ISSN 1443-850X

In this edition...
Perhaps the IPO window is open after a long spell? This week we profile the diagnostic technology company Universal Biosensors, which may be amongst the first of a long list of companies looking to list on the ASX. December and January are favoured months for floating biotech companies, and the success of the first few to float this year will set the scene for listings in 2007.

The first quarter of 2007 will be a big one for Phase II trial results from at least five companies. We detail these companies and the clinical trials they expect to report on inside.

The editors

Companies covered: AVX, CXS, MBP, PGL, PRR, Universal Biosensors

	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)	-2.7%
Cumulative Gain	**171%**
Average Annual Gain	**23.4%**

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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Individual Subscriptions (48 issues/year)
$320 (Inc.GST)
Edition Number 192 (10 November 2006)
ISSN 1443-850X

Bioshares

10 November 2006
Edition 192

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

IPO Profile

Universal Biosensors

If Universal Biosensors was a racehorse, it might be a therapeutically cloned version of Phar Lap genetically transfected with Makybe Diva lineage. At first glance, the company has the hallmarks of a quality top tier biotech company that is set to list on the ASX next month.

The company emerges from the Denis Hanley 'stable' of companies, which includes other very successful businesses, including **Memtec** and **Pharmaxis**, and the more recently floated CathRx. The offer is fully underwritten by the **Wilson HTM Investment Group**, which can lay claim to some of the largest and most successful life science listings in Australia. The company's share register includes one of the largest life science venture capital groups in Australia, **CM Capital**. And upon listing, **Johnson &Johnson Development Corporation** will own just over 15% of the company.

The Technology

The technology being commercialised by Universal Biosensors was originally developed at Memtec in the mid-1990s. Since that time the rights to this technology have been assigned to **LifeScan**, a wholly-owned affiliate of Johnson & Johnson, and licensed to Universal Biosensors. Universal Biosensors has also developed its own proprietary technology in addition to the core technology.

The core technology relates to a modified electrochemical cell used for diagnostic applications. Electrochemical cells measure the voltage drop across two electrodes which reflects the composition of the blood sample. Where standard electrochemical cells are positioned side by side (or 'co-planar') to limit electrical interference between the electrodes, the original researchers from Memtec, who now work for Universal Biosensors, discovered that this interference is predictable and can be accounted for, allowing the two opposing electrodes to be positioned parallel and close together.

Advantages of the Technology

The advantages of bringing the two opposing electrodes closely together is that not only the device can be miniaturised, but also smaller blood samples may be required, with improved accuracy potentially and a fast response time for the test. Miniaturisation of the test will also reduce product costs.

Business Model

The first biosensor being developed with this technology is for LifeScan. LifeScan, a subsidiary of Johnson & Johnson, is the second largest player in the glucose monitoring market, with 25% market share. The worldwide market for point-of-care glucose monitoring was worth US$7.7 billion in 2005. Universal Biosensors has been conducting contract R&D for LifeScan since 2002 for this product and has received US$7.2 million in revenue. It is an ongoing program.

The core technology belongs to LifeScan. Lifescan has about 27 patent families cov-

Cont'd over

ering the technology, with about 18 patents/patent families granted in the US. Universal Biosensors has four patent applications that contribute to protection over the technology. From inception, the key inventors have remained with the technology and this continues to be a core asset in itself for the company. Universal Biosensor's chief scientist, Dr Alastair Hodges, is named as an acknowledged inventor on almost every patent held by LifeScan and Universal Biosensors covering this technology.

Licensing Agreement

Universal Biosensors has an exclusive licensing agreement (see Prospectus, p.95) with LifeScan that is critical to this company. Universal Biosensors has a royalty free license to commercialise the technology in all areas excluding glucose monitoring. In return, Universal Biosensors has licensed to LifeScan any improvements it makes over the sensor for glucose monitoring. Universal Biosensors will contract manufacture the sensors for LifeScan.

There are three points that investors should immediately note about this arrangement. This licensing agreement can be terminated if Universal Biosensors fails to exploit this technology. Also, if Universal Biosensors sublicenses the technology, then LifeScan is eligible to receive 50% of any lump sum or royalty stream. And, LifeScan is not prevented from commercialising its own technology outside of glucose monitoring, although presumably it would not be able to access Universal Biosensor's improvements over the technology.

The cost of maintaining the technology patents is taken up by LifeScan.

Other Applications for Universal Biosensors

Universal Biosensors is developing the technology initially for two other point-of-care diagnostic tests. The first is for measuring 'C-reactive protein', which is an indicator for cardiovascular damage. The existing market for laboratory and point-of-care cardiac marker tests is approximately US$325 million a year.

