

In this edition...

'Does the management have a track record?' is a key question investors must ask when appraising biotech stocks. Recently listed diagnostics play, Universal Biosensors, has a very experienced board, which we think will stand the company in good stead as it sets out to commercialise its novel biosensor technology.

Typically, companies are punished for missing milestones, and this is what appears to have happened with Neuren Pharmaceuticals. However, a green light for the company's Phase III trial is expected soon from the FDA and that should provide a basis for renewed interest in the stock.

The editors

Companies covered: CGS, NEU, OIL, 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 (from 5 May '06)	18.1%
Cumulative Gain	229%
Average Annual Gain	26.9%

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Bioshares

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

Universal Biosensors Set to Succeed

Universal Biosensors (UBI: \$1.05) made a stunning sharemarket debut last month. It listed at 50 cents a share, soared to as high as \$1.30 and has since found price support at \$1.00. It raised \$22 million on listing. The company was profiled in edition #192 of *Bioshares*.

As the name suggests, Universal Biosensors is a diagnostic company. It is developing diagnostics to be used by patients and doctors that can be used at the point of care. The lead product is a glucose level monitor that is being developed by Universal Biosensors for its collaborator and stakeholder, **Lifescan**, a subsidiary of **Johnson & Johnson**. Lifescan has 25% of the glucose monitoring market.

The glucose test uses an electrochemical cell, as does the follow-on product, the prothombin test, which will measure blood clotting time for patients taking warfarin. The third product in development is an immunosensor, which incorporates antibodies to detect C-reactive protein, which measures cardiovascular damage.

The market for point-of-care (POC) glucose tests is well established, valued US\$7.7 billion in 2005. Obviously, it's a very competitive market. Having Lifescan as an investor in Universal Biosensors (it invested in previous private rounds in Universal Biosensors and in the float) and a partner (the technology was licensed from Lifescan in 2002 in the same year that an R&D agreement was formed) is critical to the success of this product. Lifescan retains product rights for any glucose monitoring product that may reach the market and

Universal Biosensors maintains manufacturing rights. However, a sales and distribution agreement between the two companies still needs to be signed. A product could reach the market as early as 2009.

The warfarin measurement market is established but is relatively small at present. In 2005, worldwide sales of POC testing for warfarin was US\$125 million. For C-reactive protein measurement, it is also an established test for the laboratory and in the doctor's surgery although is also relatively small, at US\$300 million in 2005.

Banking on a changing diagnostic landscape, Universal Biosensors strongly believes there is strong movement in place to POC testing and its technology base is being developed to capitalised the expected surge in POC home and doctor's surgery testing. Escalating healthcare costs caused by increases to aging populations are driving international government healthcare bodies' push to reduce the pressures on centralised healthcare and encourage more at-home patient treatment and monitoring. Universal Biosensors is developing an enabling technology platform to address this changing market dynamic.

Technology advantages

The technology innovations that Universal Biosensors scientists are developing may allow biosensors to be constructed that robustly and economically measure blood marker levels in a POC setting. The clear point of difference with existing platforms is that algorithms constructed by Universal Biosensors scientists allows electrodes used in the electrochemical tests

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to be placed closer together, accounting for the interference between electrodes through the algorithm, thereby requiring less volume of blood to be taken for each measurement. Another advantage is that the tests all use dry chemistry, with no need for chemical reagents, and the test is expected to be completed more quickly.

Risks

Sales and distribution agreement

A major risk for the company is that its partner, Lifescan, may not take up a sales and distribution agreement with Universal Biosensors for the glucose product. If and when an agreement is signed, this leaves Universal Biosensors exposed to the development schedule of its partner. However the glucose product represents a moderate potential income stream from manufacturing the glucose diagnostic strips and the diagnostic monitor.

With other diagnostics in development, the company will need to form sales and distribution agreements with international diagnostic groups.

Technical

The most significant risk is the technical risk, in developing sensors that work robustly and reproducibly and can pass regulatory hurdles. Development of biosensors, as seen with **Ambri**, can be a technically challenging task, although the Universal Biosensors approach is more simple, building on existing diagnostic platforms.

Relatively low funding risk

Funding risk is low for this company. Universal Biosensors raised \$18 million with strong institutional support. Further capital raisings can be expected and, if the share price continues to perform well, additional and sufficient funds for commercialisation should be available to the company.

Summary

There is a quiet air of confidence emanating from this company. Universal Biosensors has an A-grade pedigree that is revealed in the calibre of its founders and board members, but also in its investors and commercialisation partner. Board and management have an impressive track record in building successful businesses which places Universal Biosensors in an above average position for commercial success. The company has rallied strongly since listing, and now sits with a capitalisation of \$134 million, and we place a long term **Speculative Buy Class A** on the stock.

Bioshares

Stock Briefs

Cogstate

Cogstate (CGS: \$0.22) reported its quarterly sales and cashflow figures this week. It was a good quarter for the company, with sales increasing by 124% to \$0.82 million. Over the last six months, the result was less impressive, increasing by only 43% to \$1.2 million over the previous corresponding period. Net cash outflow for the last six months was \$1.0 million.

