PHARMAXIS LTD (ASX: PXS)

PHARMACEUTICAL RESEARCH

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Key Highlights

- Strong cash balance with $25m on hand (FY21 net loss of $2.9m);
- Lead asset, oncology drug PXS-5505 has passed Phase 1c trials in myelofibrosis patients - PXS-5505 proved to be safe across increasing dose levels with the highest dose giving >90% enzyme inhibition and no side effects;
- PXS-5505 commenced Phase 2 trials for myelofibrosis patients, targeting an addressable market conservatively estimated to be worth USD $1 billion per year;
- Mannitol business unit on track to be cash flow positive in FY22 following FDA approval of Bronchitol in October 2020 and US commercial launch in March 2021;
- Respiratory business sales strong, generating $3.27m revenue in Q1 FY22;
- Further revenue opportunities from appointment of new regional distribution licences of Aridol and Bronchitol to streamline operations further and reduce costs;
- PXS-5505 cleared to progress to Phase 2 trials in liver cancer with trials approved by the FDA to be conducted as an investigator-led study at the University of Rochester;
- Phase 1 trials successfully completed for anti scarring drug, PXS-6302 led by Professor Fiona Wood.

Investment Case - Speculative Buy

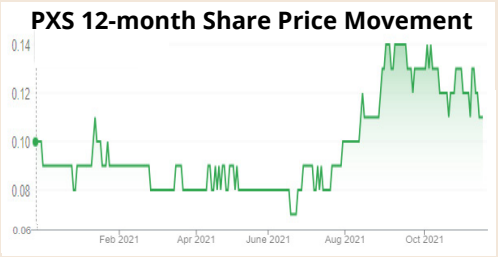
Pharmaxis is set to embark on what will be the busiest and most exciting 2-3 years in the Company's history with years of drug discovery R&D having led to their upcoming Phase 2 trials of hero drug PXS-5505.

Two sets of trials will be run in parallel, aiming to generate clinical data for the drug as a treatment for bone marrow cancer (myelofibrosis) and liver cancer (hepatocellular carcinoma). Together, demand for these drugs generates more than USD $2 billion per annum however that figure is forecast to reach $7 billion by 2027 in line with expected occurrences of the diseases increasing.

Unlike other cancer treatment drugs on the market, PXS-5505 has the potential for disease-modifying efficacy which offers new hope for many cancer patients where existing treatments deal mainly with the symptoms

Outlook:	**SPECULATIVE BUY**
Date:	**24 Nov 2021**
Price (24 Nov):	$0.105
Ticker:	ASX: PXS
52-Week range:	$0.071-$0.145
Market cap (AUD):	$54.8m
Shares on issue	522.5m

	FY21	FY20	FY19
Revenue ($m)	22.8	12.6	12.1
EBITDA ($m)	-1.33	-12.0	-15.6
NPAT ($m)	-2.97	-13.9	-20.0



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of the disease or offer limited improvements in life expectancy. In many of these cases, the limited benefits are often associated with poorly tolerability and with dangerous side effects.

Offering new hope for cancer patients and attracting global interest from investors and academic researchers, PXS-5505 has already passed Phase 1c trials in myelofibrosis patients where it has proven to be safe across increasing dose levels with the highest dose giving >90% enzyme inhibition and no side effects.

Phase 2 trials for PXS-5505 have already commenced with participants from the Phase 1c trials the first to commence dosing. Recruitment sites have also been opened in Australia and South Korea with more sites in Taiwan and the United States opening in the December quarter. Clinical data from these Phase 2 myelofibrosis trials is expected to be released before the end of 2022. The progression of these trials can be viewed as value levers for Pharmaxis based on peer valuations of those 12 months ahead of Pharmaxis in the drug development pipeline being upwards of $400 million.

