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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%**

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Bioshares

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

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.

Cytopia

An in-depth update on Cytopia was provided in Bioshares 241. The company has an engine room for drug discovery that to date has delivered a cancer drug candidate (CYT997) that this week entered Phase II trials for the treatment of multiple myeloma. A further two Phase II trials are expected to begin next year with the same compound. The company has also signed a major drug development collaboration with **Novartis** in the area of auto-immune diseases that has a total potential deal value of $274 million. The company has a highly respected drug discovery capability and employs approximately 50 people. With a market valuation of only $37 million with $14 million in cash at mid year, it is an appealing speculative investment.

Bionomics

Bionomics (see also last week's edition of Bioshares) started out as a genomics company however the model for commercial success of standalone gene-based discovery businesses went out the window very soon after the human genome was sequenced. As did **Chemgenex Pharmaceuticals**, which also had its origins as a genomics company, Bionomics has broadened its drug discovery platform through acquisition, firstly of **Neurofit** in France in 2004, then the more important acquisition of **Iliad Chemicals** in Melbourne in 2005.

Cont'd over

Benefit of acquisitions

The Neurofit acquisition provided the company with a preclinical research team focused in central nervous system disorders, a specific area of interest for Bionomics. It has also played a key role in identifying the company's lead drug candidate for the company's second program, BNC210, for the treatment of anxiety, which is expected to move into clinical trials in a year's time.

Illiad Chemicals gave Bionomics a drug discovery platform which has delivered the company its lead compound, BNC105, a vascular disrupting agent for the treatment of solid tumours. This is now entering Phase I studies.

The next level of sophistication in trial design

There are two aspects that make the lead program noteworthy, representing the next level of sophistication in drug development. The level of preclinical testing conducted with this compound is extensive, with all results very specifically supporting the suspected method of action of this drug, whereby the vasculature network supplying tumour growth is specifically targeted whilst leaving the vasculature networks in healthy tissue untouched.

The Phase I trial, which is due to start now, has been designed, in *Bioshares* view, with a level of sophistication unseen previously in Australia and is arguably at the leading edge of oncology drug trial design. While it's a Phase I trial where the primary measure is to assess safety and establish the maximum tolerable dose, the design should deliver a barrage of information on the effect of the drug candidate on tumours.

The company will measure 10 different biomarkers to assess effects on tumour vasculature, use two different methods of imaging (DCE-MRI and CT scans), with the company bringing a US-based specialist imaging group out to Australia to train radiographers at the different trial sites to ensure results are consistent across the trial centers. The company has three trial sites set up for the trial with two back up sites, and it is incorporating an adaptive design feature into the trial, whereby if efficacy is seen in patients with a particular tumour type, then recruitment of follow-on patients will be directed towards patients will similar tumour growths.

Interim updates each quarter are expected to be reported to the market on the progress of the trial. If there are any signs this drug is taking effect, Bionomics will know very quickly, which is part of the new paradigm in cancer drug development.

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 der-

Cont'd over

matology 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:
Cytopia: **Speculative Buy Class A**
Bionomics: **Speculative Buy Class A**
Starpharma: **Speculative Buy Class A**

Bioshares

Halcygen Pharmaceuticals – Mixed Outcome From FDA Meeting

Halcygen Pharmaceuticals (HGN: $0.425) recently announced the outcome of an important trial protocol meeting with the FDA for its lead drug candidate, Subazole. The company is developing a range of supergeneric compounds it has in-licensed from **Mayne Pharma International** (now **Hospira**). Subazole is being developed as an improved version of Sporanox (itraconazole), an off patent antifungal drug that generates annual sales in excess of US$600 million. The outcome of the meeting is that Halcygen will be required to conduct a more extensive Phase III study than originally anticipated. This presents both some disadvantages and benefits for the company.