Overall the company continues to generate strong growth, albeit off a low base, and growth over the last six months has been less than anticipated. The target of reaching a breakeven point for this financial year is unlikely however the company is aiming to approach a cashflow positive position in approaching quarters. This will be an important target with cash reserves now down to \$1.6 million. The company has increased staff costs with personnel added to its US operations.

As the Cogstate business continues, its ability to secure additional contracts for providing cognitive testing for the clinical trial setting to pharma and biotech should increase as the company's product becomes more established. Very successful businesses have been created over the last 20 years in providing cognitive testing for this market.

The immediate challenge for Cogstate is to secure repeat contracts from more than one large pharma (at present only **Pfizer** is a regular customer). If the company can secure four big pharma as regular clients, then work should flow on relatively quickly to biotech companies.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares



The Bioshares 20 Index

Change from June 30, 2006	43.8%
Change from Dec 31, 2006	13.9%
Change - week ago	1.8%

[Latest data from Thurs. 25 Jan Close)

Nasdaq Biotech Index

Change from June 30, 2006	9.4%
Change from Dec 31, 2006	1.8%
Change - week ago	-2.1%

Neuren Waits on IND Greenlight from FDA

Neuren Pharmaceuticals (NEU: 45.5 cents) is an Auckland, New Zealand based developer of drugs that potentially may be able to treat a range of CNS (Central Nervous System) conditions, including post-operative cognitive impairment, neurological consequences of cardiac arrest and of both severe and mild traumatic brain injury and Parkinson's disease. The compounds, broadly speaking, fall into the class of neuroprotectant drugs, which means they aim to limit damage to brain cells and tissue after an injury. Neuren's lead compounds, Glypromate and NNZ-2566, have been shown to inhibit apoptosis (cell death) and protect brain cells, including neurons, astrocytes and oligodendrocytes.

The company also has several other discovery and development programs in the areas of metabolism, peripheral neuropathy and cancer.

Neuren expects to commence a pivotal Phase III trial of Glypromate (a tri-peptide fragment of insulin-like growth factor (IGF-I)) soon, contingent on receiving the go-ahead for its Investigational New Drug (IND) application from the US Food and Drug Administration (FDA). According to a company presentation filed on January 12, 2007, Neuren has finally submitted its IND. If a company filing an IND has not heard back from the FDA within 30 days of filing, then the company can begin the clinical trial program as set out in the IND filing.

Delays

Neuren had previously indicated that its Phase III trial of Glypromate would commence in the third quarter, and then fourth quarter of 2006. This delay no doubt contributed to price weakness in the stock in the December quarter of 2006, with the inability to meet a major milestone not missed by the market. A second factor contributing to recent weakness in the Neuren share price may have been the failure of the **AstraZeneca/Renovis** stroke drug NXY-059 in a second Phase III trial (SAINT II), after seemingly achieving some success in first Phase III trial. NXY-059 is a free radical trapping agent that looked to offer a beneficial time window for delivering neuroprotection, as it was shown in animal studies that it could be administered at least four hours after an ischaemic event and still be effective. In the SAINT-I trial, NXY059 improved the primary outcome of reduced disability at 90 days, but it did not improve neurologic functioning as measured by the National Institutes of Health Stroke Scale score.

This trial result looks to have extinguished the interest of AstraZeneca in developing neuroprotectant drugs, and possibly dampened the interest of other large pharmaceutical firms. The consequence of diminished interest would be that small biotech firms would have greater difficulty in partnering any CNS program that relies on a neuroprotection strategy. However, Neuren has flagged that it would consider taking Glypromate to market by itself.

Phase III trial – Glypromate

The Phase III trial of Glypromate will recruit 520 patients undergoing Coronary Artery Graft Bypass Surgery (CABG) and valve repair or replacement, at five sites in the USA, Europe and Australia. The compound will be administered as a four hour infusion at the end of surgery. It has been shown that patients undergoing CABG surgery experience cognitive impairment. Assuming the trials start this quarter, results should be expected in the second half of 2008.

Risks and weaknesses

Funding position

Neuren listed on the ASX in early 2005, raising \$15 million. The company has been back to the market several times and raised a further \$14 million. We estimate the company's cash position as of December 31, 2006, to be \$10 million. In our view the company will be looking to raise funds in the near future to support the Phase III trial of Glypromate and other activities. However, receipt of effective acceptance of an IND application from the FDA will strengthen the company's call for funds to support working capital requirements.

Escrowed Shares

The company has 116 million shares on issue. Another 15 million shares will be released from escrow this week. Investors should note that this release of escrowed shares could contribute to a weak share price should those previously escrowed shareholders decide to dispose of their holding without sufficient demand in place to meet the sale of stock.

Technical risk

Despite supportive data obtained from animal studies about the potential efficacy of Glypromate, there remains considerable risk that Glypromate will not work as intended in human patients, because of differences between the biology of humans and animal models. One recurring difference often found in neuroprotectant studies is that many animal models use young examples, and neuroprotectant drug candidates are generally evaluated in older patients.

