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Biosshares

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Edition 254

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

In this edition...

Market conditions may not be pleasant at the moment but the flipside is there are outstanding investment considerations in most sectors, particularly the biotech sector. We look at several companies in this edition that are worthy consideration in any market. Three companies on the top of this list are Universal Biosensors, Acrux and CathRx, in that order.

Alchemia is another stock offering good value and has just made a highly relevant board appointment. Such additions to biotech boards in Australia occur far too infrequently.

In our Biotech Management Series, Tom Gumley from Freehills and Sue MacLeman from Benitec provide some very useful pointers on IP management.

The editors

Companies covered: ACL, ACR, CXD, PYC, CXD

	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)	-38%
Cumulative Gain	**101%**
Av Annual Gain (6 yrs)	**26.8%**

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Universal Biosensors – A Standout Pick In Any Market

Current depressed share market conditions provide a multiple of opportunities for investors. With a turnaround not expected for at least another 12 months, it provides an opportunity to accumulate interests in a range of companies across a number of sectors that are very attractively priced. In the life sciences sector, our current standout pick is **Universal Biosensors** (UBI: $0.95). The company is capitalised at $141 million with $39 million in cash at the end of last year and is trading at 50% off its 12-month high.

Universal Biosensors (UBS) is developing a next- generation glucose monitor system. The company has a Master Services and Supply Agreement with an arm of **Johnson &Johnson** arm, **Life Scan**. *Bioshares* recently toured the new facilities at Universal Biosensors and we remain *very comfortable* with this stock.

Universal Biosensors has designed and built an improved electrochemical cell to measure glucose levels in the blood. There are a range of glucose monitors currently available that all use metal strips on which a sample of blood is placed and a digital glucose level readout is delivered in a few seconds. There are approximately 10 billion such strips sold annually representing a market size estimated at US$5 billion a year. The market in glucose testing is all about the strips, not the meters. Life Scan has an estimated 30% of the current market.

On track for 2009

What if you could build a new improved meter with strips that can be produced at a significantly lower price? What if this system was more accurate, reliable and user friendly? This is what Universal Biosensors and Life Scan are attempting and we are confident the groups are on track to have their product on the market in 2009. (For more details about the technology refer to editions #201, #220 and #224 of *Bioshares*.)

Hurdles

Universal Biosensors remains a speculative investment. There are still hurdles that need to be overcome, particularly those concerning regulatory approval, although we believe most of the technology hurdles have been passed and the manufacturing plant is close to complete.

Counter-cyclical investment drivers

The diabetes market continues to grow at more than 10% a year and is not dependent on any economic cycles. This is a key point that cannot be over-emphasised in today's equities market environment. There is a continuing push to decentralise pathology testing and this represents further upside for Universal Biosensors as it seeks to expand the number of point-of-care products derived from its platform technology.

Follow up programs, which are about two years behind the glucose test, include a point-of-care immunoassay for C-reactive protein (CRP), which is a marker for several inflammatory conditions (current market estimated at US$350 million a year). Also a 'prothrombin time test', which measures the performance of warfarin in patients on long term blood thinning treatment (estimated market size US$150 million).

Finally it is important to note that for the glucose market, Universal Biosensors has a manufacturing and service agreement with its partner only although we believe this could still deliver a large revenue to Universal Biosensors if the technology is well accepted by the market. In the glucose testing market, acceptance by users of new technologies can be rapid where the problems can translate to an inability to scale up quickly enough.

At current prices, Universal Biosensors is a unique industrial business, that is representing exceptional value.

Bioshares recommendation: **Speculative (Strong) Buy Class A**

CathRx – UBS's Stable Mate

CathRx (CXD: $1.50) is a Sydney-based medical device manufacturer that specialises in the design and manufacture of cardiac catheters, for diagnostic and therapeutic purposes. A catheter is typically a thin hollow tube inserted into veins or arteries for the delivery of drugs of fluids or collection of fluids. However, other catheters, such as cardiac catheters may make use of the hollow core in other ways, using it for the placement of balloons or stents or to incorporate an electrical cable for processing signals.

What are cardiac diagnostic catheters ?

