Pharmaxis Ltd

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Pharmaxis transformational Bronchitol FDA approval extends cash runway to fund Myelofibrosis trial

Pharmaxis Ltd (ASX:PXS) has received FDA approval for its Bronchitol® cystic fibrosis treatment, which chief executive officer Gary Phillips labels 'transformational' for the company.

He said: "The FDA still remains the gold standard by which all biotechs judge their success and the eventual quality of their programs and I'm pleased to say that Bronchitol is our second approval with the FDA.

"The approval brings US$10 million of cash milestones into the company.

"We have a long-term agreement with an international partner Chiesi in the US who expect sales to commence in the first half of next year.

"That increased cash position and increased sales give us a cash runway of two years - and there are several opportunities to extend it further without going back to the market for more cash."

The company also has sales milestone payments in the future should the product attain certain targets.

Myelofibrosis treatment

The company's Myelofibrosis (bone marrow cancer) treatment is called PXS-5505 and has demonstrated a unique mechanism of action that has the potential for disease modification. It is a pan-LOX inhibitor that seeks to reverse the bone marrow fibrosis that drives morbidity and mortality in the disease.

Phillips said: "We're pitching it into the fight against myelofibrosis, a disease which has a high unmet need.

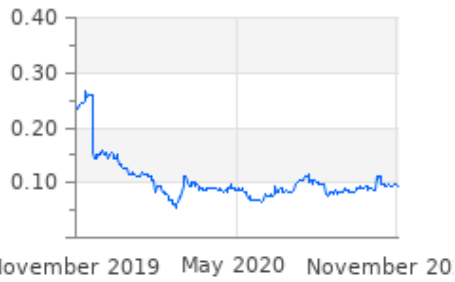
"The products in this area at the moment only give symptomatic relief and a marginal improvement in life expectancy.

"Despite this, the sales of these drugs are already approaching US$1 billion a year and we've got a drug which because of its unique mechanism of action has disease-modifying potential."

Price: 0.095

Market Cap: $37.7 m

1 Year Share Price Graph



Share Information

Code:	PXS	
Listing:	ASX	
52 week	**High**	**Low**
	0.285	**0.053**
Sector:	**Pharma & Biotech**	
Website:	**www.pharmaxis.com.au**	

Company Synopsis:

Pharmaxis Ltd (ASX:PXS) is an Australian pharmaceutical research company with expertise in developing drugs for inflammatory and fibrotic diseases and focussed on myelofibrosis.

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Company	Market cap[1]	Bourse	Asset	Description	Clinical phase
Constellation Pharmaceuticals	$1.1bn	Nasdaq	CPI-0610	BET inhibitor	Phase 2 data
Kartos Therapeutics	$0.7bn[2]	n.a. – private	KRT-232	MDM2 antagonist	Phase 2
geron	$0.5bn	Nasdaq	Imetelstat	Telomerase inhibitor	Phase 2 data
pharmaxis	$23.6m (A$32.9m)	ASX	PXS-5505	Pan-LOX inhibitor	Phase 2 ready

Compared to other companies, PXS-5505 has a unique mechanism of action which promises disease modification and good tolerability.

FDA orphan status

PXS-5505 was patented in 2018, and the company has fast-tracked the early development stages due to its potential.

Phillips said: "We've completed the long-term safety and toxicity studies, we've already completed a phase one study in healthy volunteers, we've demonstrated the product is safe, and importantly, we've already been to the FDA.

"The FDA granted the drug orphan status in July and we submitted all our data to date to secure IND approval - which gives us permission to go out and start a phase two study in patients.

"We aim to start in quarter one of next year, progressing an open label study recruiting up to 42 patients with myelofibrosis in Australia and international sites."

