

In this edition...

Over the last four months, 11 companies have announced exits or planned exits from the Australian listed biotech sector. The global economic crisis is taking its toll and looks set to continue, with the possibility other leading companies being acquired for modest 70% premiums to low trading share prices if major shareholders do not hold firm.

We provide updates on BioMD, which has had success in applying its technology to the first 20 patients undergoing heart surgery. And Circadian Technologies is building its later stage pipeline, with a new cancer diagnostic that Healthscope will bring to market in the next 18 months.

The Editors**Companies Covered: BOD, CIR**

| | 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 - current) | -36% |
| Cumulative Gain | 33% |
| Av Annual Gain (7 yrs) | 17.8% |

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

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Individual Subscriptions (48 issues/year)
\$320 (Inc. GST)
Edition Number 302 (6 March 2009)
ISSN 1443-850X

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Bioshares

6 March 2009
Edition 302 extract

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

Heart Surgery Success to Drive Further Interest for BioMD

BioMD (BOD: 3.4 cents) listed in 2004 with the objective of commercialising a suite of injection therapy products (needles) with improved safety features. This part of this business has been scaled back to the level of patent estate management. However, in November 2005, the company took an interest in a unique tissue engineering technology developed at the Fremantle Heart Institute by Professor Leon Neethling. This technology was placed in Celxcel Pty Ltd, in which BioMD holds a 76% interest. To date BioMD has invested \$1.6 million in Celxcel.

Professor Neethling has developed a protocol ('ADAPT') for processing animal tissue such as bovine pericardium, from which specially cut 'leaflets' are incorporated in prosthetic heart valves. Heart valve surgery is commonplace, however, the use of prosthetic heart valves that incorporate treated animal tissues is generally restricted to older patients owing to the calcification. Younger patients are more likely to receive a fully mechanical heart valve.

The chemical that currently dominates the process for treating animal tissue products is glutaraldehyde, which preserves collagen structure. However, treated this way with glutaraldehyde, tissue products last generally no more than eight years before calcification sets in, which makes the tissue rigid and inflexible.

The ADAPT Process

BioMD's ADAPT process looks to overcome the problems caused by the use of glutaraldehyde. The ADAPT process is initiated with the removal of fats (de-lipidation), cells, DNA and RNA, and the alpha-GAL epitope (a receptor that is involved in triggering immunological rejection). A small amount of glutaraldehyde (0.05% concentration) is used to cross-link the remaining collagen. This is 1/12th of the standard concentration of 0.625%. The result is a collagen scaffold, which is less likely to calcify. This 'bio-material' once implanted is sufficient for a patient's cells and blood vessel to repopulate and regrow. However, according to BioMD, perhaps the most important step is the de-cellularisation, since that is where the calcification originates.

Clinical Trials

CardioCel - Heart Defects

BioMD has also developed the CardioCel product, which is a patch used to treat patients, typically, new-borns, babies and young children, with heart defects such as holes between the upper chambers of the heart, holes between the lower chambers of the heart, discontinuation of the wall between the upper and lower chambers of the heart, and outflow tract reconstruction.

A Phase II trial of BioMD's CardioCel product has been underway in South Africa. To date, 20 patients have been implanted the CardioCel bovine pericardial biomaterial patch. Most of the repairs occurred inside the heart, exposing the patch to circulating

venous and arterial blood. The company reported that no implant-related complications were reported at six months. Analysis by echocardiography revealed that the patches were free from blood clots, bacterial colonization and had not degenerated. One seemingly innocuous but nevertheless important comment provided by the surgeons involved in the trial was that the patch material “handles well and easily”.

Another 30 patients are to be enrolled to complete the trial, and all patients are to be examined at the six month and twelve month marks, post-surgery. All patients are to be examined using echocardiography but a small number will also be evaluated using magnetic resonance imaging.

Pelvic Wall Reconstruction Trial

BioMD is waiting on ethics approval of a trial of ADAPT treated tissue in patients requiring pelvic wall reconstruction. It is expected trial is to be conducted at a Sydney hospital. Pelvic wall reconstruction is often required for women, after child birth, and generally but not always aged in their mid 40's or older, have developed urinary or faecal incontinence.

The opportunity exists in pelvic wall reconstructions because current existing synthetic mesh products cause adhesions and fibrosis, making the pelvic floor rigid, which generally requires further surgical intervention.

This will be the first Australian trial of the ADAPT technology and will be conducted under the TGA's CTN category.

Risks

One of the key risks investors face with a company such as BioMD is the modest scale of its operations and corporate capabilities. The company's small stature is an advantage where it can investigate and develop an emerging technology. However, as the requirements for taking the technology further down the commercialisation path increase (i.e. to ‘productise’ the technology), the company could mitigate risk with addition of experienced product development, licensing and business development staff.

Another important risk with BioMD is that core intellectual property is ultimately a matter of specialised manufacturing (processing) knowledge, and less so patented inventions. This means that the optimal way to extract most value from the technology is to build, own and operate a closed manufacturing facility for treating animal tissue. However, this would require funds of \$10 or more million, according to BioMD's management. Although a difficult challenge this is an important one that BioMD must address.

One related aspect of building a manufacturing facility in this regard is that Australia is one of two BSE free cattle countries in the world. Australia is also the natural source for any kangaroo-derived tissue products. While still at an early stage of research, kangaroo pericardium has been shown to have some unique and potentially attractive properties. Kangaroo pericardium is up to half the thickness of bovine pericardium and three-times the tensile strength. BioMD is supporting a research collaboration in South Africa for a kangaroo tissue percutaneous heart valve.

Competition is another risk for BioMD, with companies such as Covidien and Pegasus Biologics, which is developing EDC carbodimide hydrochloride to replace glutaraldehyde and Kinetic Concepts (which acquired Life Cell) operating in the tissue engineering and bio-surgical products arenas.

Funding

As of January 31, 2009, BioMD held cash of only \$0.6 million. The company is currently conducting a capital raising and is seeking to raise \$0.86 million through a 1:2, 2 cents non-renounceable rights issue. Funding is a key risk for this company.

Summary

What is appealing about BioMD's ADAPT technology is that it is innovative, presenting an improvement to tissue treatment, and does not displace any surgical interventions or medical devices as such (although the potential exists for its incorporation in new products such as percutaneous heart valves). The implication is that provided the ADAPT technology proves that the features of the products it gives rise to are safe, durable and long lasting, then the potential for this novel approach is very large, extending beyond cardiovascular opportunities, to hernia and pelvic repair, orthopedics and wound repair, and even to use as a delivery vehicle for therapeutic stem cells.

The interest in heart valve applications is expected to intensify, which could not have come at a better time for BioMD. Last month, Medtronic announced it would acquire two tissue heart valve companies, CoreValve for US\$700 million, and Ventor Technologies, for US\$325 million. The ADAPT process could be extremely useful for tissue valve manufacture. This market could increase to US\$1.5 billion in 2015, from US\$100 million according to analysts.

BioMD is capitalised at \$3 million (pre-rights issue).

Bioshares recommendation: Speculative Hold Class B

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

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48 issues per year (electronic distribution): **\$320**

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