Diagnostic catheters are used to assess electro-physiological characteristics of the heart. There are a number of cardiac conditions that are characterised by poor or incorrect electrical functioning of the heart, leading to heart rhythm disorders.

Competitive Advantage Based on Manufacturing Innovation

Similar to **Universal Biosensors**, the potential competitive advantages of CathRx's product range exist as a result of a novel approach to design and manufacture. Investors should note that both companies share two directors in common, Chairman Andrew Denver and Denis Hanley.

CathRx's catheters are assembled with the initial coiling of insulated conducting wire around a hollow plastic tube. Over this layer is laid a plastic sheet. The electrodes, which are found at the tips of cardiac catheters, are formed by laser cutting of the plastic sheeting. The plastic sheeting is cut in precisely the right place to create electrodes at the tip of the catheter. The electrodes found on existing cardiac catheters are crimped on, or welded by hand in a very labour intensive process; in contrast, CathRx's process is amenable to more machine-base manufacturing processes, offering cost advantages.

Cont'd over

– CathRx from page 2

The electrodes are used as electrical sensors that enable a cardiologist to evaluate the status of different parts of the heart and determine which section is the cause of the electrical malfunction or arrhythmia.

The hollow plastic tube is integral to the modularity feature of the CathRx product range, whereby different steering and shaping devices can be inserted into the device while it remains in place in a patient. This is a major point of difference to other cardiac catheters, which must be re-inserted should the cardiologist require a more appropriate catheter. CathRx's products lend themselves to customisation to a patients's anatomy and can be adapted to different procedures.

Steering refers to the ability to move the catheter tip inside the heart by manipulating a thumb control on the end of the catheter held by the physician. The tip can be deflected or bent into a shape as required by manipulating the controller.

Representing an older generation of catheter technology, shaping is a term associated with a stylet (electrode tip) that does not deflect. Physicians shape the stylet prior to insertion. Once inside the heart, the stylet reverts to the 'formed'curve, between 30mm-65mm in length. CathRx expects its formable stylet range will be able to replace three existing stylets and add more formable options into the offering as well.

Multiple Products in Development

CathRx is developing cardiac catheters in three main areas: (1) modular diagnostic catheters for the right side of the heart; (2) modular therapeutic catheters for the right side of the heart and (3) diagnostic and therapeutic catheters for the left side of the heart. Within these segments, multiple products are in development.

We now expect European market launch of its first product, a fixed curve diagnostic catheter to occur in H1 2008, following receipt of CE marking, which had been expected in Q4 2007.

Marketing

CathRx will market its products in Australia but will use distributors in Europe. CathRx has appointed Cardiocare as its UK distributor, Manta Medical in Italy and France, and TOP Medical in Benelux. German and Austrian distributors have also been appointed The company expects to address the US market at a later stage, following device registrations.

Summary

Understanding the CathRx investment proposition entails understanding that company's competitive advantage in a very mature and established medical devices market comes from innovation in manufacturing. The company is moving from pilot stage manufacturing to production stage manufacturing. CathRx is capitalised at $64 million and at December 31, 2007, held $25 million in cash. Its current share price is at a very attractive entry point.

Bioshares recommendation: **Speculative (Strong) Buy Class A**

Bioshares

Acrux – Update

Another core holding in the Australian life sciences sector that is offering incredibly good value is **Acrux** (ACR: $0.90). The stock is also 50% off its 12-month high with a current market capitalisation of $151 million with $38 million in cash.

The company's first product, Evamist, is a hormone replacement therapy (HRT) spray for the treatment of symptoms associated with menopause. It is due to be launched very soon in the USA. It will be marketed by **KV Pharmaceutical**.

Marketing campaign

KV Pharmaceutical has prepared an impressive marketing campaign and will add 30 people to its US sales force to sell the drug. Evamist is expected be KV Pharmaceutical's top selling product in its women's health business, which will ensure the product receives top priority. The drug and the drug spray dispenser are manufactured by third parties on behalf of KV Pharmaceutical.

The transdermal HRT market in the US is valued at US$400 million a year and KV has indicated it expects to achieve peak sales for Evamist of US$125 million. We believe this is a conservative estimate. Acrux should start to receive royalties from sales around mid-year.

