20 (US sales were nil in FY20 vs. ~$1m in FY19). Aridol sales in South Korea were particularly weak (down ~48% over pcp).

  Bronchitol sales were higher than our forecast ($5.3m vs. BPe $4.6m) driven by higher revenue from both Western Europe and Russia, with large orders shipped to distributors in 4QFY20. The ~105% increase in Bronchitol sales over pcp was driven by higher number of orders from Chiesi for Germany, UK and Italy and higher revenue from Russia in FY20. We note that on a gross basis revenue from Russia in FY20 of $1.2m doubled over pcp. On a net basis revenue from Russia in FY20 was even higher (FY19 revenue from Russia was $0.6m, however was reduced by a credit note of ~$0.4m related to expired product which was a result of delay in timing of receiving national reimbursement vs. original expectations.)

- **Operating expenses were 3% higher than expected:** Total opex of $24.7m (down 11% y/y) were 4% higher than our forecast of $24.1m. This was driven by higher drug discovery costs related to PXS pipeline assets (we did not have any spend on the SSAO combo program in our forecasts while PXS spent $0.5m on it), modestly higher spend on the pan LOX assets, and modestly higher clinical trial costs, partially offset by lower employee costs. The decrease over pcp was primarily driven by lower drug discovery costs related to the LOXL-2 and the LOX assets in FY20.

- **EBITDA loss lower than our forecast:** EBITDA loss of $12.1m was 16% lower than our forecast loss of $14.3m and was driven by higher revenue, partially offset by higher opex. The lower loss over pcp was driven primarily by lower opex and modestly higher revenue.
- **Underlying and Reported Net Loss lower than our forecast:** Underlying Net loss of $13.4m was lower than our forecast loss of $21.2m and was driven by higher revenue. The variance at the Net loss line was higher than the EBITDA loss line due to non-cash items (Fx gain and reduction in NovaQuest financing liability). Reported Net loss was $13.9m (including $0.56m share based compensation expense), which was also lower than our forecast loss.
- **~12 months cash runway:** PXS' had cash at end of 4QFY20 of ~A$14.8m, which along with the ~$4.9m R&D rebate expected for FY20, in our view, provides PXS ~12 months cash runway. A US$10m Milestone from Chiesi for Bronchitol (US$7m in 4QCY20 and US$3m in 1QCY21) and upfront from a LOXL-2 deal in 4QCY20 should further extend this cash runway. The company has a modest debt (related to finance lease) of A$8.2m.

Bronchitol milestone from Chiesi brought forward to FDA approval

PXS has successfully negotiated with Chiesi to bring forward the timing of its milestone due following FDA approval by Bronchitol.

Earlier the entire US$10m milestone was payable on PXS shipping product to Chiesi for US launch which was expected in 1QCY21.

Now, PXS will get US$7m of the milestone following FDA approval in 4QCY20 (FDA decision expected on 1st Nov'20) and the balance US$3m is expected to be received in 1QCY21 once the product gets shipped to Chiesi.

Chiesi are preparing for launch of the product in US in 2QCY21, assuming FDA approval is received on 1st Nov'20.

We view this development as extremely positive. It will reduce the pressure on PXS' balance sheet, especially given the fact that PXS intends to start a Phase 2 myelofibrosis trial with its pan LOX inhibitor in Dec'20.

It also highlights to us the strong relationship PXS and Chiesi share. We note that apart from US, Chiesi also distributes Bronchitol in ~11 other countries in EU (7 of which are recently added to Chiesi's distribution list).

FDA approval by Bronchitol will be key driver for the Bronchitol and Aridol segment moving to profitability. PXS have flagged that they will use the FDA approval for Bronchitol as the launch pad to start discussions with partners around the best way to reorganise the business. At this stage we do not know what form these discussions would take, however we do believe that FDA approval will open up strategic opportunities for PXS to evaluate.

Orphan Drug Designation received for PXS-5505 for myelofibrosis

The US FDA has granted Orphan drug designation to PXS' Phase 1 asset PXS-5505 for the treatment of myelofibrosis (a bone marrow cancer). This designation is of strategic importance.

Orphan drug status is granted in the US for drugs targeting rare diseases which affect less than 200,000 patients. It confers benefits such as extended market exclusivity (7 years post approval), FDA PDUFA application fees exemption and Tax credits. Orphan drugs target small number of patients but can command high prices and gives rise to an

expectation of some degree of flexibility from the FDA in terms of number and size of clinical trials required to satisfy approval requirements.