Pharmaxis' drug development pipeline is supported by their healthy cash balance of $25 million following a successful $7.2 million capital raise in November 2021 which was well supported by hugely successful biotech funds. This bodes well for Pharmaxis and their improving balance sheet providing a healthy cash runway heading into Phase 2 clinical trials.

Their strong bank balance is supported by sales of cystic fibrosis treatment 'Bronchitol' which secured FDA-approval in October 2020 and is manufactured by Pharmaxis in their Australian facility for export around the world.

The United States remains the most lucrative market for the product where pricing mechanisms enable higher margins on the treatment which costs around USD $27,000 for an annual supply of the recurring treatment.

Pharmaxis generated $6.6m from the sale of goods in FY21 including supply of Bronchitol to the US where the product was commercially launched in March 2021.

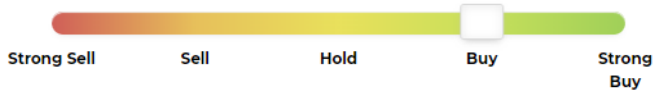
For the quarter ended 30 September 2021, Pharmaxis generated $3.27m in sales revenue – a good start to the year when compared to the same quarter last year (sales of $0.7 million) and the whole of last financial year's sales of $6.6m.

This further supports the clinical trials programs for PXS-5505 which represent their greatest upside to come from their lead drug candidate and its commercial opportunity as a breakthrough cancer treatment.

ANALYSTS CONSENSUS - BUY

Number of Analysts: **5**

Analysts Mean Price: **$0.14**



	SCORE OUT OF 100
Dividend Score	0
Quality	67.1
Price Momentum	69
Maturity Score	35.4
All Weather Score	68.5
Credit Score	25.3
Earning Score	44.6
Growth	82.7
Emerald Stock Score	82.7

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Company Summary

Clinical stage drug development company, Pharmaxis (ASX: PXS) is in a period of transition with multiple projects hitting significant milestones in recent months.

The Company's productive drug discovery group has already taken two products through to commercialisation, including FDA approval, a rarity for small cap biotech companies, but a significant testament to their ability.

Now, the Company is primarily focused on bringing their portfolio of amine oxidase inhibitor drugs to the clinic. Their lead asset, PXS-5505, is designed for treatment of myelofibrosis however, promising results from preclinical and Phase 1 studies saw the drug attract the attention of internationally renowned researchers and key opinion leaders. The University of Rochester in New York initiated a comprehensive preclinical study looking at the drug's effect on liver cancer. Results from this study have supported the University of Rochester's successful application to the FDA for approval to progress to Phase 2 trials for this indication.

Built on the same scientific platform as PXS-5505, PXS-6302 is a topical drug designed to eliminate skin scarring. The drug candidate has cleared Phase 1 trials led by prolific researcher and expert in the field, Professor Fiona Wood AM at the University of Western Australia. The collaboration with Professor Wood caught the attention of Karst Peak, a specialist biotechnology focussed hedge fund which substantially backed Avita Medical (ASX: AVH), the Company built to commercialise Professor Wood's invention - "spray-on skin". Avita has since redomiciled to the US and is experiencing compounding success with the RECELL system, from which Karst increased their investment by more than 500% within two years of identifying the commercial opportunity.

Pharmaxis' drug discovery group comprises an experienced team with backgrounds in Big Pharma like GSK and Boehringer Ingelheim. The Group has overseen 6 drugs through to clinics in as many years, a figure significantly higher than the norm in the pharma world.

Pharmaxis' research remains supported by their respiratory pharmaceutical manufacturing business with products Bronchitol and Aridol producing ongoing revenue with distribution and licencing deals.

Other assets in Pharmaxis' pipeline include drugs designed to treat neuroinflammation, chronic kidney disease and Duchenne muscular dystrophy.

Focus on fibrotic conditions

Pharmaxis' primary focus is on fibrosis, a pathological disease mechanism that results from many different diseases and conditions. Almost any organ in the body can develop fibrous connective tissue following injury or damage. Fibrosis is completely normal and a healthy part of healing, however when dysregulated can cause complications.

