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In this edition...
If investors wanted a sign that Australian biotech has bulked-up, then they need go no further than to consider that more than 70 clinical trials are being conducted by Australian listed biotechs. The results from a significant number of trials are expected to be reported this calender year, supporting the view that 2007 will be a big year for biotech.

In keeping with the clinical trials theme in this edition we comment on clinical trial results announced by Pharmaxis and Prima Biomed, and lay some groundwork for a Phase II result announcement expected from Avexa next week.

The editors
Companies covered:
AVX,PRR,PXS,TIS

	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)	14.9%
Cumulative Gain	**220%**
Average Annual Gain	**26.4%**

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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Bioshares

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

Clinical Trials Survey – 2007

Clinical trial activity by Australian biotech firms continues to expand at a strong pace. According to our annual survey of Australian listed biotech firms, 72 clinical trials are either underway or planned, with results from several completed trials to be announced in the near future. Results from at least 28 trials are expected to be announced over the remainder of 2007, with expectations that Avexa's Phase IIa results will be announced this coming Monday.

For this year's survey we have supplemented information supplied by companies with data obtained from company reports and announcements for those companies that did not respond to the survey, or were not contacted at the initial stage. We have also excluded device and other companies from this year's survey.

We have listed on page 2 a summary of clinical trials where companies have advised of the quarter or half-year period in which trial results will be announced. This table may be used by investors looking to trade a stock on the basis of a company expecting to release pivotal data, typically from a Phase II study in which some indication of efficacy is revealed, or more significantly Phase III data, in which efficacy and patient benefit is evaluated comprehensively. The survey results can be found in Appendix A, which accompanies this issue of Bioshares.

Trials to look out for

Studies to look out for include **Pharmaxis**' Phase III trial (B301) of Bronchitol for bronchiectasis, to be reported in the third quarter of 2007 (see further comments on page 4) with the possibility of interim results being made available sooner. Pharmaxis also expects to announce the results of two Phase II trials of Bronchitol in cystic fibrosis patients in the final quarter of 2007.

Results from **Alchemia**'s Phase II study of HyCAMP, a potential second line treatment for metastatic colorectal cancer, will be announced in the June quarter, and will be watched with interest, given that the trial commenced in late 2004. The program came to Alchemia through its acquisition of **Meditech Research**. Alchemia has flagged that a Phase III program will be initiated in 2008.

Results from **Prana Biotechnology**'s Phase II trial of PBT-2 for Alzheimer's Disease and **Antisense Therapeutic**'s trial of ATL-1102 for multiple sclerosis should be announced in the fourth quarter of 2007. Both companies have had setbacks with their clinical programs, and clear and positive results will determine the future of these firms one way or another.

Much attention has been focused on **ChemGenex**'s ceflatonin, with results from an 80 patient Phase II trial anticipated for the first quarter in 2008. However, a lesser known compound in the ChemGenex portfolio is Quinamed. Results from a 50 patient Phase II

Cont'd on page 3

Clinical Trials Where Companies Have Advised of Period in Which Results Will Be Announced