Rights over clinical trial data

Acrux is negotiating the rights over the clinical trial data for Evamist with KV Pharmaceutical which is currently owned by KV. Acrux has the option to either conduct another Phase III study in Europe or purchase the clinical data from KV through a commercial arrangement. A decision from Acrux on how it will proceed is expected in coming weeks.

Male testosterone gel – Phase III trial

Its leading human health product in development is the male testosterone gel, which Acrux will take into Phase III studies in this half year. The trial will recruit 150 men and the company is planning to file the drug for regulatory approval (ANDA) in the second half of next year.

The market for male testosterone is worth US$600 million and Acrux, at this stage, is planning to license the product out after it has filed its ANDA. This product is potentially worth as much as Evamist, which was sold to KV Pharmaceutical by Acrux's then marketing partner **Vivus** for US$150 million, cash. Acrux could feasibly sell the male testosterone product for a similar value if it gets approval in the US and still receive around a 10% royalty stream from sales.

Acrux has licensed its technology for animal applications to **Eli Lilly**. The lead product with Eli Lilly has moved into Phase III studies.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Stock Briefs

Alchemia – Adds very relevant director to its board

Alchemia (ACL: 47.5 cents) has appointed Carlo Montagner to its board as a non-executive director. This appointment is highly relevant and such appointments occur far too infrequently in this sector. Montagner was previously President of **Abraxis Oncology**. Abraxis developed the highly successful Abraxane, which now sells approximately US$400 million a year and has catapulted that group into a US$2.4 billion pharmaceutical company.

Abraxane is a reformulated version of the cancer drug paclitaxel. Alchemia is seeking achieve almost an identical outcome by developing an improved version of irinotecan (and potentially other cancer drugs) by coming it with hyaluronic acid to deliver superior performance outcomes, called HA-irinotecan. This is Alchemia's HyACT platform.

Montagner has worked with several companies in recent years with a specialty in building oncology businesses and potentially will be a valuable director for the company.

Bioshares recommendation: **Speculative Buy Class A**

Phylogica

Like most smaller biotechs, the tightening of credit markets and volatility in the stock market has had an effect on Phylogica (PYC: 10 cents). Not only has the company's share price been hit hard, but until markets improve, the progress on some of the company's programs will be restricted.

Following the resignation of the company's CEO Stewart Washer, the company has decided not to appoint a replacement CEO, suggesting the company may be considering M&A options both locally and internationally with listed and private companies.

Over the next six months the company will be adding and improving its proprietary peptide library which forms the basis of this platform technology company. This includes increasing the half-life of the peptides, improving their binding properties and customising its library to suit particular applications.

The company's partner **Opsona Therapeutics** may also affected by the tight capital markets and is currently seeking to raise funds. Phylogica's program with Opsona (targeting Toll-like receptors – various diseases) may suffer some delays if both groups are limited by funds to progress the program.

Phylogica has sufficient funds for the next 12-15 months, by which time capital markets should improve. In the meantime the company will seek to develop its platform further. Validation of the company's platform moving forward will come from clinical success of the wound healing program and further licensing/collaborative deals.

Bioshares recommendation: **Speculative Hold Class B**

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Bioshares Model Portfolio (7 March 2008)

Company	Price (current)	Price added to portfolio	Date added
Circadian Technologies	1.03	1.025	February 2008
Patrys	$0.34	$0.50	December 2007
NeuroDiscovery	$0.15	$0.16	December 2007
Bionomics	$0.35	$0.42	December 2007
Cogstate	$0.14	$0.13	November 2007
Ventracor	$0.39	$0.625	October 2007
Sirtex Medical	$3.15	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.32	$0.66	September 2007
Starpharma Holdings	$0.34	$0.37	August 2007
Pharmaxis	$2.42	$3.15	August 2007
Universal Biosensors	$0.90	$1.23	June 2007
Biota Holdings	$1.29	$1.55	March 2007
Tissue Therapies	$0.21	$0.58	February 2007
Probiotec	$1.17	$1.12	February 2007
Phylogica	$0.10	$0.42	January 2007
Peplin Inc	$0.58	$0.83	January 2007
Arana Therapeutics	$0.94	$1.31	October 2006
Chemgenex Pharma.	$0.75	$0.38	June 2006
Cytopia	$0.35	$0.46	June 2005
Optiscan Imaging	$0.21	$0.35	March 2005
Acrux	$0.95	$0.83	November 2004
Alchemia	$0.48	$0.67	May 2004