Fibrosis in cancer

The target disease of PXS-5505, myelofibrosis, is a pro-fibrotic condition. In this rare bone marrow cancer, fibrotic scar tissue builds up and disrupts production of normal blood cells leading to reduced immunity, bleeding issues and poor patient outcomes.

Current standard of care therapy for myelofibrosis involves treatment with a class of drugs called JAK inhibitors (ruxolitinib and fedratinib), conservatively valued at USD $1 billion per year. JAK inhibitors are only symptom treating and even with treatment, the disease still portends a poor prognosis, with life expectancy of less than 5 years.

Unlike current therapies however, PXS-5505 has unique disease modifying potential as demonstrated in preclinical studies. The drug is a pan-LOX inhibitor and works to stop lysyl oxidase enzyme activity (LOX and LOX1,2,3 and 4). These enzymes are catalysts in the process of bone marrow fibrosis. Reducing their activity in pre-clinical models of the disease results in improved blood cell count, diminished spleen size and reduced bone marrow fibrosis.

Myelofibrosis affects 15 per 1 million people worldwide. About 10% of those diagnosed go on to develop leukaemia. The FDA, having already reviewed a large

package of information on the drug, granted it Orphan Drug status in July 2020, and Investigational New Drug status in August 2020, effectively expediting the drug through the regulatory process to see it reach patients sooner.

ORPHAN DRUG DESIGNATION

The FDA has a range of programs designed to streamline drug development.
Under the Orphan Drug Act, companies can apply for an Orphan Drug Designation, which is awarded to certain drugs by the FDA to encourage and accelerate development of drugs to treat rare diseases (illnesses that affect less than 200,000 people). The designation provides financial incentives for companies to expedite drug development such as partial tax credit for clinical trial expenses, waived prescription drug user fees (approximately USD $2.2 million in value) and eligibility for 7 years of marketing exclusivity.

In addition to these marketing and development rights, the FDA provides protocol assistance, discounts on registration fees and potentially, reduced wait-time for drug approval.

