BELL POTTER

28 March 2023

Speculative

See key risks on Page 14&15 and Biotechnology Risk Warning on Page 18. Speculative securities may not be suitable for Retail Clients.

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Pharmaxis (PXS)

Pharma's Market

Recommendation
Buy (Transfer of Coverage)
Price
$0.044
Valuation
$0.10 (Transfer of Coverage)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

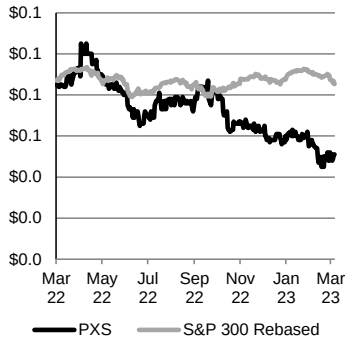
Expected Return	
Capital growth	**127.3%**
Dividend yield	**0.0%**
Total expected return	**127.3%**

Company Data & Ratios	
Enterprise value	**$15.2m**
Market cap	**$31.7m**
Issued capital	**719.6m**
Free float	**99%**
Avg. daily val. (52wk)	**$27,059**
12 month price range	**$0.042-$0.110**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.06	0.06	0.09
Absolute (%)	-7.27	-19.05	-40.00
Rel market (%)	-0.87	-15.49	-38.02

Absolute Price



SOURCE: IRESS

Targeting disease modification in myelofibrosis

Pharmaxis is a clinical stage drug development company and its key asset is PXS-5505 which is currently in Phase 2 trials (n=24) for treatment of myelofibrosis. Interim data (n=6) released in October 2022 showed stability/improvement across specific markers, however, headline data in ~ mid CY23 will provide a more comprehensive understanding of the efficacy and safety of PXS-5505. We expect further studies of PXS-5505 to be in combination with ruxolitinib which is the FDA approved first line therapy. Whilst there are three FDA approved drugs in myelofibrosis, there is currently no disease modifying therapy. PXS-5505 directly targets the fibrotic process within the bone marrow with the potential for improving rates of disease progression. The importance of disease modification is reflected by recent M&A activity: GSK acquiring Sierra Oncology (Momelotinib – Phase 3 Myelofibrosis) for US$1.9b (Apr 2022), MorphoSys acquiring Constellation Pharmaceuticals (Pelabresib – Phase 3 Myelofibrosis) for US$1.7b (Jun 2021) and Merck acquiring Imago Biosciences (Bomedemstat – Phase 2 Myelofibrosis) for US$1.4b (Jan 2023).

Strong drug development pipeline

PXS-5505 is being evaluated in an investigator led study at the University of Rochester for its potential in hepatocellular carcinoma (Phase 1b). PXS-6302 is a topical therapy with the anti-fibrotic mechanism under examination for management of hypertrophic scars, keloids and scar prevention (Phase 1c). PXS-4728 is currently at the Phase 2 stage in idiopathic REM sleep behaviour disorder (iRBD).

Investment View: Buy (Speculative), Valuation $0.10

We transfer coverage of Pharmaxis with a Buy (Speculative) recommendation and valuation of $0.10. The valuation has been generated from a sum-of-the-parts methodology combining the mannitol operations with our risk-adjusted net present valuation of the drug development segment. Pipeline assets (PXS-4728, PXS-6302) may provide further upside to this current valuation.

Earnings Forecast

June Year End A$m	FY22a	FY23e	FY24e	FY25e
Revenues	15.9	20.9	33.9	12.6
EBIT $m	-15.4	-9.7	4.7	-12.2
NPAT $m	-1.9	-9.7	4.7	-12.2
EPS (cps)	-0.40	-1.60	0.66	-1.69
EPS growth %	nm	nm	nm	nm
PER (x)	nm	nm	nm	nm
Price/FCF (x)	-2.5	10.4	6.8	-2.5
EV/EBITDA (x)	nm	nm	nm	nm
Dividend (cps)	0%	0%	0%	0%
Franking	nm	nm	nm	nm
Yield %	nm	nm	nm	nm
ROE %	nm	nm	nm	nm

SOURCE: BELL POTTER SECURITIES ESTIMATES

Investment Thesis

Pharmaxis is clinical stage drug development company that was founded in 1998 and is involved in drug development for inflammatory & fibrotic diseases. There are two operating segments: the mannitol respiratory business (Bronchitol & Aridol) and new drug development including PXS-5505, PXS-6302, PXS-4728 which are in clinical trials. Aridol uses inhaled dry mannitol powder to diagnose & assess severity of asthma and received FDA clearance in 2011. Bronchitol is used in the management of cystic fibrosis by clearing mucus secretions and received EU approval in 2012 and FDA clearance in October 2020. Sales from Aridol & Bronchitol were $7.4m during FY22. The proprietary new drug development pipeline targets fibrotic diseases through pan-Lysyl Oxidase Inhibitors (LOX) and inflammatory diseases through other amine oxidase enzymes such as semicarbizide-sensitive amine oxidase (SSAO). Key pipeline assets include PXS-5505 (oral) for treatment of myelofibrosis & liver/pancreatic diseases, PXS-6302 (topical) in anti-scarring indications (hypertrophic scars, keloids, burns) and PXS-4728 (oral) with its potential role in neuroprotection.

Investment Case

We transfer coverage of Pharmaxis with a Buy (Speculative) recommendation. The key drivers for our valuation and recommendation are:

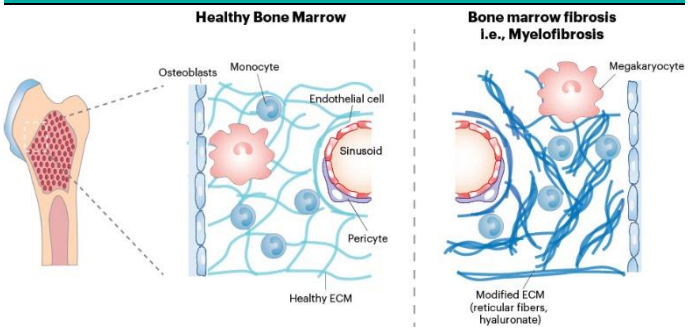
- **PXS-5505 is a Phase 2 asset with disease modifying potential:** Estimated addressable market for myelofibrosis therapy is ~ $1b. Interim data of six patients completing 6 months treatment was released in October 2022. Key findings were 2/6 patients had clinically important symptom improvement, 5/6 patients had stable/improved BM fibrosis ≥ 1 grade and 5/6 patients had stable or improved platelet and/or haemoglobin levels. Further patient data is expected in mid CY23 which will direct progression towards Phase 2b/3 studies.
- **PXS-5505 investigator led hepatocellular carcinoma study:** Phase 1b trial being conducted by University of Rochester. Patient enrolment opened in September 2022 and expected to conclude by H1 CY24. Dose escalation design in 12-18 patients over 12 weeks (Phase 1b) will be followed by selected dose Phase 2a study in ~ 40 patients over 26 weeks. Provides external validation of the interest in PXS-5505 asset and the pan-LOX drug development program.
- **PXS-6302 is a topical therapy with broad range of potential indications:** Preclinical models showed topical application improves scar appearance without compromising tissue strength. Targeted indications may include keloids, hypertrophic scars, burns and scar prevention following surgical procedures. Phase 1c established scar study is currently underway with patient recruitment completed in Q4 CY22. Headline results are expected during H1 CY23.
- **PXS-4728 being evaluated as a potential neuroprotective agent in Parkinson's:** This asset was originally purchased by Boehringer Ingelheim in 2015 for application in Non-Alcoholic Steatohepatitis (NASH) and provided ~ $83m over 5 years. Since it was returned to PXS in CY21 it has been identified as a potential therapeutic target for neuroinflammation. Accordingly, Parkinson's UK signed a funding agreement of ~ $5.3m to run the Phase 2a trial in patients with idiopathic REM sleep behaviour disorder (iRBD). Dosing for this study is expected to commence in H1 CY23.
- **Mannitol respiratory business and drug development pipeline:** Respiratory segment operating independent of the extensive R&D program and expected to be EBITDA positive in the medium-term horizon.