Halcygen's lead drug candidate

Halcygen has in-licensed what it believes to be an improved formulation of Sporanox, that may deliver an improved absorption profile as well as a preferred patient usage protocol. Sporanox (and generic versions) are currently used twice daily for fungal infections and need to be taken with a high fat food meal. Halcygen's version has shown in pharmacokinetic studies that its version of itraconazole can deliver the same amount of active drug into the blood stream at half the dose, thereby potentially reducing side effects of the drug,

Outcome of FDA meeting

Halcygen had originally anticipated conducting only a 200 person pharmacokinetic trial in the US, which was to show that equivalent levels of the active drug (itraconazole) reach the blood stream. Following the meeting with the FDA, Halcygen will be required to conduct a larger Phase III study (the company estimates about 350 people) to show its drug is bioequivalent, that its drug is safer, and also potentially investigate whether its version can be delivered in lower doses to achieve a similar blood level of the drug in patients.

The company will continue with the 505b(2) route through the FDA, which means only one Phase III study will be required. It can use data previously filed on itraconazole by others to receive approval for its drug candidate, and drug-drug interactions do not need to be investigated. In the Phase III trial, Halcygen will compare its Subazole with generic itraconazole, delivered twice daily to patients after food, and it will also be compared against a placebo. Halcygen is also likely to need to conduct a pharmacokinetic study in about 50 people, possibly prior to the Phase III study. The company will need to meet with the FDA once again before the Phase III trial commences, this time with the dermatology division rather than the anti-infectives division.

Competitors

That there are competitors developing other versions of itraconazole justifies the approach Halcygen is taking. One competitor, **Barrier Therapeutics** in the US, has just completed enrolment of a Phase III trial of a once a day itraconazole 200 mg dose (Sporanox is delivered twice daily at 100mg per dose) in precisely the same indication that Halcygen is proceeding with, an onychomycosis fungal infection of the toe-nail.

Barrier Therapeutics accessed its version of itraconzaole, which is manufactured through a melt extrusion process, from the company that developed Sporanox, Janssen (Johnson & Johnson). Barrier had an agreement with Janssen to develop this potentially improved form to treat candidiasis although that trial failed and

Cont'd over

Halcygen cont'd

Barrier retained the rights to the itraconazole version for other fungal infections.

In the third quarter of 2006, Barrier started a 1370 patient trial which took just over 12 months to complete enrollment, which occurred at the end of September this year. The trial appears to be similar in duration to the planned Halcygen Phase III trial with patients being treated for three months and monitored for a further nine months.

Halcygen expects its trial will start in the second quarter of 2008 and to be finished by mid 2009. These timelines are reasonable if the trial starts on time and if patient numbers are around 350. Judging by the Barrier trial, enrollment is less difficult (and less expensive) than for enrolling patients for a new drug trial in a more threatening disease area. However if the trial size needs to be increased similar to the current Barrier trial then this timeline may move out further.

Positive outcomes

Although Halcygen will need to conduct a larger and more onerous Phase III study, the benefits from a positive trial outcome are that its drug will be given greater claims over generic versions i.e. that its drug is a safer version and possibly the dosage required is less. This will give it a clear differentiation over generic versions, and may also allow the company to charge a premium.

On the downside, whilst Halcygen's Subazole may deliver an improved safety aspect, the Barrier product, if successful, will be dosed only once a day, as opposed to twice daily for Subazole. It is likely follow-on trials may investigate Subazole as a once-a-day dose.

A potentially surprising upside

Another development with itraconazole is worth mentioning. The Johns Hopkins University School of Medicine earlier this year found that itraconazole may be an effective angiogenesis inhibitor. It is a surprising finding but one that may have a positive impact, although not in the short term, on the itraconzole market.