The second test in development, the prothombin time test, is a clotting test for people taking the anticoagulant medication warfarin. Prothrombin is a clotting factor in the blood. Both tests seek to incorporate an immunoassay test with the company's core electrochemical cell technology. Existing point-of-care tests for this clotting factor generated sales of US$125 million last year.

Formal clinical trials of these tests are expected to begin in 2008. The company anticipates selling the tests through distributors in major markets around the world. It also plans to develop additional current immunoassay tests conducted in the laboratory at present, converting these tests to point-of-care diagnostics using its electrochemical cell technology.

Strengths and Opportunities

There are several advantages in working with LifeScan. The company is a subsidiary of Johnson & Johnson and is one of the leading companies in the area of glucose monitoring, with 25% of the global market. LifeScan will pay for the upkeep of all patents over the technology. Most importantly, LifeScan will play a pivotal role in bringing the core technology to market which will help pave the way for the range of Universal Biosensors' tests in development.

The offer under the prospectus is fully underwritten. The company is raising $18 million through the prospectus, $4 million in a concurrent private placement (in which Johnson and Johnson will participate in, as a condition of the underwriting agreement) and it has $8.9 million in cash reserves at the date of the prospectus. The company will have $29 million to fund its activities although it will need to raise additional funding in the future to complete commercialization of its technology.

The company has an exceptionally strong management, board and scientists working on its projects.

If the company can develop the holy grail in the area of diagnostics – that is an immunoassay biosensor that is affordable, easy to use and produces a fully quantifiable analytical result in the point-of-care setting that works in an accurate and highly reproducible manner – it will have a very valuable and powerful product that can be extended to a wide range of diagnostic applications.

Challenges and Risks

The first commercial biosensor for measuring glucose levels was developed by **Medisense** in 1987 and that company was subsequently sold to **Abbott Laboratories** in 1996 for US$900 million. Biosensors for glucose monitoring have now been well established, although improvements are always welcomed. However, development of immunoassay biosensors has been a substantially more difficult technical goal to achieve in the diagnostics industry.

The largest risk is the technical challenge in developing an immunoassay biosensor that works accurately and reliably. Another listed company, **Ambri**, spent over 15 years and over $100 million in its unsuccessful attempt to develop a biosensor. (Ambri is now being used by the Queensland company **Glycoz** to gain a backdoor listing.)

Successfully commercialising diagnostics in general can be an arduous task. The field is dominated by a handful of global players and it is traditionally a low margin business. Diagnostic companies in Australia that been disappointing for investors include **Ambri**, **Agenix**, **Proteome Systems** and **PanBio**. However, **Cellestis** most recently has been very successful if it is to be judged merely by its share price performance.

The Prospectus is lacking in competitive analysis of technologies and presents little information on how contestable the markets that it is seeking to enter might be.

Selling the final product through a third party distributor network has also been problematic for Australian biotech companies in any life science field, let alone diagnostics.

Cont'd over

Working with a major life science company such as Johnson & Johnson (Life Scan) presents its own risks as well as benefits. Universal Biosensors' Licensing Agreement with LifeScan leaves the company exposed and vulnerable should the relationship sour and it is deemed Universal Biosensors is not employing best endeavours to commercialise the technology. However, this risk is tempered with the view that Johnson & Johnson owns 15% of the company post-float, that Universal Biosensors employs the key inventors, and that Universal Biosensors is developing supplementary intellectual property around the technology.

Investors are required to fully read the company's prospectus prior to applying for shares in the offer. A full copy of the prospectus can be downloaded from www.universalbiosensors.com

Key dates and figures

- Amount to be raised under the offer in the prospectus: $18 million
- Amount to be raised in concurrent US private placement: $4 million
- Offer price: 50 cents per share
- Market capitalisation upon listing: $64 million
- Cash assets post listing (after costs): $29 million
- Closing date of offer: **5 December 2006**
- Expected date of listing: 13 December 2006

Pool of potential biotech floats
(in the next 12 months)

Hatchtech
Pacmab
Stem Cell Sciences
Continence Control Systems
Mimetica
Genera Biosystems
Cleveland Biosensors
TGR Biosciences
Impedimed
Opal Therapeutics
Ecobiotics
CNS Bio
Cyclopharm
Cryptopharma
Kayban
Probiotec
Vegenics