Drug Development Pipeline

Myelofibrosis Overview

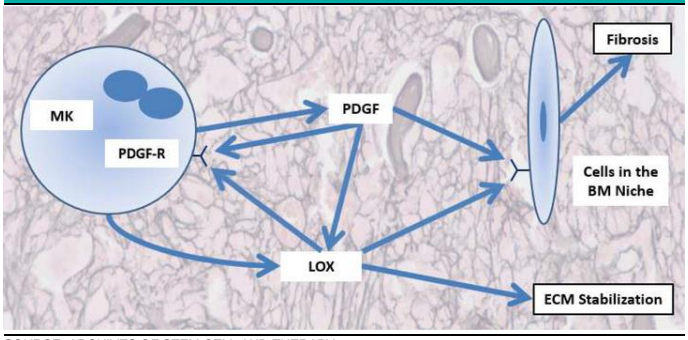
Myelofibrosis is a bone marrow cancer that disrupts the blood cell production process resulting in immune suppression, anaemia and bleeding disorders. Fibrosis of the extracellular matrix within the bone marrow disrupts its function (Figure 1) and Lysyl Oxidase (LOX) plays an integral role in accelerating this process (Figure 2). PXS has previously shown that its novel LOX inhibitors were able to attenuate bone marrow fibrosis in mice models thereby creating a potential therapeutic target.[1]

Figure 1 - Healthy bone marrow vs. myelofibrosis



SOURCE: UNIVERSITY OF PENNSYLVANIA

Figure 2 - Role of LOX in myelofibrosis



SOURCE: ARCHIVES OF STEM CELL AND THERAPY

Current treatments in Myelofibrosis

For myelofibrosis, allogeneic haematopoietic stem cell transplant is the only curative therapy and is reserved for suitable patients based on their cardiac, respiratory, renal and hepatic function. Therapy options for non-transplant candidates aim to manage disease complications such as anaemia, constitutional symptoms, splenomegaly (enlarged spleen) and bone pain.

There are currently three FDA approved therapies all of which are JAK inhibitors (ruxolitinib, pacritinib, fedratinib) which primarily target spleen volume reduction and the constitutional symptoms of disease progression (night sweats, fevers, pruritus). These therapies do not target the underlying mechanism of bone marrow fibrosis. The major concern with JAK inhibitors is the haematological toxicity which combined with myelofibrosis may worsen anaemia, thrombocytopaenia and immunosuppression.

PXS-5505 in Myelofibrosis

PXS-5505 is a pan-LOX inhibitor and the rationale in myelofibrosis is that it will inhibit the ECM protein cross-linking within the bone marrow thereby reducing fibrosis, disease severity and progression.

- The Phase 1c dose escalation study demonstrated the safety profile of PXS-5505 and effective inhibition of LOX and LOXL2 (>90% inhibition).
- The Phase 2a trial is currently underway recruiting a targeted total of 24 patients with 26-week follow-up. Interim results (n=6) released in October 2022 showed 5/6 patients had stable/improved BM fibrosis ≥ 1 grade, 5/6 patients had stable/improved platelet and/or haemoglobin scores and 2/6 patients had clinically signification improvement in symptoms. No spleen volume reduction and no serious adverse events reported.

[1] Leiva, Orly et al. "Novel lysyl oxidase inhibitors attenuate hallmarks of primary myelofibrosis in mice." *International journal of hematology* vol. 110,6 (2019): 699-708. doi:10.1007/s12185-019-02751-6

- Phase 2a Update: 18/24 patients have been recruited. Minimum of 21 patients with 6-month treatment data is required for further analyses. Further results are expected in mid CY23.
- A meeting has been scheduled with the FDA in Q2 CY23 to discuss the results of the Phase 2a study and seek feedback on the next steps in clinical development. This would potentially include progression to Phase 2b (n=150) and commencement of a Phase 2 combined PXS-5505/Ruxolitinib study over CY24-25.
- PXS-5505 was granted Orphan Drug Designation by the FDA in July 2020 and Investigational New Drug (IND) scheme clearance in October 2021.
- A key differentiating factor with PXS-5505 is the stability/improvement in haemoglobin and platelet counts. SOC therapies (JAK Inhibitors) cause haematological toxicity resulting in worsening anaemia and increased bleeding risk in MF patients.

Novel myelofibrosis therapy targets

Table 1 - Overview of Potential Disease Modifying Myelofibrosis Therapies

Therapy	Drug Development Stage	Patient Group	Study Rationale & Endpoints
Imetelstat (Geron) GERN:US	**Phase 3 trial (IMpactMF) - Imetelstat vs. Best Available therapy**	JAK Inhibitor non-responders (n=320)	Phase 2 - Higher dose treatment 41% bone marrow improvement, median overall survival of 28 months (vs. 20 months in lower dose group)
	Phase 1 (IMproveMF) - Imetelstat & Ruxolitinib combination	Intermediate-2 and High-Risk Myelofibrosis patients (n=20)	Preclinical data showed sequential treatment of ruxolitinib followed by imetelstat was inhibitory towards malignant MF stem cells
Pelabresib (Morphosys) MOR:GR	**Phase 3 (MANIFEST-2) - Pelabresib & Ruxolitinib Combination vs. Placebo & Ruxolitinib**	JAK Inhibitor naïve myelofibrosis patients (n=400)	Extends upon findings from MANIFEST study. **Primary endpoint** - SVR35 at Wk 24, **Secondary endpoint -** TSS50 at Wk 24
	Phase 2 trial (MANIFEST) - Pelabresib Combination with Ruxolitinib	JAK Inhibitor naïve myelofibrosis patients (n=84)	68% patients achieved SVR35, 56% achieved TSS50, 28% ≥ 1 grade improvement in fibrosis
Bomedemstat (Merck) MRK.US	**Phase 2 - Bomedemstat & Ruxolitinib Combination**	JAK Inhibitor naïve (n=10) or refractory/relapsed/intolerant of ruxolitinib (n=10)	19% achieved TSS50, 28% SVR20, 32% ≥ 1 grade improvement in fibrosis
Navitoclax (AbbVie) ABBV.US	**Phase 2 trial (REFINE) - Navitoclax & Ruxolitinib Combination**	Intermediate-2 or High-Risk MF patients with prior/current Ruxolitinib treatment (n=191)	Interim data (n=34) showed SVR35 in 31%, TSS50 in 30%, 38% ≥ 1 grade improvement in fibrosis
GB2064 (Galecto) GLTO.US	**Phase 2a (MYLOX-1) - GB2064**	Primary or Secondary MF (n=16)	Interim data showed 4/5 patients had ≥ 1 grade fibrosis improvement. These patients also had stable hemoglobin, white cell, thrombocyte levels and stable spleen volume over 6 months.