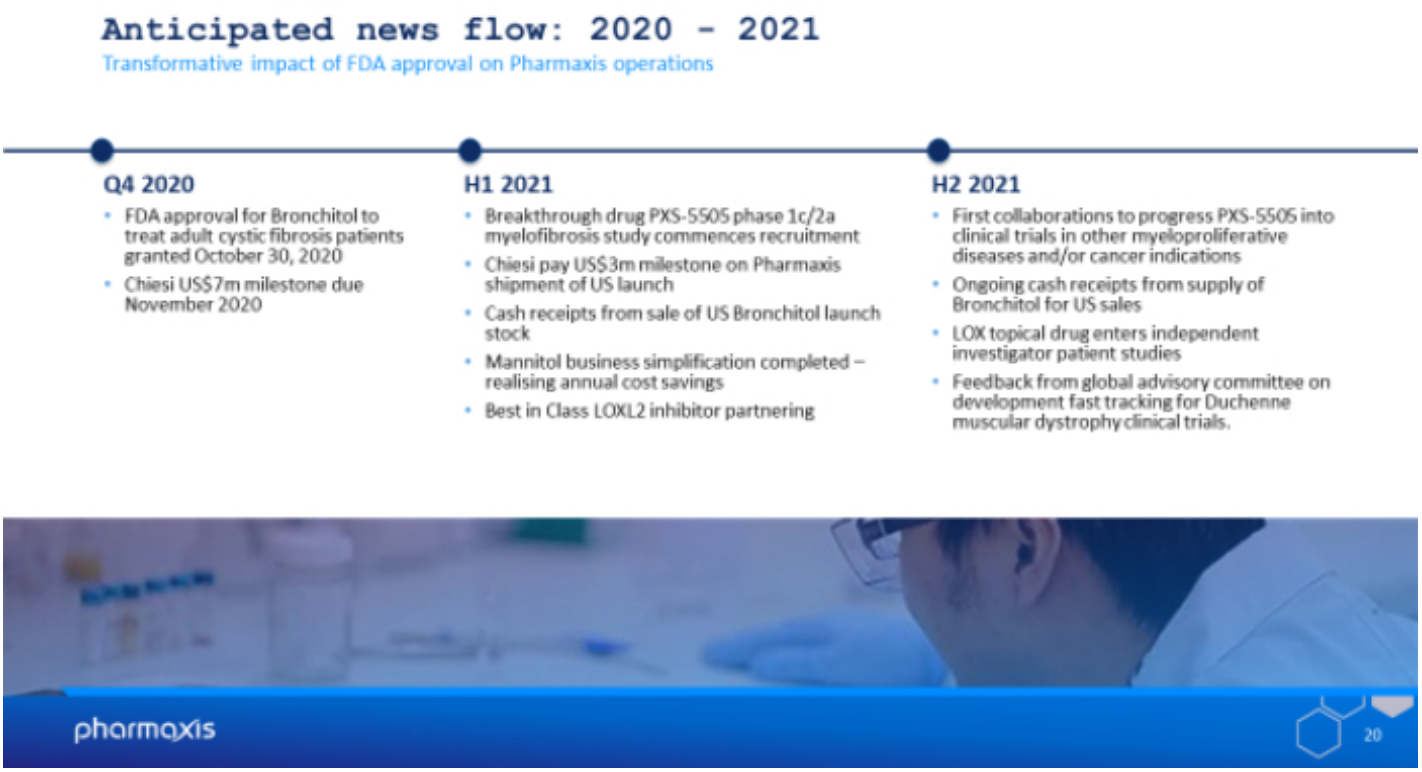
The company has also had strong academic and clinical interest in the product which can also treat other cancers such as liver carcinoma and pancreatic cancer, breaking down scar tissue which prevents the access of chemotherapy.

Potential upside

Phillips said: "Looking at a comparison with other companies with one clinical-stage product, the market capitalisation these companies are attracting demonstrates the value the market attaches to phase 2 success in this disease; over US$500 million to $1 billion.

"So, you can see the upside in valuation for Pharmaxis and its shareholders in this study which we have enough cash to complete.

"I'm confident because we've tested it in the gold standard pre-clinical models - this drug works - it really breaks down the fibrosis in the bone marrow and we expect this will allow the bone marrow to regain function and start producing normal blood cells again."



The company expects to begin the trial in early 2021 and to release data as it becomes available throughout the year.

Trial planned for Q1 2021

The company will start the PXS-5505 trial in the first quarter of next year.

Phillips said: "We've employed a global contract research organisation to help us, and due to the impact of the COVID-19 pandemic on hospitals we've put particular emphasis on feasibility testing in several different countries in order to find markets where clinical trials can run.

"We've found sites in South Korea and Australia which are open for business and we're confident that we'll be starting in quarter one next year."

Looking forward

Phillips said the clinical program was an open label trial which meant the data would be available for analysis as it came in.

He said: "You can expect to see news flow in the second half of next year when we complete the first part, the dose-escalation stage, and the data coming in throughout 2021-2022 until the final completion of the study in the second half of 2022 will allow us to make interim updates.

"The important thing here from a valuation viewpoint is how fast could we see the valuation of Pharmaxis start to reflect the clinical program.

"The next 12-18 months are going to be quite exciting."

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