Summary

Although the news may not have all been good for Halcygen following its recent FDA protocol meeting, there is a clear health outcome argument for developing a safer version of itraconazole, a point that is not likely to be lost on the FDA. The presence of competitors is positive from the viewpoint that it's a market worth investing funds into, and it does not appear to be a straightforward process to develop improved versions of Sporanox, and to bring such products to market. The timelines have been moved out for Halcygen although the company believes it has the funds to get its lead program through to the end of its Phase III trial with just under $14 million in the bank at the end of September. The next critical milestones for Halcygen will be results from further pharmacokinetic studies and the outcome of its next meeting with the Dermatology Division of the FDA.

Bioshares recommendation: **Speculative Hold Class B**

Bioshares Model Portfolio (7 December 2007)

Company	Price (current)	Price added to portfolio	Date added
Bionomics	0.415	0.415	December 2007
Cogstate	0.135	0.13	November 2007
Ventracor	$0.66	$0.625	October 2007
Sirtex Medical	$4.72	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.39	$0.66	September 2007
Progen Pharmaceuticals	$2.52	$3.52	September 2007
Starpharma Holdings	$0.36	$0.37	August 2007
Pharmaxis	$4.17	$3.15	August 2007
Universal Biosensors	$1.55	$1.23	June 2007
Biota Holdings	$1.32	$1.55	March 2007
Tissue Therapies	$0.45	$0.58	February 2007
Probiotec	$1.40	$1.12	February 2007
Phylogica	$0.23	$0.42	January 2007
Peplin Inc	$0.79	$0.83	January 2007
Arana Therapeutics	$1.17	$1.31	October 2006
Sunshine Heart	$0.16	$0.19	September 2006
Chemgenex Pharma.	$1.01	$0.38	June 2006
Cytopia	$0.50	$0.46	June 2005
Optiscan Imaging	$0.27	$0.35	March 2005
Acrux	$1.35	$0.83	November 2004
Alchemia	$0.71	$0.67	May 2004

Portfolio Changes – 7 Dec 2007

IN:

Bionomics has been added at 41.5 cents.

OUT:

No changes.

Bioshares Five Stock Wrap

Company	Biolayer	**Code**	BLS	**CMP**	$0.08	**Cap'n ($M)**	$6.0	**Cash ($M)**	$1.05	**SI**	**1.1**
• BLS has developed a chemistry platform that controls and improves the capture and orienting of antibodies on surfaces such as glass											
• The technology, in theory, offers cost of goods and performance efficiencies to such products as immunoassays											
• BLS has under-performed since its back-door listing through SSH Medical in 2005 despite collaborations with five diagnostic firms											
• Strategy has shifted to include development of own diagnostics - blood tests for Alzheimers and Parkinsons											
• Beginning 05/07, for a US client, BLS recently improved the sensitivity of a Thyroid stimulating hormone test, and a PSA test by 10-fold											
• Milestone: BLS expects to complete 3 IVD projects for clients through H1 2008.											
• Validation of a blood-based Alzheimers assay in Q3 2008 offers blue sky for BLS; current assays poorly detect beta-amyloid in blood											
Comment: Slower than expected progress in validating its technology with multiple collaborators has hit BLS hard											
Bioshares recommendation: **Speculative Buy Class B**						Timing Considerations - None					

Company	Genetic Technologies	**Code**	GTG	**CMP**	$0.155	**Cap'n ($M)**	$56.2	**Cash ($M)**	$16.28	**SI**	**N.A**
• GTG operates a DNA testing service and manages an IP estate covering non-coding DNA											
• A new CEO, Michael Ohannesian, ex Mobil Oil, Boston Consulting Group and Vision Systems was appointed in September											
• Ohannesian played a significant role as CEO of Vision Biosystems in designing and executing its immunohistochemistry strategy											
• We expect GTG to add new products to grow the testing business to replace annuity licensing revenue which we expect to cease in 2010											
• Issue - founder Dr Mervyn Jacobsen owns a 42% of GTG; balancing this holding is a register management issue for the board											
• Milestones: Quarterly cash flow statements to be monitored for signs that efficiencies are being achieved											
• Introduction of new tests											
Comment: With a new CEO at the helm, who has an impressive track record, GTG will be a stock to watch											
Bioshares recommendation: **Speculative Hold Class B**						Timing Considerations - Share register rebalance pivotal					