SOURCE: GERON, MORPHOSYS, MERCK, ABBVIE - COMPANY DATA + RELEVANT PUBLICATIONS

Whilst PXS-5505 presents a potentially novel disease modifying therapy, this has been an elusive goal for biopharmaceutical companies. Table 1 provides an overview of current Phase 1 to 3 assets targeting MF as these are relevant competing therapies for PXS-5505. The important endpoints in these trials include: TSS50 (Total Symptom Score 50% change), SVR35 (Spleen Volume Reduction of 35%) and ≥ 1 grade improvement in BM fibrosis. We note that a number of agents are currently being evaluated in combination with Ruxolitnib (Imetelstat, Pelabresib, Bomedemstat, Navitoclax). GB2064 is the only other therapy that is also targeting the fibrosis pathway and is a LOXL2 inhibitor. Similar to PXS-5505, interim data was presented at American Society of Hematology (ASH) conference in December 2022 with headline results expected in mid CY23.

PXS-5505 in Liver Cancer

Pre-clinical models have demonstrated increased expression of LOX enzymes in liver cancer resulting in accelerated angiogenesis and is associated with unfavourable outcomes and metastasis.[2,3,4]

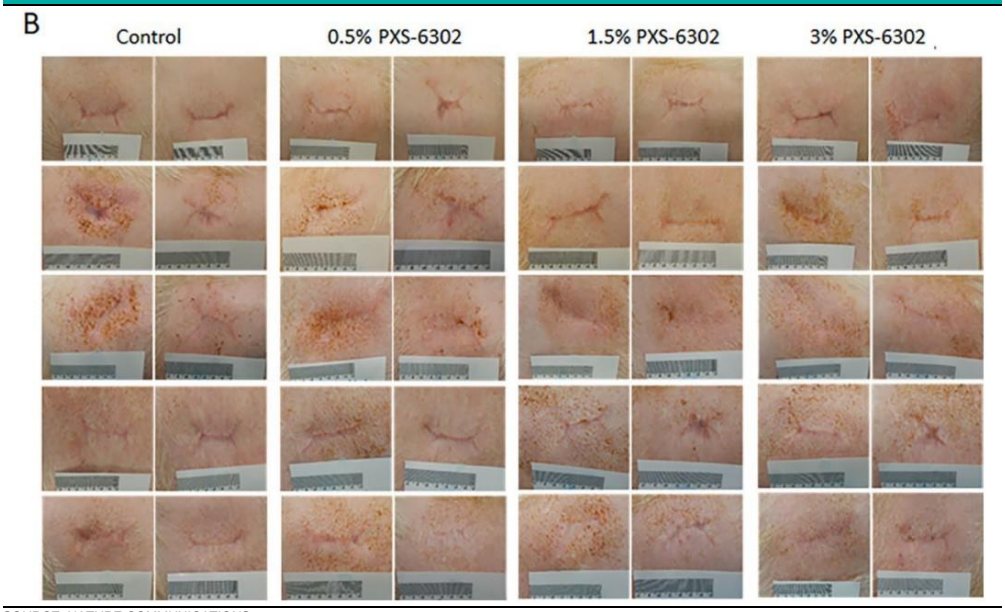
- PXS-5505 is currently being investigated as a first line combination treatment with standard of care. Phase 1b dose escalation study (n=12-18) over 12 weeks. Enrolment commenced in September 2022 and budget ~ $1.1m. Primary endpoint is maximum tolerated dose and secondary endpoints include objective response rate, progression free and overall survival.
- Phase 2a (n = ~ 40) will evaluate the selected dose in patients over 26 weeks. Study is targeted to conclude in CY24.

PXS-6302 and Cutaneous Scarring

The Pan-LOX inhibitor program of PXS includes the topical agent PXS-6302. The process of cutaneous scarring involves significant collagen deposition and extracellular matrix cross-linking which results in cutaneous fibrosis. Hypertrophic scars and keloids are abnormal responses to wound healing which create a cosmetic issue and are a common source of distress for patients following surgical procedures, burns or injuries.

Current treatments options include intralesional corticosteroid injections, cryotherapy, surgical revision procedures. Corticosteroid injections have variable response rates with recurrence rates ranging from 9% to 50%. Combinations with 5-Fluorouracil and cryotherapy have also been investigated. Other therapies such as pulsed dye laser have also demonstrated improvement in keloids and hypertrophic scars.[5]

Figure 3 - PXS-6302 in Porcine Model



SOURCE: NATURE COMMUNICATIONS

- PXS-6302 has demonstrated cosmetic and functional improvements in pre-clinical animal models. Figure 3 illustrates the comparative scar formation with different formulations of PXS-6302 at time of repair (left) and at 12-weeks post injury (right).

[2] Zhu, Jiye et al. "Lysyl Oxidase Is Predictive of Unfavorable Outcomes and Essential for Regulation of Vascular Endothelial Growth Factor in Hepatocellular Carcinoma." *Digestive diseases and sciences* vol. 60,10 (2015): 3019-31. doi:10.1007/s10620-015-3734-5

[3] Yang, Min et al. "Lysyl oxidase assists tumor-initiating cells to enhance angiogenesis in hepatocellular carcinoma." *International journal of oncology* vol. 54,4 (2019): 1398-1408. doi:10.3892/ijo.2019.4705

[4] Umezaki, Naoki et al. "Lysyl oxidase induces epithelial-mesenchymal transition and predicts intrahepatic metastasis of hepatocellular carcinoma." *Cancer science* vol. 110,6 (2019): 2033-2043. doi:10.1111/cas.14010

[5] Stephanides, S et al. "Treatment of refractory keloids with pulsed dye laser alone and with rotational pulsed dye laser and intralesional corticosteroids: A retrospective case series." *Laser therapy* vol. 20,4 (2011): 279-86. doi:10.5978/islsm.12-or-01

- Phase 1a study showed LOX inhibition in dermal tissue and good tolerability. The Phase 1c is being conducted in Perth through the collaboration with University of Western Australia. Recruitment was completed in Q4 CY22 with results expected in H1 CY23 for Solaria 2 Part 1.
- PXS expects to progress to Part 2 of the Solaria 2 study during CY23. This will evaluate whether PXS-6302 can prevent scarring with daily application for three months commencing 2-3 weeks after surgery.

PXS-4728

The third asset in the PXS pipeline is PXS-4728 acts as a neurotransmitter inhibitor (SSAO and MAOB) which is specifically of interest in Parkinson's Disease.