PXS-5505 is a pan-LOX inhibitor which broadly inhibits all the LOX family of enzymes. Phase 1 data which completed in 1QCY20 was positive showing good PK profile and dose related strong inhibition of all LOX family of enzymes. PXS has also generated positive results in preclinical models of myelofibrosis and pancreatic cancer showing reduction in fibrosis and has completed 3 month and 6 month toxicology studies.

The myelofibrosis market is estimated to be >US$1bn and PXS believes its mechanism of action will differentiate it from the current approved standard of care drugs (JAK inhibitors).

The company is now targeting a 6-month Phase 1/2 study in myelofibrosis. PXS has filed an IND with the FDA last month with clearance expected by end of Aug'20. They intend to start recruitment in the trial in Dec'20.

The trial is likely to have a dose escalation phase followed by an open label 6-month dosing study to assess safety and efficacy of the drug as a monotherapy in myelofibrosis patients (not on SOC JAK inhibitors).

We currently don't put a value to PXS-5505 as we do not have visibility on the Phase 2 trial design or positioning of the drug in the myelofibrosis market.

PXS will provide an update to the market once in clinical trial protocol gets approved by the FDA. We expect to get more details around the trial design, size and expected cost as well as endpoints and positioning of the drug following IND approval.

We intend to include PXS-5505 in our model for myelofibrosis as the company gets closer to starting its Phase 2 and we get visibility on the above details on the clinical trial following the IND approval.

Earnings and Valuation Changes

We have reviewed our assumptions for PXS and made adjustments to our forecasts based on its announcement on bringing forward the timeline for part of the Chiesi milestone from Bronchitol and its quarterly update filed on the ASX, which have impacted earnings and valuation.

Key changes to our modelling assumptions

- Earlier we had assumed the entire US$10m milestone from Chiesi was receivable in 1QCY21 on product shipment for launch of Bronchitol in US. PXS has successfully negotiated US$7m of this milestone to be brought forward to 4QCY20, which will now be payable on FDA approval of Bronchitol for cystic fibrosis in the US. FDA decision is expected on 1st Nov'20.
- We continue to risk adjust our Bronchitol US sales forecasts and milestones by 90% (given FDA approval decision is pending). However, currency revisions have modestly increased the A$ value we model for the US$10m milestone expected from Chiesi (US$7m in 4QCY20 and US$3m in 1QCY21).
- We have increased our Bronchitol sales forecast for FY21 onwards. This was primarily driven by an increase in our revenue forecasts for Russia. Our forecasts earlier were conservative as we were waiting to see the increase in traction in that market following wider reimbursement. In FY20 gross Bronchitol sales in Russia doubled over pcp. We now expect strong double digit growth in revenue from this market. We have also increased our Bronchitol US sales forecast for FY21 and reduced it for FY22, primarily expecting a higher stocking order on launch.
- 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 March. Monthly sales in the last 4 months of FY20 on average have decreased by 50% from pcp. South Korea sales were ~48% below pcp in FY20. While restrictions are likely to ease, we expect FY21 will continue to be impacted. We have further lowered our Aridol sales forecast for Europe and South Korea for FY21 and FY22. However, we note that we expect an order from the US from Methapharm in FY21 (vs. nil in FY20), which would offset the declines in other markets and overall we expect Aridol sales in FY21 to be ~$0.2m up on pcp.
- At this stage we continue to expect that a deal for LOXL-2 asset gets finalised in 2HCY20, however it is looking more likely to be later in 4QCY20. Based on this we now assume that a Phase 2 trial by the potential partner is likely to start in 1HFY22 (vs. 2HFY21). Hence we have moved our assumed milestone on Phase 2 initiation from FY21 to FY22.
- The upfront payments for some of the more recent NASH deals have been in the range of US$10m to US$40m for assets in pre-clinical to Phase 2 at the time of partnering. Based on the extended time the partnering process has taken, we believe PXS' is now negotiating from a less stronger position and hence believe it to be prudent to assume a more backended deal than we previously forecast. We continue to assume a US$700 global deal, but now assume a US$30m upfront (was. US$50m) and expect sales milestones of US$200m (was US$180m).
- We have also reduced the probability of success (POS) assigned to the LOXL-2 asset to 18% (was 22%) given its dependance on a partner to start Phase 2 trials. We will now assign a higher POS once a partner actually starts a Phase 2 trial. We risk adjust all milestones by 18% as well. We assign a 25% risk adjustment to the upfront payment, given the higher probability of a deal materialising.

