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Bioshares

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

In this edition...
A falling US dollar has implications for global biotech. This week Japan's Takeda snapped up Millennium Pharmaceuticals for US$8.8 billion, aided by a 20% appreciation of the Yen against the USD. The Aussie dollar is 30% higher from two years ago, so what might the local giant CSL do?

Acquisitions are a fact of life in biotech. And while other sectors of the economy might weaken in coming months, some of the bright spots for investors will be found amongst Australian biotechs that are singled out and bought by multi-national pharmaceutical firms that can manage currency fluctuations. No company is sacred, but it will be the solid businesses that will become take-over targets.

The editors
Companies covered: QRX

	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)	-37%
Cumulative Gain	**103.0%**
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).

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Biotech Investment Activity To Be Driven By Demand for Acquisition Targets

There are now three trends emerging in the global biotech M&A stakes across the world. Firstly, biologics companies continue to be high on the radar for most major pharmaceuticals companies. Diagnostic companies are also in high demand with the advent of personalized medicine and the shift to point-of-care diagnosis. And more recently the weakening of the US dollar is making US biotech companies more attractive to international suitors, with five major cross border acquisitions of US biotechs in the last 12 months.

This big news this week was that **Takeda Pharmaceuticals** from Japan launched a US$8.8 billion bid for **Millennium Pharmaceuticals**, which was a 50% premium to Millennium's trading price. Takeda has been making a push into the US market with the firm having no presence at all in the US 10 years earlier. The falling US share price has made the Japanese currency 20% stronger than what it was two years ago. Other US acquisitions over the last year by non-US firms include **MedImmune** by **AstraZeneca**, **MGI Pharma** by **Esai** in Japan, **Ventana Medical Systems** by **Roche** and **Dade Behring** by **Siemens** in Germany.

With such a number of significant global transactions on the books it is helpful to consider the implications for the Australian biotech sector.

Implication for Australian biotech #1

For one company that has been planning an acquisition for at least two years, **CSL**, its buying power in US dollar terms is worth 30% more than what it was two years ago. Our suspicion has been that CSL's next acquisition will be a major one. For a company valued at $20 billion, a multi-billion dollar acquisition in the US is not only achievable but also likely. By the CEO's own admission, the completion of a smaller acquisition is very useful preparation for larger purchases.

The steady stream of diagnostic acquisitions has continued. In Australia, **Vision Systems** was bought in 2006 by **Danaher Corporation** for around $800 million. Since that time, **Ventana Medical Systems**, which itself made a bid for Vision Systems, was acquired by **Roche** in February this year after Ventana acquired **Spring Bioscience** in September last year.

Inverness Medical Systems has continued on its aggressive acquisition trail, recently concluding its purchased of **PanBio** from Brisbane in January this year. **Qiagen** acquired **Digene** in July last year for US$1.6 billion. And **Illumina** acquired the genome sequencing group **Solexa** last year for US$650 million. Of interest also is the acquisition of **Molecular Devices** by **MDS** last year for US$615 million. (In 2004, Molecular Devices acquired Australia's **Axon Instruments.**)

Cont'd over

Implication for Australian biotech #2

Universal Biosensors in Melbourne has developed a revolutionary system for producing point-of-care diagnostic devices. It has a manufacturing and service agreement with **Johnson & Johnson**'s **Lifescan** to make glucose test strips for electronic glucose monitors. We expect this product will reach the market in the next 12 months. Universal Biosensors retains rights to commercialise the technology for all other applications. We expect the company will be a highly likely takeover target if its glucose monitoring system is a success.

Bristol-Myers Squibb, **Pfizer**, **GlaxoSmithKline**, **Wyeth**, **AstraZeneca**, **Astellas Pharma** (Japan) and **Eisai** (Japan) have all extended their interest into biopharmaceuticals, acquiring antibody companies, antibody-enabling technologies, and peptide-enabling technologies over the last year. In Australia we have seen the acquisition of **Evogenix** by **Arana Therapeutics**, the value of which still is missed by the market.

Implication for Australian biotech #3

The value of biologics development companies in Australia is not recognised, across the board. However, we expect interest in Australian antibody companies **Arana Therapeutics** and **Patrys to** increase over the next two to three years. Arana's lead single domain antibody drug has moved into Phase II trials for the treatment of psoriasis with an IND expected to be filed next quarter followed by the commencement of rheumatoid arthritis trials with the same compound.