Company	Prana Biotech	**Code**	PBT	**CMP**	$0.27	**Cap'n ($M)**	$49.0	**Cash ($M) est.**	$16.0	**SI**	**1.7**
• PBT is developing a drug PBT-2, a metal attenuating compound, to treat Alzheimers disease.											
• PBT has disappointed before with development of PBT-1 halted because of manufacturing impurities (di-iodo-8-hydroxyquinoline)											
• However PBT-2 is a cleaner drug; recent PII safety monitoring report said "no emergent pattern of unwanted adverse events" was observed											
• The current Phase II trial is being conducted in Sweden; if successful, a US development (regulatory) plan will need to be spelt out											
• Issue - substantial options/warrants (~60m) remain outstanding with PBT; fully diluted cap'n is $65 million											
• Milestone - Phase IIa results expected Q1 2008											
Comment: PBT offers a clear-cut short-term trial results trading opportunity; if results are unambigous expect a major transformation											
Bioshares recommendation: **Speculative Buy Class C**						Timing Considerations - buy and sell before trial result ann.					

Company	Fermiscan Holdings	**Code**	FER	**CMP**	$1.07	**Cap'n ($M)**	$153.4	**Cash ($M)**	$22.6	**SI**	**3.3**
• FER is developing a breast cancer screening technology based on X-ray diffraction in conjunction with synchotron facilities											
• The theory of the technology associates x-ray diffraction patterns taken from hair samples with the occurrence of cancer											
• FER is running a 2000 patient validation study; interim results from 500 subjects were reported in August											
• 10/14 pts were correctly identified as having breast cancer; 4 were missed due to hair chemical treatment											
• Hair colouration is widespread and an inability to distingish chemically treated hair may be a negative for the FER business											
• Another negative for FER is its reliance on dedicated beam lines; synchotrons require significant downtime for maintenance											
• In our view it is not certain that the FER technology can uniquely identify cancers by tissue type; hence more studies may be required											
• Milestones: FER expects validation trials to be complete end 2007; there is a likelihood this milestone will not be met											
Comment: Developing a screening technology exclusive of evidence-based medical practise is exceedingly ambitious											
Bioshares recommendation: **Sell**						Timing Considerations - None					

Company	Phosphagenics	**Code**	POH	**CMP**	$0.23	**Cap'n ($M)**	$143.5	**Cash ($M)**	$16.30	**S.I**	**1.5**
• POH is commercialising tocopeherol (phosphorylated vitamin E) in drug delivery, cosmetics, and nutraceuticals											
• Completed Ph. I trial for TPM Insulin (Aug); commenced Ph. I trial TPM oxycodone (pain) (Sept); commenced Ph II TPM insulin (Sept)											
• Nestle is funding a Ph.II trial of Phospa E in the management of metabolic syndrome											
• Lack of newsflow on research agreement (11/12/05) with drug delivery company ALZA is not a positive sign											
• Orbis Global Equity Fund holds a 15.2 % stake in POH (up from 7.5% 14/11/05)											
• Milestones: Complete Ph. II TPM Insulin in H1 2008; complete Ph.1 TPM Oxycodone Q1 2008											
• Filing of INDs for TPM insulin and TPM morphine											
• POH has stated that its insulin product will need to be formulated as a patch; and to reach the market in 3 yrs (Sky News 21.8.07)											
Comment: High capitalisation relative to progress made to date											
Bioshares recommendation: **Sell**						Timing Considerations - None					

Notes: SI - Survival Index - refer to Bioshares 240 for explanations

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, NeuroDiscovery, Biotech Capital, Cygenics, Cytopia, Biodiem, Arana Therapeutics, Starpharma Holdings, Cogstate, Xceed Biotechnology, Incitive, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Medical Therapies, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma

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