

In this edition...

The concept of a "Commercialise in Australia First" strategy for biotech companies is beginning to take hold, with Mesoblast and Pharmaxis looking to launch products in Australia prior to entry into EU or US markets. One argument for this strategy is that an Australian launch is a means to iron out the bugs in the market strategy. And speaking of bugs, we profile Ondek, a private company founded by Nobel Prize winner Dr Barry Marshall, that is developing a drug delivery platform based on the bacteria *H. pylori*. The technology could revolutionise vaccination. We also update readers on progress at Starpharma and note a fundraising underway at Sunshine Heart.

The Editors

Companies Covered: MSB, SHC, SPL, Ondek

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - Current)	22.0%
Cumulative Gain	137%
Av Annual Gain (8 yrs)	14.7%

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

Extract from Bioshares –

Mesoblast – An Australia First Strategy

One company that has not been hampered by the deterioration in financial markets over the last 12 months is **Mesoblast**. The company continues to accelerate its commercialisation of its adult stem cell technologies and expand the applications.

Last week the company announced it would apply for regulatory approval in Australia for the first application of the stem cells, for the treatment of non-healing long bone fractures. There are a number of sensible strategic objectives in getting the product first approved in the local market.

Too often Australian biotech companies see the first objective in commercialising their technologies as breaking into the US market, the largest healthcare market in the world. If the company has sufficient cash resources and if all goes as planned, then following this most direct path can work, but it often requires the assistance of a large partner.

By commercialising a product in Australia first, even though a small market, allows revenue to begin sooner, and product rollout to be controlled more closely. According to Mesoblast's founder, Professor Silviu Itescu, "Australian regulatory approval will enable us to formulate a template that could be duplicated in other jurisdictions on a country by country basis."

Pharmaxis has also adopted a similar strategy. Bronchitol is expected to be first approved in Australia this year for the treatment of bronchiectasis, to be followed by approval in Europe, anticipated next year, and anticipated approval in the US in 2011.

Earlier this month **CathRx**, which is commercialising a new range of cardiac catheters, announced the appointment of its fourth distributor in Europe, with 20 sales people now selling its products into 75% of the European market. Entry into the US market will be at least 12 months behind Europe, when product sales can fund the more expensive regulatory approval process in the US.

Getting the template right first in Australia has shown to be a successful strategy. **CSL** first started its toll fractionation business in Australia before acquiring large blood fractionation businesses overseas. **Sonic Healthcare** first got its pathology business consolidation template right in Australia before expanding to the UK and the US. **ASDM**, a local orthopaedic implant manufacturer built up a profitable business in Australia before it expanded into the UK two years ago. **Portland Orthopaedic** is one company that went direct to the US and failed. It is an expensive process with a challenging regulatory system and a highly competitive market.

Another advantage for Mesoblast is that commercial success in the market in Australia will help build interest from investors and partners to help fund commercialisation in larger markets.

Cont'd over

Mesoblast cont'd

Expanding applications

Mesoblast's stem cells are now in trials or have completed clinical trials in five applications. These are:

- Long bone fracture repair (to be submitted for TGA approval)
- Spinal fusion (in Phase II trials in the US)
- Knee joint cartilage regeneration (in Phase II trials in Melbourne)
- Congestive heart failure trials (through sister company Angioblast) continues with very encouraging early results (Phase II trial in 20 patients in the US)
- Bone marrow transplant trials underway (through sister company **Angioblast**) to improve engraftment using the company's stem cells to expand haematopoietic stem cells and progenitor cells. First five of 20 patients showed two week improvement in engraftment time. (Phase II trial in US under orphan drug status)

Mesoblast owns 38.4% of Angioblast. Mesoblast has rights to the stem cell technology for use in orthopaedic applications, with Angioblast the rights for re-growth of cells in cardiac, vascular and eye diseases. The companies are making exceptional clinical progress, with the move to file for regulatory approval in Australia a measure of the surprising rate of progress being achieved.

Mesoblast is capitalised at \$155 million with \$16.5 million in cash at the end of June, or two years cash at the current spend rate.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

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.

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: Phylogica, Pharmaxis, Cytopia, Arana Therapeutics, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx

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