- Boehringer Ingelheim originally purchased this asset in 2015 for application in Non-Alcoholic Steatohepatitis. PXS received ~ $83m over five years (~ $39m upfront, ~ $44m milestone payments). The full program was returned to PXS in CY21 who identified the off-target effect with MAOB inhibition in the brain only. This has driven the company to consider PXS-4728 under a new lens as a potential therapy to reduce neuroinflammation.
- PXS was engaged in a funding agreement (~ $5.3m) with Parkinson's UK in September 2022 to run the Phase 2 trial in 40 patients who will receive oral PXS-4728 for 12 weeks. The trial will be conducted at the University of Sydney and University of Oxford with dosing expected to commence in H1 CY23.

Financials

P&L

Historical and forecast P&L statements are included below.

Table 2 - Historical & Forecast P&L

Income Statement	FY21	FY22	FY23e	FY24e	FY25e
Respiratory revenues	6.7	7.4	7.6	8.0	8.4
PXS-5505 Revenues	0.0	0.0	0.0	**21.7**	0.0
Other revenue	16.0	2.5	7.7	2.3	2.3
Other Income	1.0	6.0	5.6	2.0	2.0
Total Revenue	**23.7**	**15.9**	**20.9**	**33.9**	**12.6**
Employee costs	-11.1	-10.4	-11.3	-11.7	-12.0
Administration & corporate	-2.7	-2.6	-2.8	-2.9	-3.0
Rent, occupancy, utilities	-1.1	-1.1	-1.3	-1.3	-1.4
Clinical trials	-2.7	-5.7	-7.5	-5.1	-1.5
Drug development	-2.1	-1.5	-2.0	-1.6	-1.3
Sales, marketing, distribution	-1.5	-0.8	-0.3	-0.3	-0.3
Safety, medical, regulatory affairs	-1.6	-1.6	-1.6	-1.3	-1.0
Manufacturing purchases Δ inventory	-1.2	-2.7	-2.0	-2.1	-2.2
Other	-0.3	-0.5	-0.3	0.0	0.0
Foreign exchange gains & losses	1.0	-1.1	0.6	0.0	0.0
Total Expenses	**-23.1**	**-28.1**	**-28.4**	**-26.2**	**-22.6**
EBITDA	**0.6**	**-12.2**	**-7.4**	**7.7**	**-10.0**
Total D&A	-3.2	-3.2	-2.3	-3.0	-2.2
EBIT	**-2.6**	**-15.4**	**-9.7**	**4.7**	**-12.2**
Net interest (expense)/benefit	-0.4	13.5	0.0	0.0	0.0
Profit before tax	**-3.0**	**-1.9**	**-9.7**	**4.7**	**-12.2**
Income Tax Benefit/Expense	0.0	0.0	0.0	0.0	0.0
NPAT	**-3.0**	**-1.9**	**-9.7**	**4.7**	**-12.2**

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

The key points are:

- Respiratory/mannitol segment has been stable and we expect continued growth through distribution in Australia, Europe and North America.
- We assume a partnership deal for PXS-5505 during FY24 with a risk adjusted milestone payment of $21.7m (28.9% probability of successful transition from Phase 2 to 3, ~ US$50m upfront payment assumption).
- Other revenue includes payments from Parkinson's UK (PXS-4728) and other income includes R&D rebates in FY24/25.
- Higher operating expenses in FY23 are driven by the clinical trial related expenditure involving PXS-5505 and PXS-6302. The PXS-5505 Phase 2a Myelofibrosis trial is expected to continue to FY24. FY24 clinical trial expenses also include the costs for Phase 2 investigations involving PXS-6302. We expect further drug development for PXS-5505 to be undertaken by a partnering company which is the underlying reason for lower clinical trial expenses in FY25.
- The earnings in FY24 are driven by the assumption of an upfront payment from a partnership agreement for PXS-5505.

Balance sheet & cash flow

Table 3 - Historical & Forecast Balance Sheet					
Balance Sheet	**FY21**	**FY22**	**FY23e**	**FY24e**	**FY25e**
Cash and cash equivalents	18.7	8.9	12.0	16.6	4.1
Trade and other receivables	3.0	8.0	4.9	4.6	4.4
Inventories	3.6	2.3	2.3	2.4	2.5
Property, plant, equipment	6.2	3.2	1.2	8.4	6.5
Intangible assets	1.1	1.0	1.1	1.1	1.2
Total assets	**33.6**	**25.2**	**23.2**	**34.9**	**20.4**
Trade and other payables	3.8	2.7	3.4	2.4	2.1
Borrowings (current)	2.0	2.0	2.0	2.0	2.0
Borrowings (non-current)	4.3	2.3	0.0	8.0	6.0
Total liabilities	**30.7**	**14.4**	**12.8**	**19.8**	**17.5**

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Table 4 - Historical and Forecast cash flow statements					
Cash flow	**FY21**	**FY22**	**FY23e**	**FY24e**	**FY25e**
Operating cash flow	**3.1**	**-16.1**	**-3.7**	**7.0**	**-10.2**
Purchases of PPE	-0.3	-0.1	-0.1	-0.1	-0.1
Proceeds from disposal of PPE	0.0	0.0	0.0	0.0	0.0
Payment for intangible assets	-0.3	-0.2	-0.2	-0.2	-0.2
Investing cash flow	**-0.6**	**-0.3**	**-0.3**	**-0.3**	**-0.3**
Proceeds from issue of shares	4.4	9.7	9.3	0.0	0.0
Transaction costs related to issue of shares	-0.3	-0.7	0.0	0.0	0.0
Lease liability payments	-2.3	-2.4	-2.3	-2.0	-2.0
Financing agreement payments	-0.2	-0.1	0.0	0.0	0.0
Financing cash flow	**1.5**	**6.6**	**7.0**	**-2.0**	**-2.0**

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

The key take-outs from the balance sheet and cash flows are:

- The $10m capital raising in October 2022 has strengthened the balance sheet and the platform for current R&D activities involving PXS-5505 and PXS-6302. This provides runway for PXS to 1H24.
- Given our assumption that PXS will partner with a larger pharmaceutical company for the ongoing development of PXS-5505, we do not anticipate any requirement for capital raising in the forecast period.
- The change in non-current borrowings reflects the re-negotiation of the financial lease expected in FY24 for a 5-year period.

Valuation

Sum-of-the-parts Valuation

We apply a SOTP valuation approach to Pharmaxis. We have calculated the NPV of the Mannitol business (Aridol/Bronchitol) and combined this with the risk adjusted NPV (rNPV) of the New Drug Development pipeline. The rNPV is primarily driven by our assessment of PXS-5505 in myelofibrosis.

Mannitol segment

We apply our DCF methodology with the following key assumptions:

- The calculation of the WACC of 15.0% is outlined in Table 5. There is currently no debt (outside of financial leases) and at this stage we do not expect debt financing to be a likely component of the capital structure of PXS.
- Terminal Growth Rate of 3.0% applies to the Mannitol segment given this is a relatively established market in asthma and cystic fibrosis.

