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# Bioshares

5 August 2022  
Edition 922

*Delivering independent investment research to investors on Australian  
biotech, pharma and healthcare companies*

Companies covered: **ARX, CGS, CUV,  
IMR, MX1, NEU, PXS, RAP, RNO, SOM,  
TLX**

Extract from Bioshares –

## **Pharmaxis Sells Orbital Technology for US\$5 Million**

Pharmaxis (PXS: \$0.077) has executed a deal for the license and sale of its Orbital drug inhalation device with Aptar Pharma for US\$5 million.

Pharmaxis originally developed the device to deliver its mannitol powder for its Bronchitol product and retains rights to the technology for this purpose. The device allows large quantities of drug (up to 400mg) to be inhaled at once without the need to refill with active drug powder.

Applications are expected to include for the inhalation of antibiotics. For Pharmaxis it provides useful additional funding for its clinical programs. Including the expected tax rebate this year and the payment from Aptar Pharma, it will give Pharmaxis a proforma 30 June cash balance of \$21 million.

### **Key Assets - Clinical Programs**

On an investor call last week, CEO Gary Phillips said that the main assets for the company at this point are the two clinical studies underway, with early data from both trials expected this year.

The first of those is a Phase IIa study in myelofibrosis with its antifibrotic drug candidate, PXS-5505. That study has had challenges recruiting patients due to the pandemic, with just 11 of the 24 patients recruited to date. The first patient was dosed in October last year. Another factor slowing recruitment for patients has been competition from other studies.

Full recruitment into this study is expected by the end of this year with meaningful data anticipated for release by year's end according to Phillips. It is an open label study with good tolerability of the treatment by patients. Patients will remain on the oral, twice daily treatment for six months. As such, results from only some of the patients will likely be available this year with full results expected in the first half of next year.

The second study underway is a topical treatment for existing scars being undertaken in Perth with the second drug candidate, PXS-6302. One month of treatment of the first eight of 40 patients in the study has been completed with the level of enzyme inhibition in the skin measured. This is a placebo-controlled study. Patients will be treated for three months with results expected by the end of this year. Phillips said there is very little in the pipeline for the treatment of scars with companies hungry for any assets that may be effective.

Two additional studies are due to commence with the same drug candidates. The first is with PXS-6302 in patients with recent burns injuries with the aim being to reduce the level of scarring. This trial will also be conducted in Perth. Recruitment is expected to start this year.

*Continued over*

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-35.8%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May '11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - May '14)	26.6%
Year 14 (May '14 - May '15)	23.0%
Year 15 (May '15 - May '16)	33.0%
Year 16 (May '16 - May '17)	16.8%
Year 17 (May '17 - May '18)	-7.1%
Year 18 (May '18 - May '19)	-2.3%
Year 19 (May '19 - May '20)	39.5%
Year 20 (May '20 - May '21)	86.8%
Year 21 (May '21 - May '22)	-15.6%
Year 22 (May '22 - Current)	2.7%
Cumulative Gain	1663%
Av. Annual gain (21 yrs)	19.0%

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The second is an investigator-led study in New York with PXS-5505 for the treatment of primary liver cancer. The fibrotic nature of these tumours restricts the efficacy of other drug therapies. The hypothesis is that by breaking down the fibrotic network of tumours, it will allow existing cancer treatments to destroy the tumour. In this study PXS-5505 will be given in combination with a checkpoint inhibitor (anti-PD-L1) and drugs that prevent new tumour blood vessel formation (anti-VEGF drugs).

### **Lower Peak Sales for Bronchitol Expected**

Pharmaxis has been informed by its US distributor for Bronchitol (for the treatment of cystic fibrosis), Chiesi Farmaceutici, that peak Bronchitol sales are half that originally expected (previously we estimated around US\$50 million a year). One reason cited is the more difficult access to patients during the pandemic to adopt new or additional therapies. The second reason is improving combination therapies gaining approval for cystic fibrosis for CFTR modulators. Around 90% of patients are eligible for this treatment.

The most advanced of these, Trikafta, has shown to deliver a 14% improvement in lung function, but is not a cure for the disease. Demand for mucous clearing agents such as Bronchitol (and Pluozyme from Roche) continues but is lower than previously noted.

Pharmaxis had previously forecast an EBITDA for the mannitol business (Bronchitol and Aridol) of more than \$10 million for 2026. This has now been reset to \$5 million in five year's time. The business is expected to remain EBITDA positive from this point onwards.

Pharmaxis is capitalised at \$42 million.

*Bioshares* recommendation: **Speculative Buy Class A**

**Bioshares**

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**How Bioshares Rates Stocks**

For the purpose of valuation, Bioshares divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, Bioshares grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating “Take Some Profits” means that investors may re-weight their holding by selling between 25%-75% of a stock.

**Group A**

Stocks with existing positive cash flows or close to producing positive cash flows.

- Buy** CMP is 20% < Fair Value
- Accumulate** CMP is 10% < Fair Value
- Hold** Value = CMP
- Lighten** CMP is 10% > Fair Value
- Sell** CMP is 20% > Fair Value  
(CMP–Current Market Price)

**Group B**

Stocks without near term positive cash flows, history of losses, or at early stages of commercialisation.

**Speculative Buy – Class A**

These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

**Speculative Buy – Class B**

These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

**Speculative Buy – Class C**

These stocks generally have one product in development and lack many external validation features.

**Speculative Hold – Class A or B or C**

**Sell**

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