Patrys is making solid progress with its human antibody drug candidates and with major manufacturing milestones forthcoming this year with clinical trials to begin early in 2009. Worthy of note is the acquisition in December last year by Astellas Pharma of human antibody company **Agensys** for US$387 million. Similar to Patrys, Agensys was developing human antibodies for the treatment of cancer. And Phylogica's peptide library has the potential to be the basis of a very valuable platform technology if it can optimise its peptides for binding properties and increased half-life.

Implication for Australian biotech #4

Another acquisition announced in the last week was that of **LifeCell** corporation by **Kinetic Concepts** for US$1.7 billion in cash. LifeCell has developed a range of tissue repair products. Its lead product, AlloDerm, generated sales of US$167 million last year to repair damaged tissues in hernia and breast reconstruction. This follows a bid last month by **Covidien** for UK-based **Tissue Science Laboratories**, which has developed a collagen-derived porcine tissue implant for hernia repair. This transaction may bode well for **BioMD**.

BioMD is due to start Phase II trials in South Africa for its bovine-based tissue repair product that has been stabilised using its proprietary ADAPT multiple application technology. BioMD's trial will involve the repair of congenital heart defects in 50 patients. The company is seeking to also apply the technology to hernia repair and mastectomy procedures.

** Source: Signals Magazine*

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Correction: In the table in last week's edition that listed capital raisings for the March quarter 2008, the figure for Imugene was incorrect. The correct figure was $1.828 million.

Biotech Venture Capital Model Starts To Bear Fruit

The Nanyang Innovation Fund, a fund managed by Sydney-based **Kestrel Capital** has experienced a good run over the last 18 months. Over this period the company has completed two trade sales of its investee companies and has seen another of its interests list on the ASX. The biotech venture capital investment model is starting to bear fruit and gain validation for the first Innovation Investment Funds (IIF) which were formed through support of the Federal Government in 1997. Showing that venture capital investment in the biotech sector in fact works is crucial to the continuation of investment in emerging life science companies in Australia.

The Federal Government launched the IIF program to encourage venture capital investment into emerging businesses. The program has arguably been the driver of the venture capital industry in Australia. There are limitations to IIFs such as a maximum available investment of $4 million per company which has changed to $10 million for the third IIF round. However the Government has provided incentives to venture capital firms by matching private sector investment into the fund (although the Government funds do not share in the 'carry', meaning the investment return is limited to an agreed maximum return and the excess is shared by other investors and fund managers).

Solid performance from Kestrel Capital

Kestrel Capital manages four funds. One of those funds is the Nanyang Innovation Fund which was formed in 2001 and received funding through the IIF program in 2001. This is a 10 year closed end fund and overall $50 million was raised. To date it has invested in 12 ventures. The fund, managed by Dr Mike Hirshorn and Simon Uzclias, has an approximate 50% focus in the life science sector with the remainder of the investments in manufacturing, IT and telecommunications.

Of the 12 investments made, six have been in the life science space. One investment (in **Genetraks**) has failed and the fund has recently successfully exited from two investments (**BTF** and **Catapult Genetics**). The fund has seen one investment list on the ASX in May last year raising $50m (**QRxPharma**) and has two other active investments in life sciences (**TGR Biosciences** and **Dynamic Hearing**). The fund has remaining five investments in total and the funds manager believes the company is well placed to exit its investments by 2011 when the fund is due to close (although it may be possible to extend the life of the fund if necessary).

The BTF Investment

Reading through Kestrel's BTF investment case study, however, highlights some of the difficulties involved in successful venture capital investment in early stage life science companies. BTF was born from the Sydney Water Crisis in 1998, where the water supply became contaminated from difficult to detect micro-organisms. The company was founded by two scientists, Mark Gauci and Graham Vesey from **Macquarie University**, who developed a new way to precisely measure levels of the protozoa *Cryptosporidium* and *Giardia* (C&G).

The invention was based on freeze-dried Bioballs that contained a specific number of bacteria labeled with a fluorescent that when placed in water could measure the C&G contamination/activity in a water sample on the bacteria in the BioBall.

Whilst the technology was new and had wide-ranging uses, commercialising it successfully with a limited amount of funding was certainly not easy. Kestrel invested $2 million initially in the company in 2002, when the company employed eight people, was generating sales of $0.7 million and running at a loss. Kestrel helped install a new Chairman at the company and ensured rigorous financial reporting was introduced into the business. However by 2004 funding once again became an issue.