Company	Price (current)	Price added to portfolio
Acrux	$0.87	$0.83
Alchemia	$0.65	$0.67
Avexa	$0.250	$0.15
Bionomics	$0.23	$0.210
Biosignal	$0.17	$0.22
Cogstate	$0.19	$0.18
Cytopia	$0.690	$0.46
Chemgenex Pharma.	$0.52	$0.38
Evogenix	$0.670	$0.47
Optiscan Imaging	$0.480	$0.35
Mesoblast	$1.520	$1.27
Metabolic Pharmaceuticals	$0.720	$0.53
Neuren Pharmaceuticals	$0.41	$0.70
Peptech	$1.25	$1.31
Pharmaxis	$3.28	$1.90
Prima Biomed	$0.057	$0.09
Progen Industries	$3.450	$3.40
Sirtex Medical	$3.08	$1.95
Sunshine Heart	$0.17	$0.19

The Bioshares 20 Index

Change from June 30, 2005	**-2.2%**
Change from June 30, 2006	**17.3%**
Change - week ago	**3.0%**

Nasdaq Biotech Index

Change from June 30, 2006	**11.2%**
Change - (3/11 to 10/11)	**2.9%**

Companies Reporting Phase II Results – Q1, 2007

A number of biotech companies are set to report on various Phase II trials in the first quarter of 2007. Some companies, including **ChemGenex** and **Avexa,** will report interim data, whereas **Metabolic Pharmaceuticals**, **Progen Industries** and **Prima Biomed** will report final results. That an investment horizon of around four months is associated with these five companies gives them exceptional prominence amongst the 120 or so small-to-medium biotechs listed on the ASX.

By virtue of their releasing key development information about therapeutic product candidates, these companies have the potential to generate significant investor interest leading up to the actual release of the results. A well known biotech investment strategy is to invest in the lead up to the announcement of key results and sell before the event, if significant price gains have been achieved. The rationale for this approach is that once the announcement has been made, the stock price is more likely to remain steady if expectations have been met, or plummet if the results are doubtful, or worse than expected. In the much more infrequent case of the results performing better than expectations (of either analysts or the collective wisdom of the market), then the stock could appreciate further.

Phase II trials are generally considered to be pivotal trials because, apart from assessing the safety of a drug candidate, the efficacy of the drug is also evaluated. Phase II trials are trials in which the underlying medical hypothesis is tested, or to put it more crudely, they are the trials in which it is often first determined if a therapeutic product 'works' in human subjects. Phase III trials often do much the same, but the therapeutic product candidate is evaluated in many more patient numbers, perhaps over different time periods of administration and is often evaluated against the current standard of care, if one exists.

Metabolic Pharmaceuticals

Metabolic Pharmaceuticals (MBP: $0.72) has indicated that the results from its Phase IIb study of its obesity drug candidate AOD9604 will be ready for release in March 2007. This study follows a previous Phase IIb study that was completed in September 2004. That trial delivered results that were inconclusive about the most effective dose of AOD9604. The current 'repeat' trial has enrolled significantly more subjects (536) to ensure the trial is sufficiently powered.

The current trial has been examining three different doses (0.25mg, 0.5mg and 1mg) compared to placebo. The endpoint of the trial is to achieve 1.8kg or more weight loss after 12 weeks of administration, although the trial involves AOD9604 being administered orally once a day for 6 months. Secondary endpoints include weight loss over 24 weeks, comparison of the effects of the three different dose levels, waistline reduction over 24 weeks, body fat reduction assessed by whole body scans and improvement in risk factors such as glucose control and lipid profiles over 24 weeks. Another secondary endpoint will explore bone mineral density. This endpoint will be certainly one to watch to given the possible application of AOD9604 in treating osteoporosis.

Metabolic has seen its share price lift from a recent low of 38.5 cents in August to its close today of 72 cents, a gain of 87%. The company is capitalised at $205 million and held $23 million in cash at June 30, 2006.

Bioshares recommendation: **Speculative Buy Class A**

Cont'd over

March Quarter 2007 Reporting Targets
Selected Companies - Phase II status compounds

Company	Compound	Status	Disease or Medical Condition	Comments	Num. Pts
Metabolic Pharmaceuticals	AOD9604	Phase IIb	Weight loss	200 pts have completed trial so far Results to be ann. **Mar 2007**	536
Avexa	ATC	Phase IIb	HIV Infection (where infection is resistant to other NNRT inhibitors)	21 day dosing data due	50
Progen Industries	PI-88	Phase II	Non small cell lung cancer	In comb. with Taxotere All pts have now been enrolled	99
		Phase II	Post-surgery primary liver cancer	Stage 1 (172 pts) to be reported on	340
ChemGenex	Ceflatonin	Phase II/III	Leukemia (CML with T315I mutation)	Preliminary Data	81
Prima Biomed	CVac	Phase II	Ovarian cancer	Final Data	21

Progen Industries

Progen Industries (PGL: $3.45) is developing the heparanase inhibitor PI-88 as a potential treatment for various cancers. Since the company commenced human clinical trials, more than 400 patients have been dosed with PI-88. PI-88 is believed to shut down the growth of blood vessels that feed tumours by inhibiting certain growth factors, including VEGF, FGF-1 and FGF-2, and additionally inhibit the spread of cancer (metastasis)..