Table 5 - DCF - Mannitol segment

WACC calculation	
Risk free rate	6.0%
Market risk premium	6.0%
Beta	1.5
Borrowing rate	4.0%
Tax rate	30.0%
Target gearing	0.0%
Cost of equity	15.0%
Cost of debt (after tax)	0.0%
WACC	15.0%

Key assumptions	
Valuation as at	28-Mar-24
Terminal growth rate	3.0%

	2024e	2025e	2026e	2027e	2028e	...	Beyond
Operating cash flow (US$m)	-2.7	-2.3	-1.2	0.9	3.6		
Capex	-0.1	-0.1	-0.1	-3.0	0.0		
Free cash flow	-2.8	-2.4	-1.3	-2.1	3.6		30.5
Present value of cash flows	-2.5	-1.9	-0.9	-1.2	1.8		13.5
NPV - Mannitol	**8.9**						
Equity value per share (A$)	**0.01**						

SOURCE: BELL POTTER SECURITIES ESTIMATES

New drug development segment

The key asset driving our valuation of the New Drug Development segment is PXS-5505 in myelofibrosis. In our valuation of PXS-5505 we assume a partnership deal with a larger pharmaceutical company that will take this asset forward into a combined Phase 2/3 study with Ruxolitinib.

We have reviewed major pharmaceutical partnership deals specifically in myelofibrosis. An overview of these partnership agreements is provided in Table 6. Excluding the two outlier agreements (Celgene/Impact Biosciences and Sierra/Gilead), the average upfront payment was US$82m and average additional milestones were US$466m. The royalty structures ranged from high single-digit to high-teen percentages of eventual drug sales.

Based on these previous agreements, we assume an upfront payment of ~ US$50m (A$75m) in FY24 with further potential milestone payments of ~ US$230m (A$350m). These additional milestones are contingent on successful progression to Phase 3,

regulatory filings and commercialisation. We also assume high single-digit to mid double-digit tiered royalties on eventual drug sales (annual therapy price US$100k).

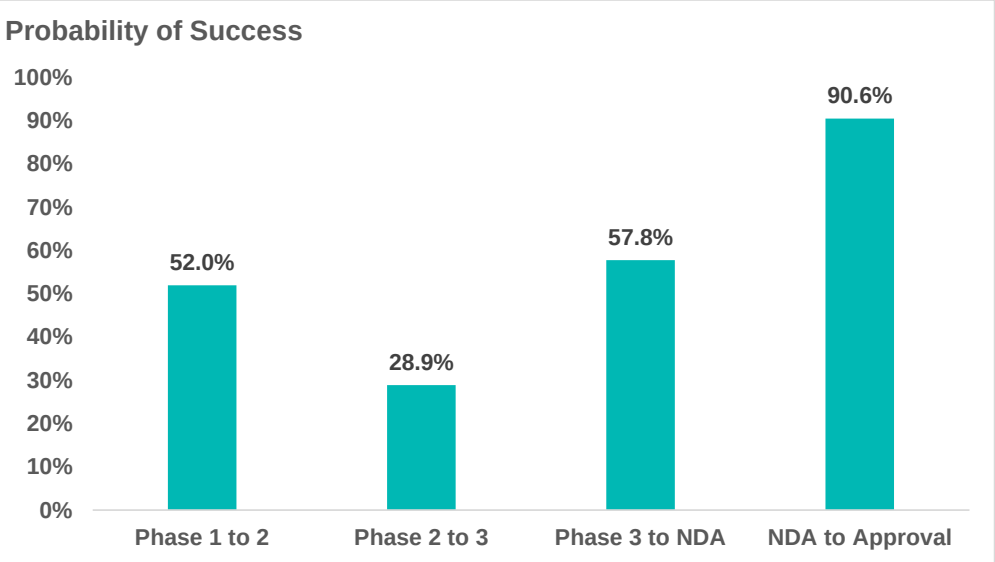
Table 6 - Partnership agreements for Myelofibrosis therapies

Date	Big Pharma	Target	Upfront Payment	Additional Payments	Royalty Structure	Assets
Nov-09	Novartis	Incyte	$150m	$60m	Tiered double digit royalties	Ruxolitinib - JAK2 Myelofibrosis therapy
Nov-13	Baxter	Cell Therapeutics	$60m	$302m	High single to mid-teen royalties	Pacritinib - JAK2 Myelofibrosis therapy
Jun-16	Janssen	Geron	$35m	$900m	Double-digit to mid-teen royalties	Imetelstat - Phase 2 Myelofibrosis, Phase 2/3 Myelodysplastic syndromes
Jan-18	Celgene	Impact Biomedicines	$1.1b	$1.4b	Tiered royalties	Fedratinib - JAK2 Myelofibrosis therapy
Aug-18	Sierra Oncology	Gilead Sciences	$3m	$195m	Low double-digit to high-teen royalties	Momelotinib - Phase 3 Myelofibrosis

SOURCE: BELL POTTER SECURITIES, RELEVANT COMPANY DATA, SEC

These assumed upfront/milestone payments and royalty revenues have been risk adjusted based on reported probabilities in drug development studies of Phase 2 to 3 transition success (28.9%), Phase 3 to New Drug Application (NDA) success (57.8%) and NDA to Approval success (90.6%) (Figure 4).[6]

Figure 4 - Overall phase transition success rates



SOURCE: BIOTECHNOLOGY INNOVATION ORGANIZATION, BELL POTTER SECURITIES

We calculate the NPV of these forecast cashflows by applying a WACC of 20% during the pre-commercial phase (FY23 to FY28) and WACC of 15% following commercialisation (FY28 onwards). We also include cashflows of ~ A$5.3m for PXS-4728 from the Parkinson's UK agreement. Combining these together our valuation of the Drug Development pipeline is A$81.2m (Table 7).

Table 7 - rNPV of Drug Development segment

	2024e	2025e	2026e	2027e	2028e	2029e	2030e	2031e	2032e	2033e	2034e	2035e	2036e	2037e	...	Beyond
Cash flows	13.5	-4.5	21.2	-6.6	20.0	12.5	11.0	6.0	8.9	18.2	14.6	16.6	19.6	21.8		186.8
Present value of cash flows	11.6	-3.2	12.6	-3.3	8.3	5.5	4.2	2.0	2.6	4.6	3.2	3.2	3.3	3.1		23.5
NPV - Drug Development	**81.2**															
NPV/share	**0.11**															

SOURCE: BELL POTTER SECURITIES ESTIMATES

Phase 2 results for PXS-5505 are expected in H1 CY23. Whilst interim data of only six patients was released in October 2022, the findings indicated stable/improved bone marrow fibrosis scores and stable platelet/haemoglobin counts. Positive headline results may facilitate progression to a combined Phase 2/3 study with Ruxolitinib and reduce the risk treatment to our forecast cashflows. Therefore, the PXS-5505 Phase 2a results in ~ mid CY23 will be critical to our risk adjusted NPV of the Drug Development segment.

Examining recent M&A activity involving myelofibrosis therapies highlights the significant upside potential within this sector (Table 8). Transaction prices ranged from US$1.35b to US$1.9b and these assets were acquired at Phase 2/3. These are highly relevant given the expected Phase 2a readout during CY23.

[6] Thomas, David et al. *Clinical Development Success Rates and Contributing Factors 2011-2020.* Biotechnology Innovation Organization. February 2021.