Options such as a merger were considered and in 2005 Kestrel made a subsequent $1 million investment into the company. Sales were disappointing initially with marketing limited to conferences and telemarketing (to Japan) with no professional sales people involved. A turning point for the company came in 2005 when an experienced sales executive, Chris Howard, was appointed (via the Kestrel network). By 2007 sales were growing exponentially after the addition of a new range of products for the food industry.

Kestrel brought with it funding, commercialisation and internationalisation experience, access to experienced personnel and strict reporting procedures that arguably were crucial to the success of the venture. However, when it was time to sell the business, there were at times conflicting agenda's between the founders and the investors who wanted an exit for their investment and a high internal investment return (IRR). And orchestrating a sale of the business appears to have been a task almost as difficult as building the company in the first place.

In 2006, **BioMerieux** from France became aware of the technology from one of its clients using the technology in the US, **Tyson Foods**. BioMerieux initially tried to access the technology as a distributor. However the BTF founder Mark Gauci declined, seeing BioMerieux as a potential acquirer of the BTF business. If the business was not sold, further funds would have been required to grow the business.

By May 2007, the companies were negotiating sale prices, although BioMerieux's first bid was one third of the price BTF had in mind. BTF was successful in convincing BioMerieux the market for the Bioball technology was substantially larger than BioMerieux was factoring in.

It took another four months to complete the sale. Crucial to that was the entry of a negotiator for BTF, Rob Sauer, a member of Nanyang Innovation Fund's investment committee. Major hurdles to overcome over this time were employment contracts for the BTF founders, who were not particularly keen to work for a large multinational at a lower salary, and personal warranties from the founders for 250 items (whittled down to only 170!) over the business.

BTF was sold to BioMerieux in September 2007 for an undisclosed price. At the time the business was profitable, generating sales of

Cont'd over

$4 million a year and employed 24 people. Over its $3 million investment Kestrel generated a three-fold return with an IRR of between 25% - 30%.

The Catapult Genetics Investment

Over 2005 and 2006, Kestrel Capital invested $2.4 million in **Genetic Solutions**, a Queensland-based biotech company. Genetic Solutions had developed and was selling a DNA test for the beef industry that could predict various properties of beef. These include expected tenderness of beef, marbling potential, tick resistance feed efficiency. The DNA tests take the hit and miss out of breeding for beef producers.

For this particular investment, M&A was crucial to the company for success to build critical mass and to reduce its burn rate. In 2006 the company has less than $1 million in sales. In 2006 it merged with **Catapult Systems** from New Zealand, which provided DNA testing technologies for sheep. The new entity was called **Catapult Genetics**.

In March this year, the merged entity was sold to **Pfizer Animal Health** for an undisclosed sum. For Kestrel Capital it was a very good outcome, having made just under a 2.6 times return on its investment since 2005, or an IRR or 35%.

Kestrel's two remaining unlisted plays in the sector in this fund are progressing well with TGR Biosciences likely to list when the market picks up and Dynamic Hearing flagged as a potential trade sale.

Lessons learnt

So what are the lessons to be learned from the Kestrel investment experience for investors in this space?

The presence of a venture capital fund on the share register of a listing biotech company arguably provides some validation as to the merit of the company (but not necessarily the valuation price at the time of listing). **GBS Venture Partners** and **CM Capital** have made stunning gains from their early investment in Pharmaxis (with GBS having exited the majority of its Pharmaxis investment from its first IIF fund launched in 1998), **Start-Up Ventures** has been successful with its investments in Iliad Chemicals (sold to Bionomics) and Evogenix (sold to Arana Therapeutics). Kestrel Capital is also confident it will exit an additional investment this financial year in a non-life science investment.

For Kestrel Capital, its success with its investments in BTF and Catapult Genetics can be boiled down to some common factors. One key is that global niche markets in the life sciences sector can be penetrated from an Australian base. Strong management, as always, is a necessity and a solid IP position with a pipeline to leverage a range of further products is helpful. However, a critical mass at some point is required, which invariably means more funding, a merger or the sale of the business to a larger group. Kestrel Capital managers say they have chosen companies with products rather than concepts for its fund. And funding risk is always a perpetual concern, which was one of the reasons for the Genetraks investment failing.

