

**In this edition...**

In stark contrast to the doom and gloom pervading investment markets, there exist companies that are capable of indicating that some clouds have a silver lining.

Universal Biosensors, a conservative company at the best of times, has flagged that revenues and profits are expected next year. And the stock is trading at very attractive levels. Universal Biosensors is very much a counter-cyclical play, as the company manufactures test strips for use in meters used by diabetics to test blood glucose levels.

The antibody companies Patrys and Circadian Technologies continue to progress towards the clinic but are both are trading at less than cash. Tissue Therapies finally looks set to start a trial in Canada and Acrux has added another product in the pain area to its pipeline.

**Companies covered: ACR, CIR, PAB, TIS, UBI**

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - current)	-28.0%
<b>Cumulative Gain</b>	<b>49%</b>
<b>Av Annual Gain (7 yrs)</b>	<b>17.8%</b>

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# Bioshares

14 November 2008  
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*Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.*

## Universal Biosensors Forecasts Strong Sales For CY2009

The current financial crisis continues to force share prices down across all sectors. The All Ordinaries Index finished the week at 3726 points, down 46% from its all time high and down 7% for the week. However, the turbulence in equity markets presents incredibly appealing investment opportunities, opportunities that would not normally be available at such large discounts to what should be fair value for many stocks. One of the stand-out picks at the moment in the biotech sector is Universal Biosensors (UBI: 59 cents).

Universal Biosensors (UBS) is a stock *Bioshares* has followed closely since it listed in December 2006. The company has developed a new process to manufacture glucose test strips. Around 10 billion strips are sold each year, and the strips are sold for around 50 cents each. The UBS approach allows these strips to be made at a fraction of the current cost (we estimate 20%) with also delivering potentially more reliable and consistent results than existing strips.

It is not hard to understand the commitment **Johnson & Johnson's** diabetes unit **Lifescan** has to the UBS project. UBS has a manufacturing and services agreement with Lifescan, which has about 25% - 30% of the global glucose testing market, and the new strips are expected to reach the market in 2009. Lifescan has global rights to sell the strips.

Having followed UBS for almost two years, our observation is that the company is extremely conservative in its forecasts. In the past the company has indicated that it would remain quiet if there were no developments to report on, which for much of 2007 that had been the case. With this in mind, it is worth reading the recent investor update released to the market by UBS.

Emerging life science companies rarely making forward looking statements about sales and profitability because of the uncertainties involved in bringing new products to market. However UBS management is forecasting revenue in 2009 (their financial year runs over the calendar year) of between \$20 million - \$30 million. The company is also forecasting a 'healthy' net profit that will be helped by carrying through some of its \$17 million of tax losses. Its closing comment is: "Things are looking good!!!!!!" Obviously management is openly confident about the outlook for the company.

The current plant has the capacity to make 750 million glucose test strips a year and is progressing towards a doubling of that capacity. The second line will be used either to make additional glucose strips, if required, or to allow the company to manufacture strips for its follow-on products in development.

UBI has no shortage of cash, with \$31 million at the end of September, and does not expect to raise additional cash. It currently has 82 employees and is capitalised at \$89 million.

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

## Positive Preclinical Results For Patrys' Human Antibody Technology

Patrys' (PAB: 10 cents) core assets are a number of novel human antibodies that have been extracted from donors. These antibodies have shown to specifically attack cancer cells and Patrys is developing these compounds as potential therapeutics for cancer treatment. The company's other core technology asset is the ability to manufacture these human antibodies and Patrys claims it is the first biotech company to produce human antibodies at commercial yields.

This week Patrys announced positive results in preclinical studies involving five of its antibody drug candidates. In the first, one of the company's leads, PAT-LM1, was tested in 20 small animals (assume mice) and compared against a control in 20 other mice. The model was designed to test the reduction of the spread of colon cancer to the liver.

In the control group, 85% of the cases saw the cancer metastasize to the liver, whereas in the PAT-LM1 group, only 35% developed metastases.

In a second series of studies involving four other drug antibody compounds, including PAT-SM6, in a gastric cancer model, 38% (of 27 mice) developed metastases in the active group versus 73% in the control group.

Patrys is moving its two leads, PAT-LM1 and PAT-SM6, into clinical studies in Melbourne and Sydney early in 2009. It is anticipating receiving data from those trials by October 2009. The trials will look at patients with a range of solid tumours.

Patrys has now produced PAT-LM1 at commercial yields and both drug candidates are currently in GMP production with material available possibly in December for the clinical studies. Both leads have shown to be highly selective to cancerous tissues, *not* binding to 30 different healthy, human tissues/organs in laboratory studies.