Portfolio Changes – 7 Mar 2008

IN:

No changes

OUT:

No changes

Biotech Management Series

IP Management – A Company Perspective

Sue MacLeman – CEO, Benitec

The rewards from investing in biotechnology research and development can be significant however it is also costly and time consuming. The average time to market for a NCE is 12 years and the cost US$800M. Given the level of investment required, IP protection is critical. IP protection clearly provides an incentive for innovation and without it the industry would be unwilling to invest in initial R&D then product development and commercialisation (PD&C). There has been criticism of Australian institutions that they have not obtained the maximum possible benefits of their IP and in fact have not adequately invested in IP prosecution and maintenance. There is also criticism that some institutions do not undertake adequate freedom to operate reviews, commercial analysis and competitive IP analysis (IP mapping) before they embark on R&D programmes.

In this brief review I have not covered the types of IP, patent procedures and costs, searching, identifying inventive subject matter or invention v. discovery as these are better discussed with your patent attorney or IP advisor. I have however tried to capture how a company could approach the strategic management of IP and how best to use this in decision making and aligning the IP strategy with business strategy.

Focus on commercial outcomes

In order to be successful a companies R&D program must be directed towards commercial outcomes. As a result commercial considerations and IP need to be complementary driving forces behind any R&D strategy. The formation of any R&D strategy will involve identifying all pre-existing IP assets (inventory audit), reviewing and modifying existing IP policies and procedures, reviewing how existing IP assets can support corporate objectives, reviewing the competitive landscape to identify FTO issues and potential opportunities (IP landscape mapping) and ensuring that all future R&D investment and IP coming from these efforts supports company objectives.

IP inventory audit

One of the most important activities is an IP inventory audit. IP including licensed rights should be grouped into core technologies, licensing opportunities and weak rights. This will allow you to access which areas should be maintained and invested in and which to abandon or outlicense. If a company is still in its foundational stage it is unlikely there are formal procedures for IP capture and management. It is essential to get a good system in place and the staff trained. This training should include how R&D results are captured, the patent filing process and what are the criteria for an invention to proceed to a patent application and ongoing review of the invention throughout the first year from filing the application.

Ownership capture

It is important to ensure HR policies capture ownership of the invention into the correct entity and that any external supply and licensing agreements have these clauses included as well. All R&D work should be written up in permanently bound notebooks with consecutively number pages, the text should be in permanent ink, their should be no blank spaces or skipped pages, entries should be signed and dated and witnessed, information should be legible, thorough and complete and completed notebooks should be scanned and appropriately stored.

Disclaimer: Benitec obtains IP services from Freehills

What is a patent?
A patent gives the patentee the rights to control the use of the patented technology and prevent or restrict others from entering the market. In biotech the majority of profits are derived from IP protected products or services.

IP mapping

A thorough knowledge of the companies own IP assets is only the part of the picture. It is also important to assess the competitive landscape through an IP mapping exercise. The IP map can help identify areas where there may be overlap and issues with freedom to operate (FTO) or reveal gaps that can be opportunities for future R&D. It also allows you to assess the competition and potential for future licensing or collaborations. These searches which should be continuously undertaken can also be used to avoid infringements and possible litigation.

IP in any entity usually represents an important asset and typically represents a significant investment from which shareholders and other stakeholders expect a return. The value of the IP will be reflected by the effectiveness of the PD&C path and the effective use and commercialisation of the IP. There are several ways to commercialise IP including manufacture and marketing of the commercial aspects of the invention your self, to undertake joint venture, collaborations or contact activities, to license the IP rights, to cross licenses or to sell or assign the IP.