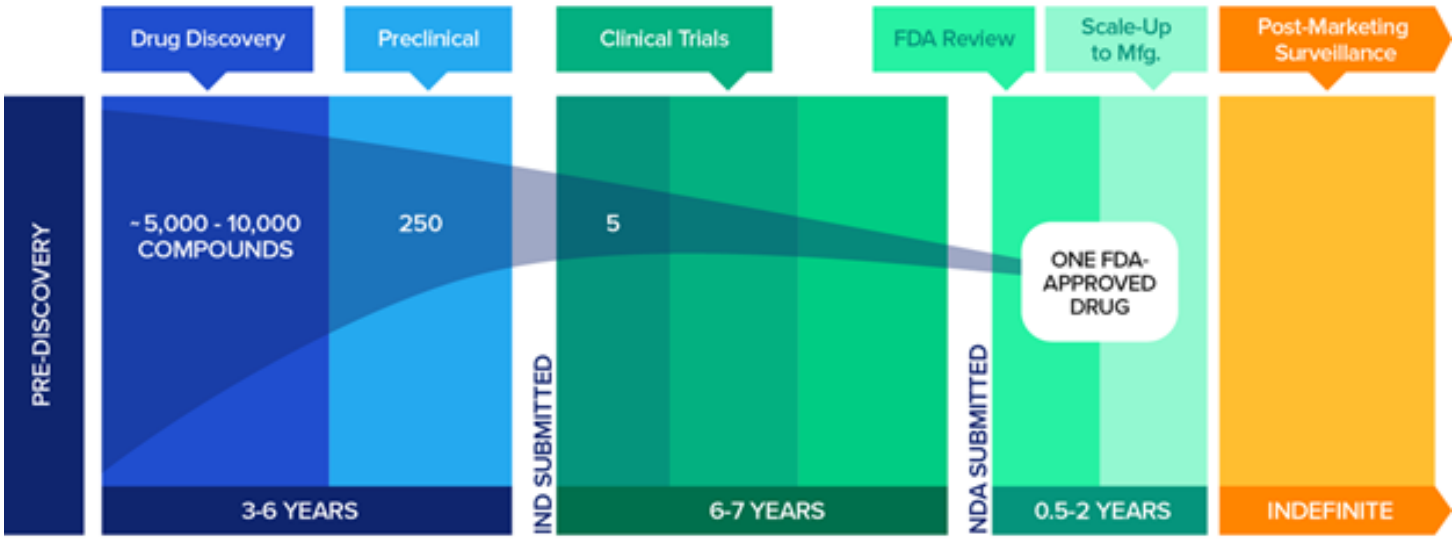
Generates positive value for companies

It's important to note that Phase 1 trials primarily evaluate the safety of the drug in healthy volunteers. Since these have already been carried out and cleared, PXS-5505 won't have to undergo the full phase 1 program again, even if being studied for another indication.

PXS-5505 entered Phase 2 trials in October, 2021 following positive results from their Phase 1c trial where it was demonstrated that the drug was safe to be taken longer term and caused a complete inhibition of the enzymes that are at the core of the disease. The dose expansion phase will now seek to evaluate the drug's performance at the highest dose in 24 patients for 6 months across trial sites in Australia, South Korea, Taiwan and the USA. Trial infrastructure and funding is in place, putting the Company on track to complete the study by the end of 2022.

Due to its unique mechanism of action, PXS-5505 has piqued the interest of renowned global researchers who have conducted their own studies on the drug, revealing that PXS-5505 holds potential for the treatment of numerous other conditions, including: brain cancer, liver cancer and pancreatic cancer. The ability of the drug to break down fibrotic tissue at the cancer site has been shown to enhance the effect of

Developing a New Medicine Takes 10-15 Years



Source: UCSD Drug Development MOOC

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chemotherapy in pre-clinical trials, and could potentially be used as an adjunct to chemo drugs, a $50 billion market.

The University of Rochester in New York conducted preclinical work looking at the role of lysyl oxidase enzymes in liver cancer and evaluating if PXS-5505 could affect change in relevant disease models.

The preclinical study showed for the first time that PXS-5505 had an effect on cancers other than myelofibrosis, opening up a new addressable market for the drug.

The research group proposed that PXS-5505 in combination with standard chemotherapy drugs represents an innovative therapeutic strategy for sufferers of liver cancer. Piggybacking on chemotherapy could open up Pharmaxis to a portion of the USD $50 billion per year market.

The drug has now gained Investigational New Drug status for this new indication, with the FDA clearing the drug for a Phase 2 study to support the addition of PXS-5505 as first line therapy to the current chemotherapy standard of care to treat unresectable hepatocellular carcinomas – the most common type of liver cancer, which only affords a 21% chance of surviving more than 5 years (in Australia).

The rapid progression of the drug to these new clinical trials is underpinned by extensive preclinical work carried out by the University, and the proven safety profile of the drug in Phase 1 trials. Since Pharmaxis has already done Phase 1 trials in healthy volunteers to prove that PXS-5505 is safe, there is no need for them to repeat these trials ($2.6m spent on clinical trials in FY21 and $2.6m in FY20). The ability to progress directly to Phase 2 is convenient in terms of accessing new addressable markets, and could see other trials initiated for other indications. PXS-5505 is undergoing studies for numerous other cancers such as brain cancer and pancreatic cancer.

Fibrosis in skin

Unchecked fibrosis in skin following burns, trauma or surgery can result in serious comorbidities. Pharmaxis is using their specialist knowledge in fibrotic processes to facilitate scarless wound healing which has game changing potential in the field of dermatology. PXS-6302, a Pharmaxis discovery, is a topical cream designed to eliminate skin scarring and reduce the incidence of comorbidities by inhibiting the lysyl oxidase enzymes responsible for fibrosis and scarring, the same scientific platform as PXS-5505.

