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Biosharesx

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

In this edition...
It can be a long road to commercialise a novel biotech technology. There have been many false starts and yes things do normally take twice as long and cost four times as much. A few companies have made exceptional progress, some through M&A and others from focused activities with few setbacks. But the hard work now appears set to deliver for a number of companies that listed in 1999 and their progress will be well worth monitoring in 2008.
Elsewhere, Halcygen Pharmaceuticals' path to market looks like it will be more difficult than originally expected but the news may not all be bad for that company. And we provide a brief investment update on five other biotechs in the sector.

The editors
Companies covered: BLS, BNO, CYT, FER, GTG, HGN, PBT, POH, SPL

	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 (from 4 May '07)	-12.6%
Cumulative Gain	**185%**
Av Annual Gain (6 yrs)	**26.8%**

Bioshares is published by Blake Industry & Market Analysis Pty Ltd. The company also provides market and company analysis of the Australian pharmaceutical and biotech industries for local and international funds management institutions, venture capital funds and other related industry groups. For further details contact David Blake (see details below).

Blake Industry & Market Analysis Pty Ltd
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence
No. 258032

Enquiries for *Bioshares*
Ph: (03) 9326 5382
Fax: (03) 9671 3633
Email: info@bioshares.com.au
David Blake
Ph: (03) 9326 5382
Email: blake@bioshares.com.au
Mark Pachacz
Ph: (03) 9671 3222
Email: pachacz@bioshares.com.au

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An abridged extract from Bioshares –

Class of '99 Steps Up to the Plate

The period 1999-2000 saw the biggest bull market in the global biotech sector. Driven by the excitement surrounding the sequencing of the human genome, records amount of investment flowed into the sector. In Australia in 2000, there were a record 26 new listings in the sector, which was extraordinary given there were only around 50 listed life science companies in Australia the previous year. There have been some success stories already from this pool, including Axon Instruments (sold to **Molecular Devices** in 2004) and **Sirtex Medical**. There has been some impressive progress made by others, such as **Peplin** (listed 2000) and **Chemgenex Pharmaceuticals** (relisted as Autogen in 1999). And now the next wave from the '99 biotech class are set to step up to the plate leading the next charge of aspiring Tier-1 biotechs.

Cytopia (listed 1999), **Bionomics** (listed 1999) and **Starpharma** (listed 1999 on the Austock Exempt Market) have been disappointing investments judging by their share price performance. Each are trading below their listing price aside from Bionomics, which is trading just above its 40 cent listing price. Biotech investors are told to be patient if their aim is to see the products under development reach the market. These three companies are now moving into pivotal phases of their development, with the next two years expected to deliver strong value recognition if their clinical and commercial programs deliver the results. What makes these companies worth considering is that the science behind technologies is leading edge, they are backed by strong management teams capable to keep the development on course, and they offer excellent value propositions to investors.

Starpharma

Progress at Starpharma was slow in the early years, however recently the level of corporate and development activity has been accelerating, unbeknown to the company's share price. The business is based around the use of a novel chemistry platform, dendrimers, that allows precise chemical structures to be built that can carry active components, such as antiviral actives, on the dendrimer three dimensional scaffold.

The technology can be applied to a multitude of chemical/pharmaceutical applications that is now being shown. In 2007, the company has signed three development collaboration agreements and one licensing and supply agreement. The most significant of these agreements is the development of the company's VivaGel compound for use in condoms to prevent the transmission of sexually transmitted diseases (HIV and herpes) and also as a contraceptive.

VivaGel

VivaGel is the leading pharmaceutical application of the dendrimer technology. The company is currently conducting trials testing Vivagel as a standalone topical application for the prevention of the transmission of genital herpes and HIV. It needs to be acknowledged that there is major unmet need for an effective agent to prevent the transmission of sexually transmitted diseases. There is also a paucity in the development pipeline of effective topical candidates to prevent the spread of STDs which also places Starpharma in a solid position.

Starpharma is currently working through small safety studies with Vivagel ahead of major efficacy studies expected to begin in 2008. For herpes, a trial involving an estimated 1800 people will be required which will be conducted in the US and in some parts of Africa. For HIV, around 3000 trial participants will be required in trials that will be conducted in Africa and other regions. The more immediate commercial focus for the company is for the use of VivaGel with condoms.

Major commercial focus – condom deals

Starpharma has signed development deals with two major condom manufacturers this year that is expected to see Vivagel on the market within three years. The condom market is valued at US$3.2 billion in major western markets, with **SSL International** having between 30%-35% market share. In October this year Starpharma signed a development agreement with SSL, which owns the Durex brand of condoms.

An effective antimicrobicide (and possible contraceptive) can generate up to a 50% pricing increase for condoms and may become an important differentiator for SSL for its products. The deal with SSL is exclusive. With about 30%-40% of condoms sold (in the US) previously having been coated with microbicides, such as Nonoxinol-9 which has now failed to show efficacy, it represents a potential market for SSL of at least US$400 million, before price premiums, for VivaGel coated condoms and assumes the company does not increase market share. The royalty Starpharma has negotiated is unknown, but even at 5% (*Bioshares* estimate), it represents a potential future royalty to Starpharma of US$20 million a year.

The other collaborative development agreement signed in the condom area was with an undisclosed manufacturer that is a leading seller of condoms into under-developed countries. This a region specific deal, outside of the regions under which the SSL deal covers.

Stiefel Collaboration

This week Starpharma announced a collaboration with Stiefel Laboratories, a major pharmaceutical company that specializes in dermatology and sells products into over 100 countries. The collaboration will investigate the use of dendrimers as carriers for dermatology products, to allow more sustained release of the active agents into the skin. The collaboration will initially look at two compounds and may be extended to cover other Stiefel products.

EMD Biosciences collaboration

Earlier this year, Starpharma signed a license and supply agreement with the chemical reagents company, **EMD Biosciences**, through the Starpharma subsidiary in the US, **Dendritic Nanotechnologies**. EMD will begin selling (this month) Starpharma's transfection agents for research purposes only that allow siRNA to transfect cells.

The market is worth US$200 million a year and there is a very high demand for vehicles that effectively help siRNA transfect into cells. It will be worth monitoring the demand for the Starpharma product in this area.

There is an even higher demand for delivering siRNA *in vivo* as a therapeutic agent. Starpharma is currently is discussion with potential partners that may seek to license this technology on a non-exclusive basis. If the technology, called Priostar, is effective *in vivo*, it is potentially a very valuable product for Starpharma, where the company could expect royalty rights from the development of successful siRNA therapeutics that incorporate the Priostar delivery technology.

Summary

Drug discovery and development is a long and difficult process. Some companies have been successful in accelerating commercialization through acquisition of later stage pipelines, such as Chemgenex Pharmaceuticals, or have been adept at focusing the development of a single drug candidate to ensure rapid progression through the drug development process, such as Peplin. Others, such as Cytopia, Bionomics and Starpharma have had delays and setbacks. However a common link with all three of these companies is that they appear to be ready to deliver on critical clinical and commercial milestones over the next one to two years that may see the companies as the next wave of Tier-1 Australian biotechs.

Bioshares recommendations:
Starpharma: **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

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Bioshares
PO Box 193 Richmond VIC 3121
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