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Bioshares

30 March 2020
Edition 836

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

Companies covered: **CYC, SOM, CGS, Coronavirus Updates**

	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 - Current)	-0.1%
Cumulative Gain	680%
Av. Annual gain (19 yrs)	15.2%

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Extract from Bioshares –

Cyclopharm Lodges Technegas NDA

Cyclopharm (CYC: $1.00) has lodged a New Drug Application (NDA) for its Technegas product in the US. The company is expecting approval for its lung imaging diagnostic either at the end of this year, or in Q2 2021, depending on whether it receives Priority Review for its application.

The company has continued to state that it believes it can secure 50% of the US$90 million pulmonary embolism (PE) testing market within the first two to three years from launch, and 80% of that market within seven years from launch. It has good reason to be confident, with its experience in the Canadian market.

In Canada, Cyclopharm has 90% of the market for PE imaging procedures, where CT pulmonary angiogram (CTPA) procedures are contraindicated (about 15% of the total market). This includes in pregnant women, and patients with diabetes, a contrast media allergy, or kidney damage.

The remaining 10% uses DTPA. However this uses a nebuliser, promotes coughing, and the quality is inferior to Technegas, particular in assessing small airway diseases, where the heavier DTPA droplets fall from suspension.

The other competing product in the US is Xenon, which Technegas almost completely displaced within the first five years in Canada. In the US, Xenon and DTPA have had an equal share of the market. The issue with Xenon is that the patient needs to continuously breath the vapour, and a contained room is required.

In Canada last year, Technegas was used with over 45,000 patients, from just over 150 generators that are in place. Technegas is in use in 59 countries, but just not in the US at the moment. The US is the only country that still uses the Xenon test.

The accessible market in the US is valued at US$90 million a year, in those 15% of patients who can not be imaged using CTPA. Last year, Cyclopharm's sales were just $14.1 million with a gross margin of 82%. Entry into the US market will obviously be a game changer for Cyclopharm.

Cyclopharm has enrolled 205 of the planned 240 patients in its pivotal study for the US. However its approval pathway changed after DTPA received official FDA clearance in December 2017. It was previously used off-label. This means the company could then reference the DTPA data and file under a 505(b)(2) pathway in the US. However the full information from the 240 patient study will still be submitted once completed.

Increased Use of Technegas from Coronavirus Pandemic

Cyclopharm believes that its Technegas test has been used in patients with suspected COVID-19 disease, most likely to differentiate between PE and COVID-19 with shortness of breath reported by patients with both conditions.

Continued over

As noted in *Bioshares* 832, long term monitoring of patients following coronavirus infection for lung diseases may be necessary which may see additional long-term demand for the test. Use of Technegas is being expanded to more informed diagnosis of asthma and COPD.

The supply of Technegas has not been interrupted to date. However, non-essential lung testing with Technegas may slow due to the current pandemic, with elective procedures reduced.

Cyclopharm is capitalised at $78 million. The company held cash of $12.7 million at the end of last year.

Bioshares recommendation: **Speculative Buy Class A**

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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 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

Corporate Subscribers: Cogstate, Bionomics, LBT Innovations, Opthea, ResApp Health, Pharmaxis, Dimerix, Adalta, Actinogen Medical, Patrys, Cyclopharm, Emvision, Antisense Therapeutics, Heramed, Imugene, Exopharm, Immutep, Neuroscientific Biopharmaceuticals