Pharmacological approaches to skin scarring are rare, so the prospect of being able to offer a solution for scarless wound healing for scar revisions, keloid scarring and burns scarring is highly attractive.

The market potential for scarless wound healing is seemingly endless. In the US alone over USD $7.5 billion is spent every year on burn care. Over 80 million surgical incisions are made and 12 million traumatic

lacerations are seen each year in US hospitals, of which scarring is a major factor, contributing a further USD $12 billion to the overall addressable market. Scarless wound healing and scar revision could have major applications in the multi billion dollar beauty and dermatology industries as well. Prophylactic use of the cream again expands the market potential even further.

Renowned researcher and leader in the field of skin scarring, Professor Fiona Wood AM led the Phase 1 clinical trials of the drug to completion, delivering promising results.

Completed at the University of Western Australia (UWA) and the Fiona Stanley Hospital, the trial saw the testing of the cream on a total of 10 subjects in varying strengths and durations. The trial proved that topical treatment with PXS-6302 is safe and was well tolerated in healthy volunteers. Results showed full inhibition of the lysyl oxidase enzymes within the skin, with minimal systemic exposure. The drug will now progress to a 3 month study of the drug in patients with scars which is expected to report in 2H 2022.

With a career long goal of scarless healing, Professor Fiona Wood made her mark with the invention of 'spray-on skin', commercialised as the RECELL system by Avita Medical. Now, Professor Wood continues to pioneer innovation in her field and was optimistic following the positive results, saying: "Scars are a constant reminder of trauma with both physical and psychological impact. Our aim is to reduce the scar and reduce the impact."

"It's exciting for the research team to explore a novel path to reduce scarring and to be moving closer to that goal. Scarless healing is the vision that has motivated our work over many decades."

Professor Wood's involvement with the PXS-6302 may have been a catalyst for specialist biotech fund Karst Peak to invest. The specialist biotech fund previously held a substantial position in Avita Medical (ASX: AVH) which experienced major success with spray-on skin, Professor Wood's invention.
In 2018, Karst Peak held a 14.9% stake in Avita when

AVH shares were trading around $1.00. AVH shares then traded as high as $16.30 in February 2020 before Avita redomiciled to the United States in June 2020.

In April 2021, Karst Peak entered Pharmaxis with a 8.90% position. and has since increased that to 12.1%.

Respiratory Business and Cashflow
Narrow drug pipelines with limited indication diversity and no guarantee of success means it is difficult to predict the performance of emerging micro cap biotech and pharmaceutical companies. Pharmaxis' point of difference is their already commercialised products which are a testament to their drug development group and business strategy. Pharmaxis has two respiratory products approved in numerous markets, Bronchitol® and Aridol®.

Designed to treat cystic fibrosis, Bronchitol® is an inhaled antibiotic that clears mucus from the lungs. The drug comprises a spray-dried form of mannitol,

delivered to the lungs via the purpose-designed Orbital Inhaler. Following extensive clinical trials Bronchitol received FDA approval in October 2020 and is now approved for marketing for the treatment of cystic fibrosis in Australia, Russia, the EU and the US.

Pharmaxis' first commercial product, Aridol® is a bronchial challenge test designed to aid in the diagnosis and assessment of asthma. The lung function test detects active airway inflammation through measuring airway hyperresponsiveness. The test is the first and only approved Europe-wide bronchial challenge test and is approved for sale in Australia, major European countries, the United States, Canada and South Korea. The test is also included in both international and Australian clinical best practice guidelines for the management of asthma.