Table 8 - Recent M&A Activity involving Myelofibrosis therapies

Date	Acquirer	Target	Transaction price	Drug Asset	Drug Development Stage
Jun-21	MorphoSys	Constellation Pharmaceuticals	$1.7b	Pelabresib	Phase 3 Myelofibrosis
Apr-22	GSK	Sierra Oncology	$1.9b	Momelotinib	Phase 3 Myelofibrosis
Jan-23	Merck	Imago Biosciences	$1.35b	Bomedemstat	Phase 2 Myelofibrosis, Essential thrombocythemia, Polycythemia vera

SOURCE: RELEVANT COMPANY DATA

The key take-outs from these transactions are:

- The acquisition of Constellation Pharmaceuticals by MorphoSys in June 2021 for US$1.7b centred around Pelabresib which was in Phase 3 testing in myelofibrosis. Preliminary results are expected in early CY24. Key findings from combination therapy with ruxolitinib are that 68% of patients achieved SVR35 at 24 weeks and 60% at 48 weeks. 56% of patients had TSS50 at 24 weeks and 43% at 48 weeks. 28% of patients had ≥ 1 grade improvement in BM fibrosis at 24 weeks. However, the most common adverse events were anemia (35%) and thrombocytopenia (12%). Again, we recognise that PXS-5505 is at an earlier stage of development, however, it will assess for similar endpoints in the Phase 2 study. Further, due to the unique mechanism targeting fibrosis within the bone marrow the adverse effects such as anaemia and thrombocytopenia have not been observed in safety data to date.
- GSK announced its acquisition of Sierra Oncology in April 2022 for its Phase 3 asset momelotinib for US$1.9b. Complete data from the Phase 3 MOMENTUM trial was presented in June 2022 at the American Society of Clinical Oncology meeting (ASCO) with all primary and key secondary endpoints met. The deadline for FDA review and decision regarding momelotinib in myelofibrosis patients with anaemia is 16 June 2023.
- More recently Merck acquired Imago Biosciences for US$1.35b in January 2023. The key therapy is bomedemstat which is currently in Phase 2 of development in indications such as myelofibrosis, essential thrombocythemia and polcythemia vera. Of patients evaluable for BM fibrosis scoring (n=59), 85% were stable or improved by ≥ 1 grade at 24 weeks. Results from Phase 2 of PXS-5505 are also expected in mid CY23, however, we note this study is in a smaller cohort (n=24).

PXS Valuation

We apply our sum-of-the-parts methodology in our valuation of PXS. The calculation is shown in Table 9. Corporate costs are calculated using a five-year DCF model and are $33.9m which is ~ 7.5x multiple of annual corporate costs.

Table 9 – Pharmaxis Valuation

Sum-of-the-parts valuation	
Segment	**NPV ($m)**
Mannitol	8.9
New Drug Development (risk adjusted)	81.2
Total	**90.1**
Corporate costs	-33.9
Enterprise value	**56.2**
Net debt/(cash)	-16.5
Equity value	**72.7**
Shares on issue	719.6
Equity value $/sh	**0.10**

SOURCE: BELL POTTER SECURITIES ESTIMATES

Our valuation of PXS is $0.10 and we transfer coverage with a Buy (Speculative) recommendation.

Company Overview

Pharmaxis is a clinical stage drug development company involved in drug development for inflammatory & fibrotic diseases. There are two operating segments: the mannitol respiratory business (Bronchitol & Aridol) and new drug development (PXS-5505, PXS-6302). Aridol uses dry mannitol powder to diagnose & assess severity of asthma and received FDA clearance in 2011. Bronchitol is used in the management of cystic fibrosis by clearing mucus secretions and received FDA clearance in October 2020. This respiratory segment has assisted in supporting the proprietary drug development pipeline which targets fibrotic diseases through pan-Lysyl Oxidase Inhibitors (LOX). Key pipeline assets include PXS-5505 (oral) for treatment of myelofibrosis & liver/pancreatic diseases and PXS-6302 (topical) in anti-scarring indications (hypertrophic scars, keloids, burns).

Drug Development Pipeline

Extracellular matrix proteins such as collagen and elastin are involved in a process of cross-linking in fibrosis. Lysyl oxidase (LOX) and Lysyl oxidase-like (LOXL) enzymes play a critical role in this cross-linking process and pre-clinical models have shown that suppression of the LOX family can suppress fibrosis in various types of tissue (cardiac, pulmonary, hepatic, renal, bone marrow). PXS is targeting fibrosis through its novel LOX inhibitor therapies for indications such as myelofibrosis, liver/pancreatic cancer and dermal applications (hypertrophic scars/keloids, burns). PXS-5505 has been shown to significantly inhibit LOX and LOXL2.

Table 10 - Drug Development Pipeline

PXS Asset	Indication	TAM (US$)	Trial design	# patients	Status	Data Timeline
PXS-5505	Myelofibrosis (MF)	$1b	Phase 2 open label 6 month study in JAK intolerant / ineligible myelofibrosis patients	24	Recruiting	Results mid CY23
PXS-5505	Hepatocellular Carcinoma (HCC)	$7b	Phase 1c open lable dose escalation study in newly diagnosed unresectable HCC on top of SOC	18	First Patient 1Q CY23	CY24
PXS-6302	Modification of established scars	$3.5b	Phase 1c 3 month placebo controlled study, established scars > 1 years old	50	Full recruited	H1 CY23
PXS-6302	Scar prevention post surgery	$3.5b	Phase 1c 3 month placebo controlled study, skin scarring after burns	50	First patient CY23	CY24
PXS-4728	Isolated REM sleep behaviours disorder (iRDB)	$3.5b	Phase 2 double blind, placebo controlled study in iRBD patients	40	First patient CY23	H1 CY25

SOURCE: COMPANY DATA

An overview of the drug development pipeline is included in Table 10. These assets include:

- **PXS-5505 (Myelofibrosis)**: Lead asset for PXS, oral pan-LOX inhibitor. Multi-national open label phase 2 trial in myelofibrosis underway with interim data expected in mid CY23. Presents multiple targeted indications with the potential for disease modifying therapy in myelofibrosis where standard of care primarily addresses patient symptoms (JAK inhibitors) and spleen volume. PXS-5505 may be considered as a combination therapy with Ruxolitinib to effectively address fibrosis & symptoms concurrently.
- **PXS-5505 (Liver Cancer):** Phase 1b/2a investigator led study (University of Rochester). Combined PXS-5505 with atezolizumab and bevacizumab in newly diagnosed hepatocellular carcinoma (liver cancer) patients. Phase 1b study budget $1.1m. Recruitment opened in 4Q CY22 and expected to conclude by 1H CY24.
- **PXS-6302**: Topical drug being evaluated in its ability to improve established scars (Phase 1c). Headline results are due in 2Q CY23. Further indications that may be considered include scar prevention, keloid/hypertrophic scars, Dupuytren's contracture.
- **PXS-4728:** Targeting isolating REM sleep behaviour disorder (iRBD). Pre-clinical models demonstrate that inhibition of SSAO and MAO-B may potentially provide neuroprotection. PXS has been engaged by Parkinson's UK with a funding agreement of up to $4.9m to run the Phase 2 trial. This will evaluate the efficacy of PXS-4728 in 40

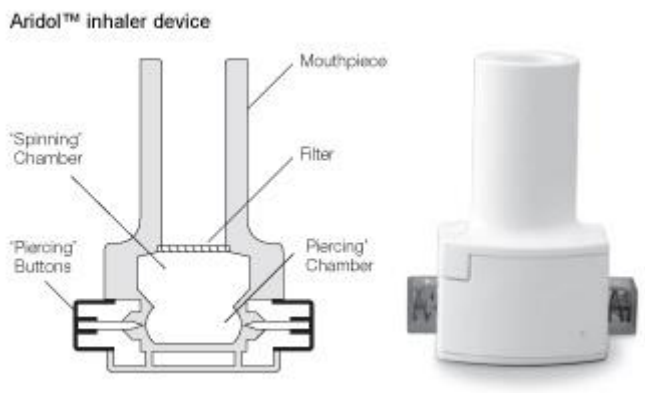
patients with iRBD over 12 weeks at two sites (University of Sydney, University of Oxford).