Currently, Progen has four Phase II trials underway. These include a 90 subject study of PI-88 in combination with Taxotere (docetaxol) in patients with advanced prostate cancer and a 118 subject study of PI-88 in combination with dacarbizine as a first line treatment in patients with advanced melanoma. Two studies, 340 subject study of PI-88 at two dose levels as a post-surgery treatment of patients with primary liver cancer (Stage 1 - 172 patients) and a 99 subject study of PI-88 in combination with Taxotere in patients with non small cell lung cancer (NSCLC) are scheduled to deliver reportable results in the March quarter of 2007.

With so many trials completed (eight) or underway, it is perhaps less likely that the NSCLC trial will become a direct basis for a significant lift in the Progen share price, prior to the announcement of results. What is more likely is that the data comes to hand, it will increase and support the interest of companies looking to partner PI-88, if indeed such prospects are not already being closely studied.

Progen is capitalised at $140 million. The company's cash resources at June 30, 2006 amounted to $15.8 million.

Bioshares recommendation: **Speculative Buy Class A**

Prima Biomed

Prima Biomed (PRR: $0.057) has, despite technical obstacles, corporate difficulties and funding challenges, almost completed a Phase II trial of its CVac ovarian cancer immunotherapy. To date 21 patients (from 28 enrolled) with late stage ovarian cancer with no treatment alternative have been treated under the trial protocol of three infusions of the CVac cell therapy product at monthly intervals, followed by four injections at ten week intervals. Interim data reported in May showed that the therapy generated a 21% response rate, as measured by changes in the level of a protein in blood, CA125. That this exceeded a bench mark of 15% was considered significant by the trial's principal investigator.

The CVac technology involves the collection of a certain type of immune system cell (a dendritic cell) which is then presented with a manipulated version (MFP - mannan fusion protein) of a protein common to a number of cancers called the MUC1 protein. Having trained the dendritic cell to recognise MFP, the 'primed' cells are reintroduced into the body to cause components of the immune system to identify and destroy cancer cells.

With some idea of the what achievement the therapy against the primary endpoint is likely to be, interest in the final results is likely to focused on the secondary endpoints, including disease progression-free survival and immune system responses to CVac.

It is worth noting as a sign of Prima and its clinical investigators' confidence in CVac that the company has developed plans for improved manufacturing processes for CVac in advance of a Phase III trial of the therapy.

Prima Biomed is capitalised at $8 million, with $2 million in cash. It is currently intending to raise $1 million through a placement.

Bioshares recommendation: **Speculative Buy Class B**

Avexa

Avexa (AVX: $0.25) has been conducting a Phase IIb trial of its non-nucleoside reverse transcriptase inhibitor ACT (apricitabine) in a 50 patient trial. The trial was hampered by slow recruitment but now appears to be back on track following expansion of recruitment in Argentina. ACTis is designed to inhibit HIV that carries the M184Vmutation. The current trial is designed to proceed in several stages, with double blind dosing occuring for the first three weeks, followed by unblinding then optimisation, then 21 weeks of more blinded dosing. At this point interim data can be obtained. The first 24 weeks are to be followed by 24 weeks in which all patients are administered ATC. ATC has to date shown that it can generate a 44 fold decrease in virus load.

Avexa is capitalised at $49 million. At the end of September, the company held $15.8 million in cash assets.

Bioshares recommendation: **Speculative Buy Class A**

ChemGenex Pharmaceuticals

ChemGenex Pharmaceuticals (CXS: $0.52) commenced a Phase II/III trial of Ceflatonin in June this year in chronic myeloid leukemia (CML) patients who are positive for the T315I bcr-abl gene mutation. The **Novartis** drug Gleevec and the **Bristol-Myers Squibb** drug Sprycel are ineffective when this mutation is present. The paradox is that the increasing uptake of these drugs is bound to increase the pool of Gleevec resistant patients, and hence increase the opportunity for compounds such as Ceflatonin that can treat the CML patients with the T315I mutation.

In this trial of between 81 and 100 patients, Ceflatonin will be administered subcutaneously twice a day for 14 days every 28 days. The endpoint of the trial is the degree of complete hematological response (hematological response refers to the degree of presence of cancer cells in the blood). In previous (smaller) trials, response rates of between 67% and 92% have been recorded. In this larger trial, a goal will be to achieve a statistically significant result.

ChemGenex is capitalised at $79 million, and at June 30 recorded $15.5 million in cash assets.

Bioshares recommendation: **Speculative Buy Class A**

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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