Both of these products provide a source of non-dilutive cash to fund Pharmaxis' clinical pipeline projects. The Company has a specific corporate strategy to grow this cash flow and limit expenditure on the commercial stage mannitol business. To ensure recurring revenue and cost savings, Pharmaxis has sold international distribution licenses in Russia which secured $2m for the Company. A further $2m was then secured in July 2021 when the Australian distribution rights were sold. This reduces cash expenditures and ensures that the products maintain regulatory compliance. Marketing costs are also taken care of by distributors.

Pharmaxis continues to earn a portion on sales from distributor activities, ensuring that the arm of the business which is on track to deliver be cash flow positive in FY22.

For the quarter ended 30 September 2021, Pharmaxis generated $3.27m in sales revenue which represented a 395% increase on the $0.61m from the previous corresponding quarter.

Pharmaxis Ltd - Consolidated income statement

For the year ended 30 June 2021

	2021 $'000	2020 $'000
Revenue from continuing operations		
Revenue from sale of goods	**6,680**	7,027
Other revenue	**16,017**	364
Other income	**979**	5,638
	23,676	13,029
Other expenses from ordinary activities		
Employee costs	**(11,114)**	(11,425)
Administration & corporate	**(2,659)**	(2,041)
Rent, occupancy & utilities	**(1,098)**	(999)
Clinical trials	**(2,681)**	(2,632)
Drug development	**(2,086)**	(3,709)
Sales, marketing & distribution	**(1,469)**	(1,346)
Safety, medical and regulatory affairs	**(1,621)**	(1,058)
Manufacturing purchases and changes in inventory	**(1,168)**	(1,456)
Other	**(274)**	(592)
Depreciation & amortisation	**(3,152)**	(3,236)
Foreign exchange gains & losses	**1,045**	(638)
Finance income (costs)	**(369)**	2,160
	(26,646)	(26,972)
Loss before income tax	**(2,970)**	(13,943)
Income tax expense	**-**	-
Loss for the year	**(2,970)**	(13,943)

Valuation Lever - Phase 2 Trial Data

The Company has seen significant share price growth of almost double in the past few months with more significant value inflection points in the future with their Phase 2 trials.

Industry research valuations estimate PXS-5505 is the highest value program at $116 million for the myelofibrosis opportunity alone based on the current status of development, the market opportunity and standard industry probabilities of completing clinical trial sand obtaining approval.

While it is handy to have a revenue-generating mannitol division, the greater future value of Pharmaxis is in its pipeline. It is well established that biotech companies with little revenue can still be worth billions. This was proven in 2017 when Gilead bought Kite Pharma for $12 billion despite their loss making balance sheet. The value was however found in their pipeline of CAR-T cell therapies, designed to treat cancers.