In 200 tumours tested across a range of tumour types, PAT-LM1 was shown to attack close to 98% of the tumours in the laboratory, and PAT-SM6 attacked almost 90% of tumours. The high specificity for cancerous tissue should help deliver a good safety profile with the potential therapies.

Most antibody drugs on the market are derived from mice (murine antibodies) and have been humanized to some degree by adding human protein 'components'. There are no antibody drugs on the market that are fully human, despite the use of the term 'fully humanised antibody'.

Patrys has isolated its antibody candidates from humans. People naturally produce cancer specific antibodies in the blood stream to protect the body from attack from cancerous cells. However as people age, the immune system deteriorates and the probability of falling ill to cancer increases significantly.

There are no human antibody drugs on the market because of the

difficulty in producing human antibody drugs on a commercial scale. Patrys believes it has overcome this obstacle, being the first group to produce human antibodies on a commercial yield scale.

### Targets – An asset

One of the other benefits of the Patrys approach is that finding novel cancer-attacking antibodies, it is able to establish the target on the cancer cells which the antibodies are directed by the body to attack. This has delivered new cancer targets in some cases for Patrys, which it itself becomes a potentially valuable asset. Since November 2007, Patrys has filed eight new patents against new leads, new targets, new disease targets and new applications including treatment of cancer metastases. While it is early days, the possession of unique targets could translate into very significant benefits for Patrys.

Patrys has a suite of drug candidates and is moving towards a position where efficacy of two of those leads will begin to be established in 2009. It is potentially a very valuable platform for Patrys and one where Patrys is a leading player. Patrys is capitalized at \$10 million (post Acceptys deal) with an estimated \$17 million in cash following completion of the Acceptys deal.

*Bioshares* recommendation: **Speculative Buy Class B**

**Bioshares**

### Correction

In Bioshares 288, the text in the last paragraph on page 2 should read:

“The major deal between Osiris and Genzyme helps put mesenchymal stem cell treatment on the pharmaceutical industry map and should greatly assist Mesoblast with future commercialisation negotiations.”

We apologise for the confusion this may have caused.

## Circadian's People

Circadian Technologies (CIR: 68 cents) has now essentially concluded its transition from a biotech investment company to a drug development company focused on developing therapies that modulate the VEGF-C and VEGF-D cytokine targets.

These targets are of interest because inhibition may not only halt tumour growth by inhibiting the growth of tumour blood vessels but also interfere with tumour metastasis (the spread of cancer to other parts of the body), where the metastasis occurs through the lymphatic system.

To mark the break with the 'old' Circadian model, Dr John Stocker retired at the company's AGM, held on Friday. Stocker joined the Circadian board in 1996. Now the company's most senior board members are Don Clarke and Dominique Fisher, who both joined the board in September 2005. Four board members have been appointed so far in 2008, commencing with Tina McKeckan (January), CEO Robert Klupacs (March), Carlo Montagner (July), and Jonathan Skipper (August). On the face of it, the Circadian board looks to have a well balanced blend of members with corporate experience outside biotech in addition to very strong biotech company development, drug development and IP experience.

Investors should also note that CEO Robert Klupacs has expanded the management team, a necessary task for a drug developer. In addition to CFO and Head of Operations Natalie Khorchev and Head of Business Development Alex Szabo, the Circadian team now includes Megan Baldwin as Scientific Affairs Manager, Richard Chadwick (Intellectual Property Manager), Susan Foran (Product Development Manager) and Dr Mike Gerometta (CMC and Manufacturing Manager). The appointment of Mike Gerometta is significant as sourcing Australian professionals with experience in antibody drug manufacturing is difficult, and Gerometta brings considerable experience from his years at Agenix.

### Milestones

Over the next 6-18 months the company expects to achieve or record the following milestones:

- Ark Therapeutics (a licensee) to commence Phase III studies with Trinam
- Imclone/Eli Lilly (a licensee) to commence clinical studies with IMC-3C5
- Divestment of listed investments (Antisense Therapeutics – 22.8% stake; Avexa – 1.8%; Optiscan – 7%)
- VGX-100 – complete pre-clinical development
- VGX-200 series – confirm lead product development candidate
- VGX-300 – select a product development candidate
- Secure at least one strategic partnership

The company's overall objective is to take a drug candidate as least as far as Phase II proof-of-efficacy. Circadian is capitalised at \$31 million and holds cash resources of \$46 million.