Company	Code / Name of Trial	Phase	Qtr/HY	Year
	2006			
ChemGenex Pharmaceuticals (CXS)	Ceflatonin CGX-635-CML-201	Phase II	Q4* **Initial data announced*	2006
	2007			
pSiVida (PSD)	BIOSP202	Phase IIb	2007	2007
pSiVida (PSD)	DB2-201	Phase IIa	2007	2007
Peplin (PEP)	PEP005-006	Phase IIb	Mid-2007	2007
Peplin (PEP)	PEP005-007	Phase II	Mid-2007	2007
	2007 - Q1			
Avexa (AVX)	Apricaticbine	Phase IIb	Q1	2007
Biota (BTA)	1833/093 (BTA798)	Phase Ib	Q1	2007
Peplin (PEP)	PEP005-008	Pilot	Q1	2007
	2007 - Q2			
Acrux (ACR)	NES03	Phase I	Q2	2007
Acrux (ACR)	NES04	Phase I	Q2	2007
Alchemia (ACL)	CTA2004 - HyCamp	Phase II	Q2	2007
ChemGenex Pharmaceuticals (CXS)	Quinamed CGX-571	Phase I/IIa	Q2	2007
Cytopia (CYT)	QP04C07 (CYT997)	Phase I	Q2	2007
Dia-B Tech (DIA)	DIAB-ISF402-001	Phase I	Q2	2007
Progen Industries (PGL)	PI-88 - HCC post resection	Phase II	Q2	2007
Acrux (ACR)	MTE05	Phase II	Q2/Q3	2007
	2007 - Q3			
Acrux (ACR)	MTE06	Phase Ib	Q3	2007
Cytopia (CYT)	CCL0600 (CYT997)	Phase I	Q3	2007
Neuren Pharmaceuticals (NEU)	NNZ-2566	Phase Ib	Q3	2007
Narhex Life Sciences (NLS)	Narhex DG/005	Phase IIa	Q3	2007
Pharmaxis (PXS)	B301	Phase III	Q3	2007
Pharmaxis (PXS)	COPD101	Phase I	Q3	2007
Progen Industries (PGL)	PI-88 - Adv. Lung Cancer (NSCLC), comb. with docé	Phase II	Q3	2007
Phosphagenics (POH)	Phospha-E	Phase II	Q3	2007
	2007 - Q4			
Antisense Therapeutics (ANP)	ATL 1102	Phase IIa	Q4	2007
Biodiem (BDM)	BDM-E	Phase I/II	Q4	2007
Bone Medical (BNE)	Capsitonin(oral salmon CT)	Phase II	Q4	2007
Pharmaxis (PXS)	CF203	Phase II	Q4	2007
Pharmaxis (PXS)	CF202	Phase II	Q4	2007
Prana Biotech (PBT)	PBT2-201 EURO	Phase II	Q4	2007
	2008			
ChemGenex Pharmaceuticals (CXS)	Quinamed CGX-571	Phase IIb	H1	2008
ChemGenex Pharmaceuticals (CXS)	Ceflatonin CGX-635-AML-204	Phase II	H2	2008
ChemGenex Pharmaceuticals (CXS)	Ceflatonin CGX-635-CML-202	Phase II	Q1	2008
ChemGenex Pharmaceuticals (CXS)	Ceflatonin CGX-635-CML-203	Phase II	Q1	2008
ChemGenex Pharmaceuticals (CXS)	Ceflatonin CGX-635-MDS-200	Phase II	Q1	2008
Progen Industries (PGL)	PI-88 - Metastatic Melanoma in combination with DTIC	Phase II	Q1	2008
Benitec (BLT)	Vector-encoding multiple anti-HIV RNAs	Phase I	Q4	2008
Neuren Pharmaceuticals (NEU)	SNUG-2 (Glypromate)	Phase III	Q4	2008
Neuren Pharmaceuticals (NEU)	NNZ-2566 Mild-Moderate TBI trial	Phase II	Q4	2008
	2009			
Pharmaxis (PXS)	B302	Phase III	Q1	2009
Pharmaxis (PXS)	CF301	Phase III	Q3	2009
Pharmaxis (PXS)	CF302	Phase III	Q3	2009

Clinical Trials Where Companies Have Not Advised of Period in Which Results Will Be Announced