Assessment

Neuren's progress is typical of many biotech firms, in that meeting key milestones is difficult with many factors outside of the control of the company. However, what is worth noting about Neuren is that it has an attractive and low cost plan (approximately \$10 million) to evaluate the clinical benefit of Glypromate in a single registration level study for the treatment of post-operative cognitive impairment (POCI). The opportunity to evaluate a CNS compound such as Glypromate in a single pivotal trial, and for which the FDA has indicated will be sufficient for a new drug application, should be seen as an extremely attractive investment proposition.

Neuren's POCI trial is a very clever approach, both in time and money, to ascertain the potential benefit of administering Glypromate in a small indication of POCI that serves as a proxy

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for the much larger market of stroke. Also, the company's ability to harness now well-studied biomarkers, such as the S100 protein, to improve the range of the data it generates in its clinical trials should also work in its favour.

We recommend that investors continue to accumulate the stock, especially if it weakens to the 35 cents to 40 cents range, but to also keep in mind the prospect of additional investments through placements, SPPs or right issues. The effective 'green light' from the FDA for Neuren to commence its Phase III trial should be seen as re-rating event for the stock.

Neuren is capitalised at \$60 million.

Bioshares recommendation: **Speculative Buy Class A**

Sales of Pentax and Optiscan Imaging's Confocal Endomicroscope Edge Higher

Optiscan Imaging (OIL: 47.5 cents) has released sales forecasts for the second half of the current financial year. Unit sales of its confocal endomicroscope system to **Pentax** are expected to be slightly higher than the previous six months - we estimate around 45 units compared to 42 in the previous half – and there will be an increase in sales of the miniature scanners. Total sales in excess of \$5 million are expected in this financial year for Optiscan.

Assessment

It's not a great forecast for Optiscan but it isn't a bad one either. This is the third consecutive half of recorded system sales from Optiscan to Pentax. The total number of systems expected to be sold to Pentax by the end of this financial year should total approximately 130. The US market is believed to be gaining some traction now and secondary teaching units have now been formed in Germany independent of Optiscan/Pentax by specialists trained at the Mainz teaching facility (in Germany).

Our view is that Optiscan/Pentax need to reach an installed base of 500 units worldwide to pass a tipping point that would mark a wider acceptance of this technology. A forecast increase in the level of miniature scanner orders for this half year is an encouraging sign for Optiscan, indicating that existing users are increasing the number of procedures conducted with the systems.

While it is a slow process to gain initial market penetration for this novel imaging technology, if system sales continue to hold, then a significant ramp up in sales should occur. Just when this will happen is difficult to predict. This technology represents a quantum shift in medical imaging modalities. Once a critical mass is reached (500 units), the take-up can be expected to accelerate and be sustained.

Future milestones/events to monitor

In May this year Optiscan/Pentax will once again present studies that have trialed the ISC 100 endomicroscope at Digestive Diseases Week in the US. This is the major meeting for gastroenter-

ologists and a key marketing opportunity for the companies. Other developments to look out for are partnering agreements for the rigid endoscope although few developments are expected in the short term.

Pentax-Hoyer merger

Last month Optiscan's partner Pentax announced plans to merge with another Japanese firm, Hoyer Corporation. Hoyer is a larger company manufacturing specialist IT parts and ophthalmology equipment. It's expected the combined business will continue its commitment to the flexible endomicroscope system, which represents a high growth business opportunity. However, it is a well recognised risk when two companies merge that programs can be reprioritized and this risk should be acknowledged.

Summary

Optiscan Imaging presents an outstanding long term investment opportunity. Risk is mitigated with an existing sales record, albeit brief, products on the market and a strong growth outlook. The company is well managed. And further value creation opportunities exist in applying the existing technology to rigid endoscopes for use in other medical imaging procedures such as tumour resection procedures. At current prices, an attractive entry opportunity is possible for new investors into this stock.

Optiscan is capitalised at \$48 million with an estimated \$6 million in cash. The company is expected to near breakeven for the half year just passed due to a back payment of royalties from desktop microscope sales using the confocal-fibre optic technology.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares Model Portfolio (25 Jan 2007)

Company	Price (current)	Price added to portfolio
Acruz	\$0.76	\$0.83
Alchemia	\$0.86	\$0.67
Bionomics	\$0.26	\$0.210
Cogstate	\$0.22	\$0.18
Cytopia	\$0.73	\$0.46
Chemgenex Pharma.	\$0.68	\$0.38
Evogenix	\$0.80	\$0.47
IDT Australia	\$1.95	\$1.80
Optiscan Imaging	\$0.48	\$0.35
Metabolic Pharmaceuticals	\$1.05	\$0.53
Neuren Pharmaceuticals	\$0.46	\$0.70
Peplin	\$0.84	\$0.83
Peptech	\$1.56	\$1.31
Phylogica	\$0.48	\$0.42
Prima Biomed	\$0.056	\$0.09
Progen Industries	\$6.67	\$3.40
Sirtex Medical	\$3.18	\$1.95
Sunshine Heart	\$0.22	\$0.19
Ventracor	\$1.06	\$0.92

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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