*Bioshares* recommendation: **Speculative Buy Class A**

**Bioshares**

## Acrux's Steady Stream of Products

Acrux (ACR: 57 cents) continues to mine its drug delivery technology asset base. This week the company announced the addition of spray formulations of several non steroidal anti-inflammatory drugs (NSAID) to its product pipeline. The company has tested diclofenac, ketaprofen and ibuprofen and demonstrated between 5 and 9 times higher delivery of active drug through the skin.

The topically delivered NSAID market gained traction last year when **Novartis'** Voltaren (diclofenac sodium topical gel 1%) was approved by the FDA for use in treating pain associated with osteoarthritis.

Endo Pharmaceuticals has licensed Voltaren from Novartis, but only has market exclusivity till 2010, although license agreement covers a five year term.

The market for NSAIDs for managing osteoarthritic pain is in the order of US\$3.3 billion, with Endo expecting that it will generate peak sales of US\$250-\$300 million. Sales of Voltaren in the September quarter, the first effective quarter of sales, following the launch of the product, totalled US\$10.3 million.

Acrux's plan with the development of NSAID spray formulations is to out-license the formulations (and associated delivery technology) to companies better able to fund and navigate clinical trial, regulatory and market development hurdles. A larger company is likely to be in a stronger and better informed position to decide whether the transdermally delivered NSAIDS would be best taken down the OTC or the prescription medicines path.

What is worth noting is that Acrux has not needed to devote extensive resources to establishing a partnering opportunity for topically delivered NSAIDS. Acrux has commenced partnering discussions.

Acrux is capitalised at \$91 million and retained cash resources of \$32 million at September 30, 2008.

*Bioshares* recommendation: **Speculative Buy Class A**

**Bioshares**

### **Tissue Therapies Trial To Commence**

After a period of considerable delay, Tissue Therapies (TIS: 9.5 cents) has finally received approval from Health Canada for a trial of VitroGro in patients with the diabetic, venous and pressure ulcers.

VitroGro is a protein formulation that can accelerate cell growth, cell migration and protein production, and in doing so contribute to tissue repair and wound healing.

The trial will commence prior to the end of 2008, with results expected in the first half of 2009. This trial was originally planned for the second half of 2007.

The company has also released more results from a trial of VitroGro at Fremantle Hospital in WA. With four chronic wound patients treated to date, evidence of activity and benefit is emerging, with greater than, on average, 50% of wound closure occurring. Although the results are not statistically significant, there appears to be strong consistency in wound size closure across the four patients.

Tissue Therapies is in a financially challenging position, with \$0.7 million cash available to the company as of September 30, 2008. The company anticipates a reduced cash burn for the next few months and has said that it will conduct a capital raising around the time results of the Canadian trial are announced in H1 2009.

*Bioshares* recommendation: **Speculative Hold Class C**

#### **Bioshares Model Portfolio (14 November 2008)**

<b>Company</b>	<b>Price (current)</b>	<b>Price added to portfolio</b>	<b>Date added</b>
Hexima	\$0.50	\$0.60	October 2008
Atcor Medical	\$0.18	\$0.10	October 2008
CathRx	\$0.70	\$0.70	October 2008
Impedimed	\$0.73	\$0.70	Aug-08
Antisense Therapeutics	\$0.05	\$0.07	Aug-08
Mesoblast	\$0.99	\$1.25	Aug-08
Cellestis	\$2.01	\$2.27	April 2008
IDT	\$1.94	\$1.90	March 2008
Circadian Technologies	\$0.66	\$1.03	February 2008
Patrys	\$0.13	\$0.50	December 2007
Bionomics	\$0.28	\$0.42	December 2007
Cogstate	\$0.16	\$0.13	November 2007
Sirtex Medical	\$2.00	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.26	\$0.66	September 2007
Starpharma Holdings	\$0.28	\$0.37	August 2007
Pharmaxis	\$1.59	\$3.15	August 2007
Universal Biosensors	\$0.55	\$1.23	June 2007
Biota Holdings	\$0.43	\$1.55	March 2007
Probiotec	\$1.28	\$1.12	February 2007
Peplin Inc	\$0.38	\$0.83	January 2007
Arana Therapeutics	\$0.78	\$1.31	October 2006
Chemgenex Pharma.	\$0.56	\$0.38	June 2006
Cytopia	\$0.15	\$0.46	June 2005
AcruX	\$0.64	\$0.83	November 2004
Alchemia	\$0.21	\$0.67	May 2004

#### **Portfolio Changes – 14 Nov 2008**

##### **IN:**

No changes.

##### **OUT:**

No changes.

**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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