IP valuation process

Where a patent owner does not want to develop and commercialise their IP themselves they will need to undertake an IP valuation process. This valuation will be a point in time review of the strength (and weaknesses) of the IP. This valuation will be important when negotiating terms for license including future royalties. There are number of methodologies used to value IP including market based methodologies, cost-based methodologies or income based methodologies.

IP is usually an important asset of the company and needs to be properly resourced. Patent prosecution and maintenance are important strategic activities and in house expertise and external advisors should be used to help craft the IP strategy to maximise its commercial worth and provide the maximum return on investment. With jurisdictional change it is also important to get advice in key markets e.g. US from a US advisor. Too often companies in foundational stage do not adequately invest in good IP management and longer term this increases risk or worse results in a company with compromised or useless IP assets.

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Biotech Management Series

IP Management – A Patent Attorney Perspective

Tom Gumley – Patent Attorney, Freehills

If you know the biotech sector then you will know that biotech business leaders can generally be put into one of three groups. First are those who know what value their patents add to their business. Second are those who don't know what value their patents add. These may be those who know they don't know and include those who once knew but now know they no longer know. Or they may be those who don't know they don't know. And the third are those who don't know and don't care.

This article is intended for those in the second group who want to get into the first. It is also for those who might like to test the assumptions by which they placed themselves in the first group. For those in the third group, if you are happy there you can stop reading now! But first, why aspire to be in the first group? What is so special about these people? Here's a few thoughts:

They know their business

To know what value patents add to business, one must understand that part of the products and services that the competition would copy if they could, and that part of the business processes that but for the patents would leave a loop hole for the competition.

They are better leaders

A leader who knows all of this stuff is the type of person who takes time to listen. He has to be - because business leaders are not at the same coalface as their tech, patent and BD guys. They have to listen to them to know this stuff. And good listeners are naturally better leaders.

They deliver on their promises - and their partners know and respect this

Promises are not delivered on when limitations have not been realised. A leader who knows the extent of his patent rights knows what in fact he can deliver to an industry partner and what he can't.

They know how to handle the competition

A leader who is aware of the value of patents to his business is more likely to have awareness of his competitor's position and to be able to weigh the strength and weaknesses between the parties.

They are accountable to their shareholders

A leader who knows what value patents add to his business is naturally better at managing the spend on patents and the R&D investment that supports them. He is also well placed to explain the spend to shareholders.

So if you are in the second group, what might you be doing wrong and what could you be doing to graduate to the first?

For those who know they don't know

You are aware of your knowledge gap. Your problem is that you have not yet in your mind nor in practice recognised that on the scales of importance your patents weigh as heavily if not more so than any other business issue requiring your day-to-day management. Perhaps patents are managed in isolation of core business activities? Would you ever ask the question as you progress a clinical trial "am I sure that the product we are trialling is within the scope of our patent claims?"

For those who once knew but now know they no longer know

You may well be a good manager of change in your organisation. Unfortunately this has not extended to management of your patent portfolio. For example, the things that you see as big ticket items – such as making money from a lead compound – have distracted you from a realisation that your patents remain focused on what was once more important to you, but now less so – making money from a platform from where the lead was obtained.

For those who don't know they don't know

While all seems well to you on the surface - you are forging ahead with plans to license the manufacture of a diagnostic -your patents are proceeding in another direction - as if you will make money from licensing the use of the diagnostic to a health care provider. In short there is a total disconnect between your understanding of your business and your patents. Your problem (and you certainly are not alone) may be that you have heard the well worn line "align business and patent strategy" but you have not really listened enough to implement it in your business. Otherwise you may have listened but not understood (again plenty here who do not understand that the patent claims are the key). Either way it is vital that you do something here urgently. If you even suspect that there may be a problem, you must take an honest account of the situation.

And what things might you now do to graduate to the first group of business leaders? Here's a few:

- structure your company so that your tech and BD guys are encouraged to speak to your patent guys daily
- create a forum for them to talk and to be listened to by you
- take some time to understand patent basics - so that you at least might understand what your people see as being a concern
- ask the tough questions of your patent attorney: "what do my patents really protect?" -and don't assume that they will be aware of your underlying business issues.

A final thought for those in group three - if you don't know or care how your patents add value to your business, the market will either not know about or care about you!

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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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