Mannitol/Respiratory Segment

The respiratory segment for PXS consists of two key products: Aridol and Bronchitol. These operations accounted for $7.4m sales revenue during FY22 with sales primarily through distributor channels in Australia, Europe and North America (US, Canada).

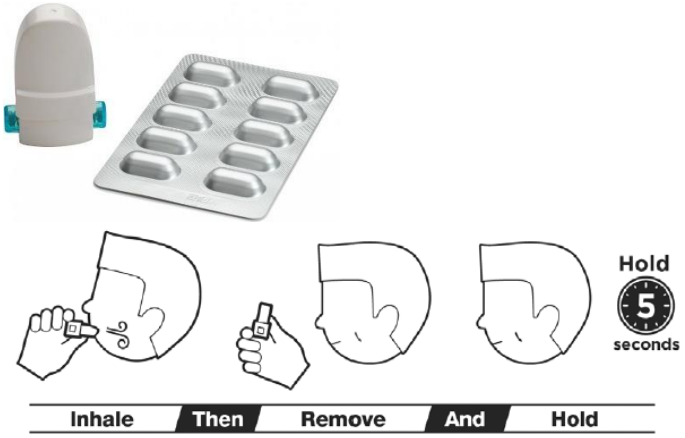
- **Aridol:** Standardised test kit for the mannitol challenge test to diagnose and assess severity of asthma (Figure 5). Achieved regulatory approvals ~ 10 years ago (FDA 2010, Europe 2012, TGA 2012). Currently sold in Australia, Europe, North America (US, Canada) and South Korea.
- **Bronchitol:** Inhaled dry powder mannitol used in the management of cystic fibrosis by promoting airway surface hydration and clearing mucus secretions (Figure 6). Three large scale clinical trials have been completed with EU approval in 2012 and FDA clearance in October 2020. Bronchitol is approved and marketed in Europe, Australia, Russia and the US.

Figure 5 - Aridol device



SOURCE: COMPANY DATA

Figure 6 - Bronchitol device



SOURCE: COMPANY DATA

Key Risks

Clinical trial risk

The key driver for the valuation of PXS is the proprietary drug development pipeline. The main asset is PXS-5505 which is at a critical stage of the clinical research pathway. Whilst pre-clinical and earlier Phase data has been supportive, there is a risk that these pipeline assets fail to reach their endpoints which would impact commercial and partnering prospects. The risks associated with translational research must be considered as findings in pre-clinical models are not always replicated in human studies. Clinical trial risks also include patient enrolment/recruitment delays, selection of inclusion/exclusion criteria and endpoints that will address regulatory body criteria (FDA, TGA, European) and appropriate statistical analyses & powering. We have accounted for these clinical trial risks by adjusting forecast revenues based on the stage of clinical development. We apply reported probabilities of successful Phase 2 to 3 transition of 28.9%, Phase 3 to New Drug Application (NDA) transition of 57.8% and NDA to Approval of 90.6%.

Drug development partnership risks

An important part of the drug development strategy will be to secure valuable partnering deals for the pipeline assets. PXS is a relatively small Australian biotechnology company with limited infrastructure and will require a larger biopharmaceutical partner to support larger scale studies and commercialisation of these assets. The success of the drug development projects is intrinsically linked with the ability of PXS to secure an attractive partnering deal for its Pan-LOX program (PXS-5505, PXS-6302). Failure to attract partners or negotiate favourable deal terms will impact ongoing operations.

Regulatory risk

Successful commercialisation of the PXS pipeline is dependent on approval from regulatory authorities in relevant jurisdictions. Specifically, FDA clearance for PXS-5505 and PXS-6302 will be critical in progressing towards commercialisation of these key assets. It is expected that potential partners will be experienced with the regulatory process. Failure to achieve regulatory approval (FDA, European, TGA) will significantly impact the pathway to market and present a significant downside risk to our valuation.

Reimbursement Risk

Our revenue forecasts assume an eventual annualised therapy price for PXS-5505 in myelofibrosis of ~ US$100k. We assume reimbursement for PXS-5505 from Centre of Medicare Services (CMS) and insurance providers given its potential as first in class therapy and lack of disease modifying treatment options in myelofibrosis. Inability to secure these reimbursement agreements will materially impact our forecasts. There are additional commercial risks relating to other therapies under investigation which will also be seeking reimbursement contingent on study results.

Estimates For Market Size

Estimates of the annual addressable market are based on existing incidence & prevalence data relating to myelofibrosis and dermal scarring/keloid treatment. Changing incidence/prevalence and inaccuracies in these estimates will impact revenue forecasts and expected commercialisation.

Mannitol business clinical adoption risks

The current business comprises of the respiratory mannitol segment. Sales of Bronchitol and Aridol contribute towards the DCF valuation of the legacy operations. Within this operating segment, US Bronchitol sales are the key driver for revenue and achieving profitability. Therefore, failure to achieve clinical adoption in line with our forecasts will adversely affect our valuation of this segment.

Commercial risk

The pharmaceutical market is intensely competitive and there are currently a number of emerging therapies targeting disease modification in myelofibrosis. The commercial risk for PXS-5505 is that even if clinically significant results are achieved in Phase 2/3 studies, clinical adoption will be contingent on treatment guidelines, regulatory approvals and reimbursement. These clinical studies must be able to demonstrate superiority compared with standard of care to achieve the pricing and market share assumptions within our model. Similar commercial risks are present for PXS-6302 which may potentially target a broader market of hypertrophic scars/keloids. Competing therapies within this market include pulsed-dye laser, corticosteroid injections and surgical excision/revision procedures. Appropriate pricing strategies will be critical to the commercialisation of PXS-6302.

Funding risk

Proforma cash of $21m provides runway through to 1H FY24 (includes cash $16.5m as at 31 December 2022 and $5m R&D tax credit from January 2023). Bronchitol/Aridol sales and rights sale of the Orbital inhaler technology to Aptar Pharma in August 2022 have strengthened this development platform. We expect engagement with larger biopharmaceutical companies during CY23 and CY24 for licensing/distribution arrangements for PXS-5505. These agreements are likely to include upfront & milestone payments (commencing various phases of clinical trials, regulatory approvals) and potential royalties contingent on commercialisation. If PXS is unable to secure these partnership agreements, it will require additional funding either from dilutive or non-dilutive sources. Given the current macroeconomic environment, we believe dilutive funding will be the more likely option in this scenario.