Company	Code / Name of Trial	Phase	Qtr/HY	Year
	Not disclosed/Other			
Neuren Pharmaceuticals (NEU)	NNZ-2566 Phase 1a	Phase Ia		Final DSMC has been undertaken
Clinuvel (CUV)	CUV011 (CUV1647)	Phase II		Not disclosed
Clinuvel (CUV)	CUV015 (CUV1647)	Phase III		Not disclosed
Clinuvel (CUV)	CUV016 (CUV1647)	Phase II		Not disclosed
Mesoblast (MSB)	MCTNUT001	Pilot Study		Not disclosed
Mesoblast (MSB)	MCTIHD002	Pilot Study		Not disclosed
Mesoblast (MSB)	Allogeneic MPSC	Phase II		Not disclosed
Mesoblast (MSB)	Allogeneic MPSC	Phase II		Not disclosed
Metabolic Pharmaceuticals	METACV102	Phase IIa		Not disclosed
Metabolic Pharmaceuticals (MBP)	METACV102	Phase IIa		Not disclosed
Neuren Pharmaceuticals (NEU)	NNZ-2566 Severe TBI Trial	Phase II		Not disclosed
Neuren Pharmaceuticals (NEU)	CaOH	Phase II		Not disclosed
Novogen (NRT)	NV06-0025	Phase I/II		Not disclosed
Novogen (NRT)	NV06-0031	Phase I		Not disclosed
Novogen (NRT)	NV06-0034	Phase I		Not disclosed
Novogen (NRT)	NV06-0037	Phase Ib		Not disclosed
Novogen (NRT)	NV06-0039	Phase III		Not disclosed
Novogen (NRT)	Yale 27640	Phase II		Not disclosed
Novogen (NRT)	NV196-0001	Phase I		Not disclosed
Novogen (NRT)	NV52-0002	Phase I		Not disclosed
Peplin (PEP)	PEP005-009	Phase II		Not disclosed
Starpharma (SPL)	SPL7103-004 (Vivagel)	Phase I (Exp.)		Not disclosed
Starpharma (SPL)	Vivagel	Phase I		Not disclosed
Phosphagenics (POH)	Transdermal Insulin : TPM-02/Insulin	Phase II		Planned and imminent
Progen Industries (PGL)	PI-166	Phase Ib		TBA
Progen Industries (PGL)	Adv. Prostate Cancer (androgen indep.) in comb. with docetaxel	Phase II		TBA
Progen Industries (PGL)	PI-88 - HCC post resection	Phase III		TBA
Tissue Therapies (TIS)	Non-Healing Wounds (Diabetic/ Venous Ulcers)	Phase I		TBC
Tissue Therapies (TIS)	Burns	Phase I / II		TBC
Phosphagenics (POH)	Transdermal Morphine : TPM-01/M	Phase IIa		Underway

From page 1

trial are expected in the second quarter of 2007. Quinamed, a small molecule drug, is being evaluated in cancer patients with solid tumours. Patients are selected for treatment on the basis of their genetic metabolic disposition (NAT2 genotype). The company has submitted an abstract for the June 2007 meeting of the American Society of Clinical Oncology (ASCO), and it is through this process that results will be revealed.

Finally, one other stock to monitor closely is **Tissue Therapies**, which plans to conduct at least two clinical trials of VitroGro this year, and may generate data rapidly from these burns and ulcers studies.

Pharmaxis Continues to Broaden Clinical Trial Program

Pharmaxis (PXS: $3.36) released results this week from a trial assessing its lung function test in patients with Chronic Obstructive Pulmonary Disorder (COPD). The result was a mixed bag, with the structure of the trial delivering insufficient information for a meaningful outcome.

Aridol update

Aridol, an inert mannitol powder, measures a person's airway hyper-responsiveness. It is approved in Australian and Europe (Sweden) as a disease management tool in patients with asthma. The COPD study involved 79 patients with mild to moderate COPD. The trial was designed to measure the effect on patients who measured hyper-responsive with Aridol when these patients were then given corticosteroids.

The problem with the trial was that all patients had no changes in lung function after treatment with corticosteroids as measured by a spirometer, which measures the total air and air flowrate being exhaled.

On the positive side, 76.5% of patients who measured positive with Aridol had a significant improvement in hyper-responsiveness after three months of corticosteroids. In summary, steroids do not generate substantial improvements in breathing function as measured by changes in airflow and flowrate. However, steroids do improve the hyper-responsiveness of COPD patients' airways as measured with the Aridol test.

Further tests will be conducted with Aridol, supported by Pharmaxis, with patients taking corticosteroids and a bronchodilator. With Aridol now on the market, Pharmaxis is seeking to broaden the application of this test to a wider patient pool than just asthma sufferers. It's an appropriate strategy.

Pharmaxis continues to await wider approval of Aridol in the rest of Europe. A Phase III trial in the US has now been completed and the company will file the drug for approval towards mid year. Approval is expected in the US in 2008 and in the remainder of Europe this year.

Bronchitol update

Bronchiectasis

Pharmaxis has completed a study in Europe and Australia in patients with bronchiectasis. Bronchiectasis is a degeneration of the respiratory system, whereby the lungs become fibrotic and the airways become dilated. This condition occurs for a variety of reasons and in up to half of the cases, the exact cause remains undetermined. Known causes include damage to the lungs from infection, as occurs in almost all patients with cystic fibrosis and in patients with HIV and pneumonia.