Industry Innovation Fund Licencees

Company	Capital Committed ($M)
Round One, 1997	
Allen & Buckeridge	$41
AMWIN	$41
CM Capital	$41
Momentumn Funds Management	$30
GBS Venture partners (formerly managed by Rothschild)	$42.50
Round Two, 2001	
Start-Up Australia	$39
Kestrel Capital (formerly Nanyang)	$50
Neo Technology Ventures	$36
Stone Ridge Ventures (formerly Foundation Capital)	$35
Round Three, 2007	
Cleantech Australia	$50
Prescient Ventures	-
Accede Capital	-
Brandon Capital Partners	$40

Kestrel's fund was limited by the IIF restrictions on investments, which has meant it has focused on investments in companies that did not have a large financial risk (the investment in QrxPharma is an exception). Its approach also differs in that it has looked for a spread of successes within its portfolio and not necessarily searching for that one major success that will return the fund (eg a Pharmaxis), although QRxPharma has the potential to provide a very good return for the fund.

Summary

The IIF program has been an important initiative that has helped build the venture capital industry in Australia. It has seeded the formation of 13 new venture capital management firms, with 11 funds having been launched to date (see table). Most recently, Brandon Capital Partners has launched a $40 million 10 year IIF (with $20 million invested by the Government) which will make dedicated investments into the Australian life sciences sector.

This IIF initiative has not only provided finding that has helped to create a sustainable biotech industry in Australia (through companies such as Pharmaxis, Bionomics and Arana Therapeutics), but it has provided the support to establish an experienced venture capital management base in Australia, some of whom are expanding into major venture capital investment firms that are approaching the size of their international peers.

Bioshares

The Commercial Context for QRxPharma's QR8003IR

QRxPharma (QRX: $1.02) is a developing the pain drug candidate Q8003IR as an immediate release dual-opioid pain therapy. The company has initiated two Phase III trials, the first of which commenced in November 2007 in 250 patients experiencing acute post surgical pain. The second (an extension study) started in December 2007, for the purpose of evaluating the longer term use and effects of Q8003IR over 28 days.

Q8003IR combines two well known compounds, morphine and oxycodone, that bind to the *mu* opioid receptors. Other compounds that act on these targets include codeine, tramadol, fentanyl, naltrexone, heroin and hydrocodone among others. Opioid drugs have been used to quite successfully treat moderate to severe pain for decades. However, limiting side effects stem from tolerance, dependency and abuse, nausea and very significantly, constipation. This has instigated the development of drugs such as Entereg (**Adolar**, **GlaxoSmithKline**) and MNTX (**Progenics**, **Wyeth**), which block the activation of certain opioid receptors in the gut but allow it act on those in the CNS (see table, next page).

Many morphine-based drugs have been off-patent for years, which means that any commercial considerations must be based on the new patented combinations or formulations, or based on new combinations and novel delivery systems, especially those that discourage abuse. New molecular entities that target the opioid receptors with superior efficacy and diminished side effect profiles have been hard to find. Another area of development has been the development of a sub-class that focuses on break through pain, which is the pain that occurs when the pain drug patients are receiving (e.g. morphine) for chronic pain fails. This sub-class is dominated by the opioid drug fentanyl, with at least eleven formulation/delivery systems approaches in development based on that compound. (*Note, Acrux is developing a Metered Dose Transdermal Spray delivery system for fentanyl.*)

QRxPharma's combination of compounds have been shown to achieve an analgesic effect equivalent to approximately half of a standard dose of morphine.

The QRxPharma approach is not dis-similar to that developed by **Elite Pharmaceuticals** and **Pain Therapeutics**, which have developed products that combine oxycodone and naltrexone (although in the different release formats of extended and immediate release respectively).

For companies working with known chemical entities, the path to market is typically shortened with often only one pivotal Phase III study required. (e.g. Pain Therapeutics' Remoxy – twice daily oxycodone – only required one Phase III study.)

Pain drug markets represent a classic drug market paradox. They are replete with many approved compounds that over many sub-sectors garner billions in sales. At the same time, there exist major opportunities to generate sales from improvements to existing medicines or introduce new chemical entities.