- Based on our revised revenue forecasts we don't expect an R&D rebate in FY22, instead have moved it to FY23.
- Changes to our opex forecast for FY21-FY22 was not material. We have reduced our opex forecast for FY21 by ~3% and for FY22 by 1%, driven by modestly reduced employee costs.
- Our interest income forecasts have reduced due to lower cash balances.
- We have updated our model with revised BPe USD/AUD and EUR/AUD currency assumptions for FY21-23.
- We have rolled forward our DCF model.

We value PXS at $0.20/sh

Revisions to our model led to a large decrease in our NPAT forecast for FY21, which was partially offset by a 11% decrease in our Net loss forecast for FY22, driven primarily by moving timeline for a Phase 2A initiation milestone for LOXL-2 asset to FY22 (was FY21), assuming more backended deal (smaller upfront of US$30m vs. US$50m) and assigning a lower probability of success to it (18% vs. 22%), partially offset by higher Bronchitol sales and milestone revenue from Chiesi and a reduction in our opex forecasts. We have also moved an estimated R&D rebate from FY22 to FY23. Earning changes, rolling forward of our DCF model and revised currency estimates have led to a modest increase in our valuation for PXS to A$0.20/sh (was A$0.19/sh). **We retain Buy (Spec) on PXS.**

Table 2 - Key Changes to our FY21-22 Forecasts

	FY2021E			FY2022E		
	Old	New	Change (%)	Old	New	Change (%)
Revenues	39.9	31.4	-21%	19.2	20.2	5%
Interest Income	0.4	0.3	-27%	0.4	0.3	-33%
Operating Costs	25.9	25.2	-3%	26.2	25.9	-1%
EBITDA	14.1	6.2	-56%	-7.0	-5.7	-19%
EBIT	10.9	3.0	-72%	-10.2	-8.9	-13%
NPAT (adjusted)	10.8	2.8	-74%	-10.1	-8.9	-12%
Adjusted Diluted EPS	2.7	0.7	-74%	-2.5	-2.2	-12%
NPAT (reported)	9.7	1.9	-81%	-11.3	-10.0	-11%
Reported Diluted EPS	2.4	0.5	-81%	-2.8	-2.5	-11%

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 3 - Summary of Valuation

Forecasts	Base case
Enterprise value from DCF (AUDm)	75.4
Add: Current Cash (AUDm)	14.8
Less: Current Debt	8.2
Equity value (AUDm)	82.1
Total diluted shares (million)	413.9
Value per share (AUD)	**$0.20**
Current Share price (AUD)	$0.098
Expected Capital Growth	104.1%

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	$28	**$0.07**	34.3%	Bronchitol - US (90%)	Marketed for Aridol, Marketed for Bronchitol (Ex-US and Canada)
New Drug Development	$74	**$0.18**	90.0%	BI_1467335 (DR - 23.5%), LOXL-2 (NASH -18.0%)	BI_1467335 for DR (Phase 2A) and LOXL-2 (Phase 1 complete)
Corporate/Non-Allocated	($27)	**-$0.06**	-32.3%	NA	NA
Reported Cash	$15	**$0.04**	18.0%	NA	NA
Reported Debt	($8)	**-$0.02**	-9.9%	NA	NA
Equity Value	**$82.1**	**$0.20**	**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	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	18.0%

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

Table 6 – 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	30	470	200	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 will allow us to assign a higher probability of success and therefore will lead to material upgrades in our numbers. Similarly, we currently assign an 18.0% 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$200m 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 pan 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 MAD (multiple ascending dose) part of the study was completed 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 PXS-5505 in myelofibrosis and pancreatic cancer in preclinical models and has completed 3 month and 6 month toxicology studies in parallel with the Phase 1 trial in healthy volunteers. IND to start Phase 1/2 (in myelofibrosis, a bone marrow cancer) has been filed with the FDA and PXS intends to initiate recruitment in 4QCY20. PXS-5505 has also been granted orphan drug designation from the FDA for myelofibrosis. PXS' estimate that the myelofibrosis market is valued in excess of US$1bn per annum.