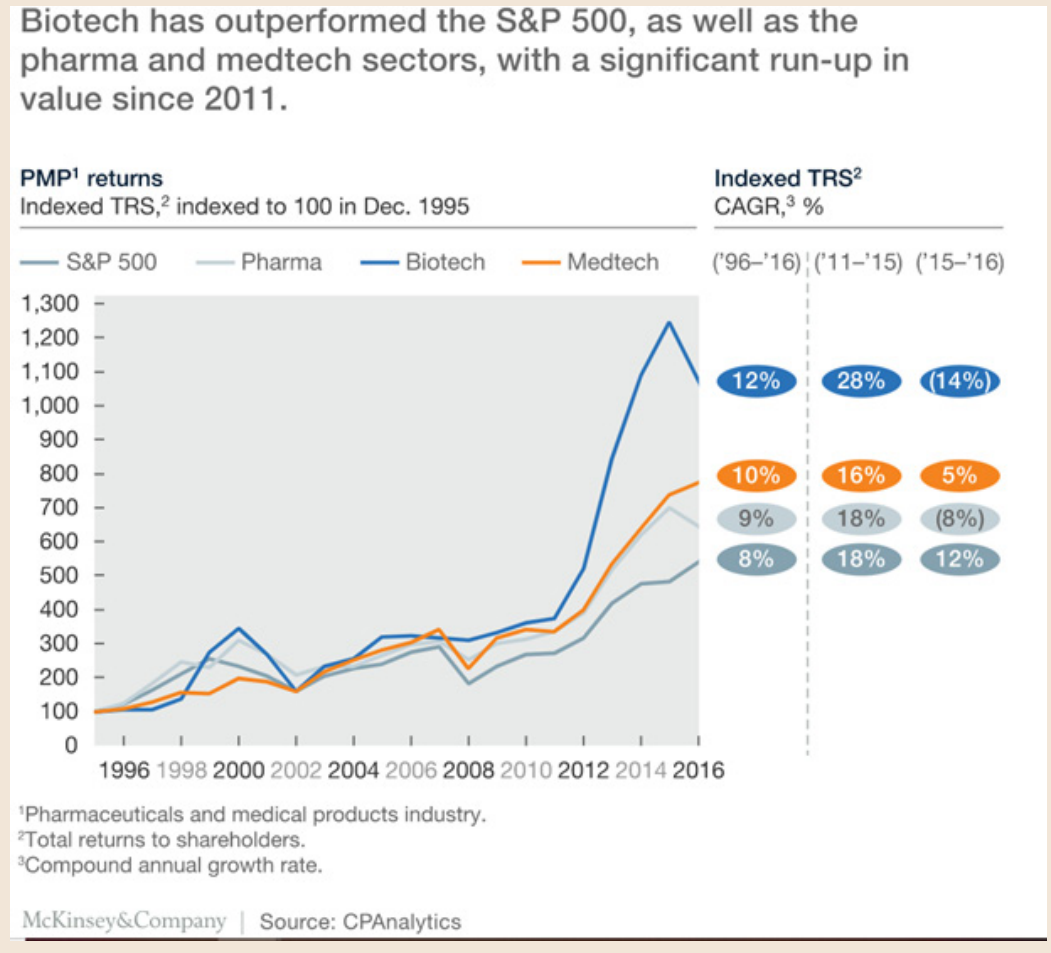
Irrespective of bottom line performance, venture capital investment in biotechs has more than doubled over the past decade. A McKinsey report looking at the performance of biotech companies in capital markets found that the sector outperformed the S&P 500 in terms of total returns to shareholders (TRS) over the past 20 years. The report estimates that the biopharmaceutical industry has created $1.7 trillion in shareholder value over the same time period.

Despite high cost per patient basis for development, margins are improved for companies creating drugs for specialty and rare disease areas by avoiding expensive commercial programs such as large scale primary care focussed sales and direct to customer marketing.

The rigorous multi stage drug trial process offers several value inflection points for biotech companies. Multiple studies have confirmed that passing each clinical trial phase results in a proportionally larger lift in share price as value increases and speculative investment risk decreases (eg: clearing Phase 2 trials causes more of an uplift than clearing Phase 1).

CLINICAL TRIAL PHASES

- Phase 1 trials assess the safety of a drug in healthy individuals. Typically 70% of drugs pass this stage.
- Phase 2 trials evaluate the efficacy of the drug in people with the target condition. Only a third of drugs will pass both Phase 1 and 2 trials.
- Phase 3 is a continuation of Phase 2, but on a larger scale. Once this Phase is complete the Company can apply for FDA approval.
- Phase 4 is undertaken after the drug has been approved for use. This Phase includes post-marketing surveillance.
reduced wait-time for drug approval.