QRxPharma is capitalised at $77 million and helds cash assets of $40 million at December 31, 2007.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares Model Portfolio (11 April 2008)

Company	Price (current)	Price added to portfolio	Date added
IDT	$1.97	$1.90	March 2008
Circadian Technologies	$1.01	$1.03	February 2008
Patrys	$0.29	$0.50	December 2007
NeuroDiscovery	$0.14	$0.16	December 2007
Bionomics	$0.34	$0.42	December 2007
Cogstate	$0.14	$0.13	November 2007
Sirtex Medical	$3.25	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.41	$0.66	September 2007
Starpharma Holdings	$0.28	$0.37	August 2007
Pharmaxis	$2.33	$3.15	August 2007
Universal Biosensors	$0.87	$1.23	June 2007
Biota Holdings	$1.20	$1.55	March 2007
Probiotec	$1.17	$1.12	February 2007
Peplin Inc	$0.50	$0.83	January 2007
Arana Therapeutics	$0.96	$1.31	October 2006
Chemgenex Pharma.	$0.87	$0.38	June 2006
Cytopia	$0.29	$0.46	June 2005
Optiscan Imaging	$0.26	$0.35	March 2005
Acrux	$0.84	$0.83	November 2004
Alchemia	$0.43	$0.67	May 2004

Portfolio Changes – 11 April 2008

IN:

No changes.

OUT:

No changes.

Portfolio Correction

Please note there has been a slight error in calculating the portfolio overall change in recent weeks (on page 1). The figure is now accurate.

Opioid receptor targeted pain drugs in development [excluding fentanyl products]

Company	Drug Candidate	Indication	Description	Status	Comments
Adolor Corporation	Entereg (Alvimopen)	Post-operative illeus	peripherally acting mu opioid antagonist	NDA	Partnered with GSK
	Entereg (Alvimopen)	Opioid Bowel Dysfunction	peripherally acting mu opioid antagonist	Phase III	Partnered with GSK
	ADL5859			Phase II	Partnered with Pfizer
	ADL5747			Phase I	Partnered with Pfizer
Javelin Pharmaceuticals	Rylomine	Acute pain	Intra-nasal morphine	Phase III	
Progenics	MNTX (Methyl-naltrexone sub-cutaneous)	OIC Palliative care	peripherally acting mu opioid antagonist	NDA	Partnered with Wyeth
	Methyl-naltrexone i.v.	Post-operative illeus	peripherally acting mu opioid antagonist	Phase III	
	Methyl-naltrexone oral	OIC	peripherally acting mu opioid antagonist	Phase II	
Neuromed	OROS Hydromorphone	Chronic medium to severe pain	Controlled release	Phase III	US rights lic. from ALZA; marketed in EU by Janssen Cilag
Elite Pharmaceuticals	EL-216	Pain Management	Oxycodone ER and naltrexone (once-a-day, abuse resistant oxycodone)	Phase III pending	
	EL-154	Pain Management	once daily oxycodone	Phase III pending	
Theraquest	TQ-1015	Chronic cancer/ non-cancer pain	abuse deterrent, sustained release opioid agonist	?	
LaboPharm	Tramadol Contramid OAD	Chronic medium to severe pain	Has extended and immediate release components	NDA	Under mediation with FDA; approved in Australia, Sth Korea and 22 EU countries
Penwest	Nalbuphine ER	Medium chronic pain	TIMERX drug delivery system	Phase IIb	
Acura Pharmaceuticals	Acurox	acute moderate to moderately severe pain	Oxycodone IR	Phase II	
Pain Therapeutics	Remoxy	Chronic pain	Twice daily oxycodone - abuse deterrent system	NDA (exp Q2 2008)	Partnered with King Pharmaceutical
	Oxytrex	Persistent severe chronic pain	Oxycodone IR and naltrexone	Phase III	
Zogenix	ZX002	Mod. to severe chronic pain	Oral hydrocodone IR and ER	Phase II	
CeNeS	M6G	Post-operative pain	Morphine-6-glucoronide	Phase III	
Alpharma	Kadian NT	Chronic pain	Morphine and naltrexone Extended release	Phase III	
QRxPharma	Q8003IR (Oral)	Moderate to severe pain, acute pain	Morphine and oxycodone extended release	Phase III	4 dosage strengths;post-surgery, acute pain setting
	Q8003IR (Oral)	Moderate to severe pain, acute pain	Morphine and oxycodone extended release	Phase III Safety extension study	collection of additional 28 days data
Phosphagenics	TPM-01/Morphine		Transdermal morphine	Phase II completed ??	
	TPM-01/Oxycodone		Transdermal oxycodone	Phase I completed	

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, Cytopia, Biodiem, Arana Therapeutics, Starpharma Holdings, Cogstate, Xceed Biotechnology, Incitive, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems

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