  Preclinical development for the topical asset PXS-6302 was completed in 2QCY20, including initial stability studies of the formulation. Investigator initiated studies to assess the drug in burn related scars and pre-existing scars are being discussed with an Australia based hospitals' burn unit and expected to start in 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 aaproval and launch milestones 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 now model revenue from Canada. Aridol received approval in Canada in June 2019 and supplied its first (launch) order to Methapharm for Canada in 2QFY20.

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. 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 is approaching a key inflexion point with the US approval for Bronchitol expected on 1st Nov'20. US approval will see the segment generate cash (milestone from partner Chiesi) and become profitable.

INVESTMENT STRATEGY

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

$0.20 valuation: We value PXS using a risk adjusted DCF at $0.20. The valuation is approximately a 104.1% premium to the previous closing share price of $0.098/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. We believe current price levels are not attributing much value to PXS' drug development business which is approaching key inflexion points in 4QCY20 which could drive a turnaround for PXS. These include: a) Results from phase 2A trials for BI_1467335 partnered with BI in Diabetic Retinopathy and BI's commercial decision regarding further development of the asset in 4QCY20; 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. PXS has been in partnering discussions for a while (since Jan'19) which have taken longer than it initially expected. The discussions and due diligence by interested parties are ongoing and we now expect a conclusion of the partnering process in 4QCY20; and c) Initiation of Phase 1/2 myelofibrosis trial with PXS-5505 in Dec'20, for which we currently do not assign any value. Also in 4QCY20 we expect FDA approval decision on Bronchitol, which will trigger a US$7m milestone from PXS' partner Chiesi in 4QCY20 and another US$3m 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. NASH is now the fastest growing reason for a liver transplant in the US and is expected to surpass Hepatitis C Virus (HCV) as the leading cause of liver transplants. 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. However, we note that a string of keenly awaited trials have been unsuccessful and the first of the drugs awaiting approval was recently knocked back by the FDA. There have been a number of high value deals in this space and active companies are looking to license or acquire to build a portfolio of assets targeting different stages of NASH. Average deal sizes are ~US$860m, however some have also been over $1bn.

Scarcity of anti-fibrotic assets in development for NASH: Drugs targeting NASH 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 (~A$292m) in Phase 3 initiation, filing, approval and pricing 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' oral pan LOX inhibitor PXS-5505 is targeting the bone marrow cancer myelofibrosis with an estimated market value of >$1bn per year. Phase 1 trial is complete and PXS has been granted orphan drug designation by the FDA. IND for a Phase 1/2 trial has been submitted to the FDA (approval expected later in Aug'20), with trial expected to start in 4QCY20. Pre-clinical studies for the topical LOX asset PXS-6302 targeting scarring is now complete. Investigator initiated clinical studies to assess safety and efficacy of the drug in burns related scars and pre-existing scars is expected to start in 2HCY20. 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 4QFY20 of ~A$14.8m, which along with the ~$4.9m R&D rebate expected for FY20, in our view, provides PXS ~12 months cash runway. A US$10m Milestone from Chiesi for Bronchitol (US$7m in 4QCY20 and US$3m in 1QCY21) and upfront from a LOXL-2 deal in 4QCY20 should further extend this cash runway. The company has a modest debt (related to finance lease) of A$8.2m.

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 its development for DR (as it has already done for NASH) it will have a material adverse effect on our valuation.
- **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:** Bronchitol and Aridol, (PXS' currently marketed products) account for ~34% of our current valuation for PXS. US Bronchitol sales are the key driver for revenue and the segment achieving profitability. Therefore if FDA does not approve Bronchitol, it will adversely affect our valuation. FDA decision is expected on 1st Nov'20. 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). 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$14.8m and debt related to finance lease of A$8.2m. This along with the expected R&D rebate for FY20 should provide ~12 months cash runway. A US$10m milestone from Chiesi is due over 4QCY20/1QCY21. However, dependent on the size and cost of a phase 2 myelofibrosis trial, PXS may need to raise additional capital to fund it should there be delays in partnering its LOXL-2 asset.