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Myelofibrosis – examples of other programs

PXS-5505 unique mechanism of action designed for disease modification and good tolerability

Company	Market cap[1]	Bourse	Asset	Description	Clinical phase
KEROS THERAPEUTICS	$0.9bn	Nasdaq	KER-050	TGF-β ligand trap	Phase 2
Constellation PHARMACEUTICALS	$1.6bn	Nasdaq	CPI-0610	BET inhibitor	Phase 3
KARTOS THERAPEUTICS	$0.7bn[2]	n.a. – private	KRT-232	MDM2 antagonist	Phase 3
geron	$0.4bn	Nasdaq	Imetelstat	Telomerase inhibitor	Phase 3
pharmaxis	$43m (A$57m)	ASX	PXS-5505	LOX inhibitor	Phase 1c/2 commenced

PXS-5505 unique mechanism of action expected to deliver additional efficacy on top of existing standard of care and/or known pipeline drugs without adding to tolerability issues

Having completed Phase 1 trials for PXS-5505 and demonstrating safety in healthy volunteers, Pharmaxis has multiple value inflection points on the horizon with the initiation of more Phase 2 trials in cancers other than myelofibrosis. This significantly expands the Company's potential addressable market for the disease modifying drug. The potential to show clinical proof of concept in myelofibrosis trials has already garnered significant attention from key opinion leaders globally and could see the launch of more studies for various other pro-fibrotic indications to expand the addressable market for PXS-5505.

Further highlighting the value to be capitalised upon is the valuations of other drug developers targeting myelofibrosis. Companies that are developing treatments which have reported encouraging Phase 2 data and are in the process of moving to Phase 3 trials are valued at a significantly higher market cap than Pharmaxis (see table below). However, in the case of myelofibrosis, the rarity of the disease and its small patient numbers suggest there is minimal value-add for an investment case between successful data from ~50 patients in Phase 2, to ~250 patients in Phase 3. For this reason, the value multiplications are more likely to be realised upon reporting of Phase 2 data as per the companies in the table below which have all surpassed $400 million valuations with Pharmaxis expected to report its Phase 2 results before the end of 2022.

Investment Risks

Funding Risk

Pharmaxis is well funded with $25m after incurring a net loss of $2.9m in FY21. Going forward, additional clinical trial expenses will be incurred under the myelofibrosis program and liver cancer program which will run independent of each other. Additional expenses will also be incurred should PXS-6302 progress to Phase 2 trials. The cash position will be assisted by incoming revenues from Pharmaxis' mannitol division.

Clinical Risk

Drug development carries a range of associated clinical risks including clinical trial delays or failures which could have a significant impact on the progress of individual assets and related candidates.

Regulatory Risk

Market approval will depend on satisfying the requirements of multiple regulators. While Pharmaxis has achieved recent success with Bronchitol approved by the FDA, the application process encountered regulatory delays before approval was granted in October 2020.

Pharmaxis Ltd - Consolidated balance sheet

As at 30 June 2021

	2021 $'000	2020 $'000
ASSETS		
Current assets		
Cash and cash equivalents	**18,712**	14,764
Trade and other receivables	**2,959**	**7,098**
Inventories	**3,638**	2,630
Total current assets	**25,309**	24,492
Non-current assets		
Receivables	**942**	1,077
Property, plant and equipment	**6,226**	8,906
Intangible assets	**1,113**	941
Total non-current assets	**8,281**	10,924
Total assets	**33,590**	35,416
LIABILITIES		
Current liabilities		
Trade and other payables	**3,765**	3,475
Borrowings	**2,032**	1,832
Other liabilities	**1,018**	478
Provisions	**1,072**	1,040
Total current liabilities	**7,887**	6,825
Non-current liabilities		
Borrowings	**4,290**	6,322
Other liabilities	**18,515**	20,722
Provisions	**53**	116
Total non-current liabilities	**22,858**	27,160
Total liabilities	**30,745**	33,985
New assets	**2,845**	1,431
EQUITY		
Contributed equity	**371,366**	367,301
Reserves	**22,636**	22,317
Accumulated losses	**(391,157)**	(388,187)
Total equity	**2,845**	1,431

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Recommendation Rating Guide	Total Return Expectations on a 12-mth view
Speculative Buy	Greater than +30%
Buy	Greater than +10%
Hold	Greater than 0%
Sell	Less than -10%

*A Speculative Buy is speculative in nature for companies that do not have significant historical data