In the western world approximately 500,000 people are estimated to suffer from this condition. Pharmaxis is awaiting results from the Phase III study, which should be available midyear. If positive, the company will file for regulatory approval in Europe, Australia, Canada and South Korea this year and the product may be on the market in 2008. In the US, Pharmaxis will need to conduct another trial that should start at the end of 2007. Of particular relevance is uptake of this drug by patients in the Phase III trial through a Special Access Scheme. An extraordinarily high number of the 364 patients in the Phase III trial have requested to continue with treatment. Also noteworthy is that the competing product on the market, Pulmozyme, failed in this indication although that product is used by patients with cystic fibrosis, generating sales of US$244 million last year for Genentech.

Cystic Fibrosis

A Phase III cystic fibrosis trial is ready to begin recruiting 220 patients in Europe. The patients will be treated for six months and followed up for a further six months. A second Phase III trial is expected to begin in the second half of 2007. The European trial should be completed next year and the US Phase III trial should finish in early 2009.

Distribution

The attraction to Pharmaxis is that it is seeking to become a fully integrated pharmaceutical company. It expects to sell Bronchitol directly in major markets, including the US. Selling directly to respiratory physicians, the company believes it could adequately access the majority of the US market with only 25 sales representatives. The company currently manufactures Aridol and Bronchitol in Sydney.

Market Size

It is potentially not an insignificant market for Bronchitol. Whilst pricing has not been set, if treatment will cost each patient US$3000 a year, and we assume a penetration level of 20% for bronchiectasis and 30% (of 75,000 patients) for cystic fibrosis, it equates to potential sales of over US$350 million for Pharmaxis.

Summary

Pharmaxis is Australia's leading biotech company (after CSL) for good reasons, including depth in management, a capacity to execute and products with market relevance. It is currently capitalised at $595 million and has $86 million in cash. Look for price weakness to add this stock to your portfolio.

Bioshares recommendation: **Speculative Buy Class A**

Tissue Therapies Collaborates with Novozymes

Tissue Therapies (TIS: 54 cents) continues to improve as an investment consideration. Earlier this year it signed a distribution deal with Invitrogen to supply its VitroGro product to Invitrogen for distribution as an animal-free growth factor product for the growth of stem cells in the laboratory in cell culture. This week, it has signed a development agreement with **Novozymes** (Denmark) to combine both groups' respective technologies for the development of wound dressing products.

Independently, Tissue Therapies is also expected to begin three clinical trials midyear in 240 patients. The trials will involve testing the VitroGro product in treatment three types of wounds, these being burns, venous ulcers and diabetic ulcers.

Australian investors should be very familiar with Novozymes, following its acquisition of Gropep earlier this year. There are many synergies between Tissue Therapies and Novozymes, including using the VitroGro serum-free product in biopharmaceutical production. This collaboration with Novozymes could well be considered as a 'try-before-you-acquire' collaboration. We place the possibility of a collaboration moving to an acquisition over the next 12 months as moderate-to-high.

Bioshares recommendation: **Speculative Buy Class A**

Prima Biomed Releases Full Phase IIa Trial Results

Prima has released the full results from its Phase IIa trial for its ovarian cancer vaccine. The principal investigator for the trial, Associate Professor Paul Mitchell summed up the trial well, saying the product clearly showed benefit, despite the advanced stage of disease in patients.

The result showed there was a 19% response rate overall in the 21 patients, with two patients showing a major response (CA125 levels falling > 50%), one patient with a minor response (25%<CA125<50%) and one patient with disease stabilization (CA125 change <25%). This is a great result given the patients had exhausted other treatment options. The treatment was shown to be very safe and potentially a better result should be achieved if the patients could be treated earlier.

Funding is a concern

The concern remains for this company is how it will fund subsequent trials. A Phase IIb trial is the next step for Australia, after which the company may be in a position to file for registry approval in Australia. It will also need to conduct a larger international study to access major overseas markets. The company is also considering conducting another Phase II trial locally for another cancer indication.

Prima is capitalised at $9.1 million and and has enough cash currently to take it to mid year. The company is investigating funding options. Major drivers for this stock will be support from a major investor or investors and the imminent approval of a competing product from **Dendreon** by May this year. As the company itself states, its technology is a new paradigm for the treatment of cancer. Unfortunately investors prefer business models that are based on more commercially proven approaches which makes it more difficult to secure investment into an important product that could become available in this and other countries. Our recommendation for investors is to wait for this company to secure its funding situation before consiering this stock.