Pharmaxis Ltd.
as at 5 August 2020

Recommendation	Buy, Speculative
Price	$0.098
Valuation	$0.20

Table 7 - Financial summary

Pharmaxis Ltd (PXS) — **Share price (A$)** **$0.098**
As at 5 August 2020 — **Market cap (A$m)** **38.7**

Profit and Loss

Y/e June 30 (A$m)	2019A	2020E	2021E	2022E	2023E
Product Sales Revenues	5.7	7.0	9.1	12.3	14.1
Other Revenue (commercial)	0.0	0.0	21.8	7.4	0.0
Other Income	6.5	5.6	0.5	0.5	3.5
Total Revenue	**12.2**	**12.7**	**31.4**	**20.2**	**17.7**
EBITDA	**-15.7**	**-12.1**	**6.2**	**-5.7**	**-4.4**
Depreciation & Amortisation	-2.6	-3.2	-3.2	-3.2	-3.2
EBIT	**-18.3**	**-15.3**	**3.0**	**-8.9**	**-7.6**
Net interest & Other Income/(Expense)	-0.7	1.9	-0.2	0.0	0.0
Pre-tax profit	**-19.0**	**-13.4**	**2.8**	**-8.9**	**-7.7**
Tax	0.0	0.0	0.0	0.0	0.0
Net profit (loss) normalised	**-19.0**	**-13.4**	**2.8**	**-8.9**	**-7.7**
Abnormal items	-1.1	-0.6	-1.0	-1.1	-1.1
Reported Net profit (loss)	**-20.1**	**-13.9**	**1.9**	**-10.0**	**-8.7**

Cashflow

Y/e June 30 (A$m)	2019A	2020E	2021E	2022E	2023E
Reported NPAT	-20.1	-13.9	1.9	-10.0	-8.7
Non-cash items	5.6	2.2	4.6	4.6	4.4
Net change in Working capital	-5.4	-1.6	4.6	-0.2	-3.2
Operating cashflow	**-19.8**	**-13.3**	**11.1**	**-5.6**	**-7.5**
Capex	-0.6	-0.3	-0.3	-0.5	-0.7
Investments	0.0	0.0	0.0	0.0	0.0
Investments in intangible assets	-0.4	-0.3	-0.3	-0.3	-0.4
Other investing cash flow	0.0	0.0	0.0	0.0	0.0
Investing cashflow	**-1.0**	**-0.6**	**-0.6**	**-0.8**	**-1.1**
Change in borrowings	-1.6	-2.2	-2.2	-2.4	-2.5
Equity issued	22.7	0.0	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	-0.3	-0.3	-0.7	-0.8	-1.0
Financing cashflow	**20.8**	**-2.5**	**-2.9**	**-3.2**	**-3.5**
Net change in cash	**0.1**	**-16.4**	**7.7**	**-9.6**	**-12.1**
Cash at end of period*	31.1	14.8	22.4	12.9	0.8
* Includes effect of exchange rate fluctuations on cash balance					
Free cash flow (op. CF less capex and intangibles)	**-20.8**	**-13.9**	**10.5**	**-6.4**	**-8.6**

Balance sheet

Y/e June 30 (A$m)	2019A	2020E	2021E	2022E	2023E
Cash	31.1	14.8	22.4	12.9	0.8
Current receivables	7.2	6.4	1.7	1.8	4.9
Inventories	2.1	2.6	2.8	3.0	3.2
Other current assets	0.1	0.1	0.1	0.1	0.1
Current assets	**40.6**	**23.9**	**27.1**	**17.8**	**9.0**
PPE	10.3	9.3	6.3	3.4	0.7
Non-current receivables	1.1	1.2	1.2	1.2	1.2
Intangible assets	0.8	0.9	1.1	1.3	1.6
Other non-current assets	0.0	0.0	0.0	0.0	0.0
Non-current assets	**12.1**	**11.5**	**8.6**	**5.9**	**3.6**
Total assets	**52.7**	**35.4**	**35.7**	**23.7**	**12.6**
Payables	4.8	2.5	2.5	2.5	2.5
Debt	7.2	8.2	6.4	4.3	2.0
Provisions	1.1	1.2	1.3	1.4	1.5
Financial liabilities (Novaquest financing agreement)	23.6	21.2	20.5	19.8	18.8
Deferred Lease Incentive	1.1	0.9	0.7	0.4	0.2
Other liabilities	0.0	0.0	0.0	0.0	0.0
Total liabilities	**37.9**	**34.0**	**31.4**	**28.4**	**24.9**
Net Assets	**14.8**	**1.4**	**4.3**	**-4.7**	**-12.4**
Shareholders' equity	367.3	367.3	367.3	367.3	367.3
Reserves	21.8	22.3	23.3	24.3	25.4
Retained earnings/(losses)	-374.2	-388.2	-386.3	-396.3	-405.1
Total shareholders equity	**14.8**	**1.4**	**4.3**	**-4.7**	**-12.4**