Pharmaxis
as at 28 March 2023

Recommendation	Buy, Speculative
Price	$0.044
Valuation	$0.10

Table 11 - Financial summary

Pharmaxis (ASX:PXS)

Share price:	**$0.0440**	**Target price:**	**$0.01**
No. of issued shares:	**719.6m**	**Market cap:**	**$31.7m**

Profit & Loss (A$m)

Year end 30 Jun	2021	2022a	2023e	2024e	2025e
Respiratory revenues	6.7	7.4	7.6	8.0	8.4
PXS-5505 Revenues	0.0	0.0	0.0	21.7	0.0
Other revenue	16.0	2.5	7.7	2.3	2.3
Other Income	1.0	6.0	5.6	2.0	2.0
Total Revenue	**23.7**	**15.9**	**20.9**	**33.9**	**12.6**
Employee costs	-11.1	-10.4	-11.3	-11.7	-12.0
Administration & corporate	-2.7	-2.6	-2.8	-2.9	-3.0
Rent, occupancy, utilities	-1.1	-1.1	-1.3	-1.3	-1.4
Clinical trials	-2.7	-5.7	-7.5	-5.1	-1.5
Drug development	-2.1	-1.5	-2.0	-1.6	-1.3
Sales, marketing, distribution	-1.5	-0.8	-0.3	-0.3	-0.3
Safety, medical, regulatory affairs	-1.6	-1.6	-1.6	-1.3	-1.0
Manufacturing purchases Δ inventory	-1.2	-2.7	-2.0	-2.1	-2.2
Total Expenses	**-23.1**	**-28.1**	**-28.4**	**-26.2**	**-22.6**
EBITDA	**0.6**	**-12.2**	**-7.4**	**7.7**	**-10.0**
Total D&A	-3.2	-3.2	-2.3	-3.0	-2.2
EBIT	**-2.6**	**-15.4**	**-9.7**	**4.7**	**-12.2**
Net interest (expense)/benefit	-0.4	13.5	0.0	0.0	0.0
Profit before tax	**-3.0**	**-1.9**	**-9.7**	**4.7**	**-12.2**
Income Tax Benefit/Expense	0.0	0.0	0.0	0.0	0.0
NPAT	**-3.0**	**-1.9**	**-9.7**	**4.7**	**-12.2**

Cash Flow (A$m)

Year end 30 Jun	2021	2022a	2023e	2024e	2025e
EBITDA	0.6	-12.2	-7.4	7.7	-10.0
Change in working capital	-2.8	-4.8	3.8	-0.8	-0.2
Gross cash flow	**-17.6**	**-19.0**	**-3.7**	**7.0**	**-10.2**
Operating cash flow	**3.1**	**-16.1**	**-3.7**	**7.0**	**-10.2**
Purchase of PPE	-0.3	-0.1	-0.1	-0.1	-0.1
Payment for intangible assets	-0.3	-0.2	-0.2	-0.2	-0.2
Investing cash flow	**-0.6**	**-0.3**	**-0.3**	**-0.3**	**-0.3**
Proceeds from issue of shares	4.4	9.7	9.3	0.0	0.0
Lease liability payments	-2.3	-2.4	-2.3	-2.0	-2.0
Financing cash flow	**1.5**	**6.6**	**7.0**	**-2.0**	**-2.0**
Net change in cash	**3.9**	**-9.8**	**3.0**	**4.6**	**-12.5**
Cash at start of period	14.8	18.7	8.9	12.0	16.6
Cash at end of period	**18.7**	**8.9**	**12.0**	**16.6**	**4.1**

Balance Sheet (A$m)

Year end 30 Jun	2021	2022a	2023e	2024e	2025e
Cash and cash equivalents	18.7	8.9	12.0	16.6	4.1
Trade and other receivables	3.0	8.0	4.9	4.6	4.4
Inventories	3.6	2.3	2.3	2.4	2.5
Receivables (non-current)	0.9	1.7	1.7	1.7	1.7
Property, plant, equipment	6.2	3.2	1.2	8.4	6.5
Intangible assets	1.1	1.0	1.1	1.1	1.2
Total assets	**33.6**	**25.2**	**23.2**	**34.9**	**20.4**
Trade and other payables	3.8	2.7	3.4	2.4	2.1
Borrowings (current)	2.0	2.0	2.0	2.0	2.0
Other liabilities	1.0	0.3	0.3	0.3	0.3
Provisions	1.1	1.1	1.1	1.1	1.1
Borrowings (non-current)	4.3	2.3	0.0	8.0	6.0
Other liabilities	18.5	5.9	5.9	5.9	5.9
Provisions	0.1	0.1	0.1	0.1	0.1
Total liabilities	**30.7**	**14.4**	**12.8**	**19.8**	**17.5**
Net assets	2.8	10.8	10.4	15.1	2.9
Contributed equity	371.4	380.4	389.7	389.7	389.7
Reserves	22.6	23.5	23.5	23.5	23.5
Accumulated losses	-391.2	-393.1	-402.8	-398.1	-410.3
Total equity	**2.8**	**10.8**	**10.4**	**15.1**	**2.9**

Valuation data

Year end 30 Jun	2021	2022a	2023e	2024e	2025e
NPAT	-3.0	-1.9	-9.7	4.7	-12.2
Diluted EPS	-0.7	-0.4	-1.6	0.7	-1.7
Change		*-43%*	*297%*	*-141%*	*-358%*
P/E ratio (x)*	**nm**	**nm**	**nm**	**6.7**	**nm**
CFPS	0.01	-0.02	0.00	0.01	-0.02
Price/FCF*	**5.0**	**-2.5**	**10.4**	**6.8**	**-2.5**
DPS (cps)	0.0	0.0	0.0	0.0	0.0
Yield	**0.0%**	**0%**	**0.0%**	**0.0%**	**0.0%**
Franking	nm	nm	nm	nm	nm
EV/EBITDA (x)	nm	nm	nm	nm	nm
NTA per share	0.00	0.02	0.02	0.02	0.00
Price/NTA (x)	**10.3**	**2.5**	**2.8**	**2.3**	**18.6**

Performance ratios

Year end 30 Jun	2021	2022a	2023e	2024e	2025e
EBITDA margin	nm	nm	nm	nm	nm
EBIT margin	nm	nm	nm	nm	nm
Return on assets	nm	nm	nm	14%	nm
Return on equity	**nm**	**nm**	**nm**	**31%**	**nm**
Payout ratio	0%	0%	0%	0%	0%
Effective tax rate	0%	0%	0%	0%	0%

Segmentals (US$m)

Year end 30 Jun	2021	2022a	2023e	2024e	2025e
Respiratory revenues	6.7	7.4	7.6	8.0	8.4
PXS-5505 Revenues	0.0	0.0	0.0	21.7	0.0
Total revenue	**23.7**	**15.9**	**20.9**	**33.9**	**12.6**

Interims (US$m)

Year end 30 Jun	1H22a	2H22a	1H23e	2H23e
Revenue	**8.8**	**7.1**	**9.2**	**11.8**
Change		*-19%*	*28%*	*29%*
Expenses	**-15.6**	**-12.5**	**-12.6**	**-15.8**
Change		*-20%*	*1%*	*25%*
EBITDA	**-6.8**	**-5.3**	**-3.4**	**-4.0**
Change		*-22%*	*-36%*	*16%*

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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