Avexa's Phase II HIV Drug Trial Results Expected Soon

According to an announcement leaked to the *Australian Financial Review,* Avexa will be reporting a positive result from its Phase II HIV trial for its lead drug candidate apricitabine. The goal of the trial was to achieve a drop in viral load of 0.6 $\log_{10}$ in patients with an M184V mutation. According to the article, the company achieved a 0.8 $\log_{10}$ drop in viral load. As expected this was lower than a Phase IIa trial conducted by **Shire Pharmaceuticals**, from whom the drug was licensed, which saw a 1.6 $\log_{10}$ drop in viral load in HIV patients with a non-mutated virus.

Avexa has generated substantial shareholder value since it was spun out of Amrad and much of this should be credited to its CEO, Julian Chick. Apricitabine has a strong chance in receiving a respectable royalty stream in three to four years time.

The key question with this stock now is how much is that future royalty stream worth to Avexa. Avexa was valued at $173 million (at 68 cents) before it went into a trading halt. Having licensed the compound from Shire, it is required to pay Shire a low double digit royalty from sales in the US and five major European countries, a single digit royalty in other western regions, and no royalty is payable to Shire for sales to the developing world.

It is important to also note that the composition of matter patent over apricitabine expires in 2013 in the US and Europe, although the company should receive a five year market exclusivity upon approval in the US and Europe. In other regions, the patent protection extends out to 2022 and 2025.

The market size for HIV drugs is US$6 billion and there are about 20 HIV drugs on the market. This translates to an average market size of US$300 million per drug.

To date, Avexa has paid Shire in cash and shares a total of $18 million (based on a 68 cent share price) and must pay Shire a royalty stream. The value in Avexa is the sum of the company's preclinical programs and the difference between what it must pay Shire and that what it stands to receive from a future licencee to the technology.

Apricitabine holds considerable value to a potential licencee. This is because HIV drug companies seek to ward off generic competitors by combining newer drugs with older off patent drugs, thereby fending off the generics and allowing HIV patients to take a substantially lower number of tablets each day.

Avexa has proved to be an outstanding success to date. However, based on its current valuation, which will be $25 million higher following the anticipated capital raising listed in the AFR article (approximately $200 million at 68 cents), we recommend investors look to any price surges to take profits.

Bioshares Model Portfolio (16 March 2007)

Company	Price (current)	Price added to portfolio
Acrux	$1.32	$0.83
Alchemia	$1.03	$0.67
Biodiem	$0.29	$0.29
Biota Holdings	$1.55	$1.55
Cytopia	$0.65	$0.46
Chemgenex Pharma.	$0.76	$0.38
Optiscan Imaging	$0.47	$0.35
Neuren Pharmaceuticals	$0.46	$0.70
Peplin	$0.82	$0.83
Peptech	$1.92	$1.31
Phylogica	$0.35	$0.42
Probiotec	$1.07	$1.12
Progen Pharmaceuticals	$6.86	$3.40
Sunshine Heart	$0.23	$0.19
Tissue Therapies	$0.54	$0.58

Portfolio Changes

Biodiem has been added to the portfolio at 29 cents. The company is currently capitalised at $15 million. It has partnered its influenza vaccine program with Nobillion and this trial is program is expected to enter the clinic next year. It is also conducting a Phase II trial with its lead proprietary compound, BDM-E, in 192 patients with diabetic macular oedema. This trial is expected to be completed by midyear with results released at year's end. The company had $5.6 million in cash at the end of last year. We have upgraded our recommendation to a **Speculative Buy Class A** and will complete an extended analysis on this company in coming weeks.

Biota Holdings has been added at $1.55. It remains a quality investment consideration and we believe there to be further upside from Relenza sales and a possible settlement next year with GlaxoSmithKline.

Ventracor has been removed from the portfolio. The company is down to one year's cash ($36 million at the end of 2006) at current spending and an expected capital raising this year will place pricing pressures on the stock.

Cogstate has been removed at 18 cents. It is now trading at fair value and is an earnings driven stock. As it approaches a position of profitability, expected over the next six months, it will warrant reassessment. And we will take some profits with **Bionomics**, which was added to the portfolio at 21 cents.

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, Neuren Pharmaceuticals, Pharmaxis, NeuroDiscovery, Prima Biomed, Biotech Capital, Cygenics, Cytopia, Biodiem, Peptech, Starpharma Holdings, Cogstate, Xceed Biotechnology, Incitive, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Medical Therapies

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