Valuation data

Y/e June 30	2019A	2020E	2021E	2022E	2023E
Net profit -normalised (A$m)	-19.0	-13.4	2.8	-8.9	-7.7
EPS - normalised (c)	-4.8	-3.3	0.7	-2.2	-1.9
EPS growth (%)	N/A	N/A	NM	N/A	N/A
P/E ratio (x)	N/A	N/A	14.1	N/A	N/A
FCFPS (c)	-5.3	-3.5	2.7	-1.6	-2.2
Price/FCF (x)	-1.9	-2.8	3.7	-6.1	-4.5
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	-2.1	-2.7	5.2	-5.6	-7.3
EV/EBIT	-1.8	-2.1	10.7	-3.6	-4.2

Share price now (A$)	$0.098
Valuation (A$):	$0.20
Premium (discount) to price	104.1%
Recommendation:	Buy
Risk Rating	Speculative

Profitability ratios

Y/e June 30	2019A	2020E	2021E	2022E	2023E
EBITDA margin (%)	N/A	N/A	19.8%	N/A	N/A
EBIT margin (%)	N/A	N/A	9.5%	N/A	N/A
Return on assets (%)	-36.0%	-37.8%	7.9%	-37.6%	-61.0%
Return on equity (%)	-128.1%	NM	66.4%	NM	62.2%
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	2019A	2020E	2021E	2022E	2023E
Net debt (cash) (A$m)	-24.0	-6.6	-16.0	-8.6	1.2
Net debt/equity (%)	N/A	N/A	N/A	N/A	N/A
Net interest cover (x)	NM	N/A	NM	N/A	N/A
Current ratio (x)	5.0	3.9	4.0	2.4	1.2

Segmentals

Y/e June 30	2019A	2020E	2021E	2022E	2023E
Bronchitol and Aridol					
Product Sales	5.7	7.0	9.1	12.3	14.1
Other revenue (Clinical trial cost reimbursement)	0.0	0.0	12.9	0.0	0.0
Other income	0.0	0.0	0.0	0.0	0.0
Total Revenues	**5.7**	**7.0**	**22.0**	**12.3**	**14.2**
EBITDA	**-5.0**	**-4.0**	**10.5**	**0.4**	**1.7**
New Drug Development					
Product Sales	0.0	0.0	0.0	0.0	0.0
Other revenue (Milestone+license+royalty)	0.0	0.0	8.9	7.4	0.0
Other income (R&D tax incentive etc.)	6.0	5.2	0.0	0.0	3.0
Total Revenues	**6.0**	**5.2**	**8.9**	**7.4**	**3.0**
EBITDA	**-6.8**	**-5.1**	**-1.1**	**-2.8**	**-2.8**
Corporate					
Other income	**0.5**	**0.5**	**0.5**	**0.5**	**0.5**
EBITDA	**-3.9**	**-3.0**	**-3.3**	**-3.2**	**-3.2**
Total Company					
Revenues	**12.2**	**12.7**	**31.4**	**20.2**	**17.7**
EBITDA	**-15.7**	**-12.1**	**6.2**	**-5.7**	**-4.4**

Interims

Y/e June 30 (A$m)	2H19A	1H20A	2H20E	1H21E	2H21E
Revenue	9.7	3.8	8.9	21.7	9.7
EBITDA	-5.8	-8.0	-4.1	10.2	-4.0
Depreciation & Amortisation	-1.3	-1.6	-1.6	-1.6	-1.6
EBIT	**-7.2**	**-9.6**	**-5.7**	**8.6**	**-5.6**
Net interest & Other Expense	0.1	-0.2	2.1	-0.1	-0.1
Pre-tax profit	-7.1	-9.8	-3.6	8.5	-5.7
Tax	0.0	0.0	0.0	0.0	0.0
Net Profit (loss) - normalised	**-7.1**	**-9.8**	**-3.6**	**8.5**	**-5.7**
Net Profit (loss) - reported	-7.5	-10.3	-3.6	8.0	-6.2

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

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

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

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

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

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

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