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In this edition...
Imagine an Australian biotech with a capitalisation of $1 billion and $250 million in the bank. Well, we don't have one yet, but we do have five companies that when measured in aggregate, achieve those figures. In times past, $1 billion represented the entire capitalisation of all the drug discovery companies listed in Australia. So there are signs at least that some companies, and five in particular, represent a maturing of listed biotech in Australia.

Consolidation is emerging as a key theme for the sector, with Peptech ringing the M&A bell. And Cytopia's JAK3 licensing deal looks set to eventuate...finally.

The editors
Companies covered: ACR, ACL, CYT, EGX, CGS, PEP, PXS, PSD, PTD

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Bioshares

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

Tier-1 Biotechs: Which Companies are Leading the Way?

Over the last seven years the Australian biotech sector has been significantly transformed. This transformation has included many individual disappointments that collectively highlight the difficult challenges of drug development and commercialization. Although it remains too early to boast the sector's first billion dollar drug development company, there is a leading pack of players emerging that are signalling to the market that they serious about using their intellectual property assets and commercial skills to build viable businesses.

For the last three years, between $550-$600 million a year has been invested to support the biotech sectors commercialisation goals. The result is that now a handful of biotechs are well funded, with products nearing the later stages of commercial development, or that have been approved for marketing.

Even better news for investors is that there is another handful of companies in the sector that not far behind these 'Tier-1 Biotechs', also with products entering registration trials in the next 12 months, although funding to complete this final stage of development remains a significant challenge for those companies. And into the third category, we can add companies that have successfully developed revenue generating products and businesses.

Tier-1 Biotechs
There are five companies in particular that warrant classification and discussion as Tier-1 biotech companies. These are **Acrux**, **Alchemia**, **Peplin**, **Pharmaxis** and **pSiVida**. Combined, these companies have cash assets of $250 million at their disposal (including current capital raisings underway). Their products have generated positive clinical data in substantial patient populations in most cases, and they are in very strong positions to successfully commercialise their products, although a technology risk remains with most of them. We emphasise that this is a strength relative to other Australian listed biotech companies.

One common link with these five companies is their low technology, or molecule risk, at least in one part of their business. This seems to be a feature that appeals to institutional investors.

We profile these companies on pages 2 and 3.

Tier-1 Company Profiles

Alchemia

Alchemia (ACL: $1.29) has been closely followed by *Bioshares*. The company's technology enabled generic for synthetic heparin is due to be filed for registration in December 2006 and should be on the market in the US either in late 2007 or early 2008. The drug will compete with **GlaxoSmithKline**'s Arixtra, which is vying for a share of the US$3.5 billion heparin market. The majority of this market has been firmly secured by **Sanofi-Aventis'** Lovenox, with annual sales of approximately US$2.4 billion.

GSK started selling Arixtra at the beginning of 2005. The March quarter shows annualised sales are currently tracking at US$76 million a year and we expect sales to be tracking at US$300 million by the time Alchemia's product comes onto the US market, through its partner **Abraxis BioScience**. Alchemia can begin selling the product in Europe in 2012.

Alchemia is currently in the process of acquiring **Meditech Research**, which will allow the company to build up its expertise in the area of oncology. There is very little technology risk with this company (over the synthetic heparin generic). The company is capitalised at $182 million with $30 million in cash. Alchemia is poised for aggressive growth over the next two years with its first product expected to reach the market and further M&A transactions a distinct possibility.

Alchemia – Key points
- Neglible 'molecule' risk for synthetic heparin
- Potential to present strong competition against Arixtra and Lovenox
- Alchemia's technology base has potential for yielding many more drug assets

Bioshares Recommendation: **Speculative Buy Class A**

Pharmaxis

Pharmaxis' (PXS: $2.09) bold capital raising last year of $87 million has firmlyentrenched it as a Tier-1 Biotech stock. The company has almost 30 institutional investors on its register, both locally and abroad, and is in a very strong position to commercialise its later stage technologies.

The company's first product, Aridol, is an asthma diagnostic tool. It has been released in Australia this year and approval from European regulators is expected soon. Phase III studies for the company's Bronchitol product in cystic fibrosis are expected to get underway in Europe this year and in the US early next year. We expect the company may be in a position to file for regulatory approval in 2008.

A Phase II study in 39 patients with cystic fibrosis showed that Bronchitol generated a 7% improvement in lung function over a placebo in a result that achieved statistic significance. The company has been granted orphan drug status in the US and Europe for its Cystic Fibrosis program, with benefits from that status including a guaranteed seven year market exclusivity (in the US).

In April this year, Pharmaxis began enrolling for a Phase III study in 350 patients with bronchiectasis. The trial will involve centers in Australia, New Zealand, the UK and Northern Ireland.

Pharmaxis has built the manufacturing capacity to produce its lead products and has aspirations to become a vertically integrated pharmaceutical company. Whilst it is using distributors in Europe for Aridol, it is expected Bronchitol will be sold directly by Pharmaxis into cystic fibrosis clinics throughout the world.

Pharmaxis – Key points
- Strong institutional support
- Has built the manufacturing capacity to produce its lead product
- Aridol now marketed in Australia

Bioshares Recommendation: **Speculative Buy Class A**

Peplin

Peplin (PEP: 73 cents) has leaped into the Tier-1 biotech category this year for two reasons. Firstly, it has generated very positive Phase II clinical data for its compound PEP005 for the treatment of non-melanoma skin lesions and cancers. The factor that warrants the company's inclusion is its decision to raise $40 million to fund its development activities. Whilst these funds will not be sufficient to fund Phase III studies, it will allow the company to expand its studies into leukemia with PEP005 and to complete Phase II studies in precancerous and non-melanoma skin cancers.

The funds place Peplin in a strong position to generate further Phase II data and prepare for its Phase III programs, either alone or in conjunction with a partner. However securing the investment interest from **MPM Capital** in the US, which will be represented on the Peplin board and also at an executive management level, confirms the quality of this company.

Peplin's Phase II results have shown that PEP005 is extremely effective in removing pre-cancerous and cancerous (not melanomas) skin lesions using only two applications of its topical formulation. In separate studies involving 120 patients, 70% of lesions were completely removed. Both trials produced statistically significant results.

At the completion of the capital raising, Peplin will have $51 million in cash and will be capitalised at $134 million. (See last week's Bioshares for more coverage of Peplin).

Peplin – Key points
- Low 'molecule' risk for PEP005 as a topical
- PEP005 offeres attractive treatment benefits
- Substantially mitigated funding risk

Bioshares Recommendation: **Speculative Buy Class A**

Cont'd over

Acrux

Acrux (ACR: 78 cents) is commercialising transdermal delivery technology for existing pharmaceutical products. Its lead applications are for Evamist (estrogen hormone therapy) for the treatment of menopause symptoms such as hot flushes, and a testosterone product for the treatment of low libido in women.

Recent Phase III studies completed by Acrux's partner in the US, Vivus, showed that in a Phase III trial involving 450 women, Evamist was shown to reduce hot flushes by 78%. It's expected that Vivus will file the product for registration in the US in the second half of this year and it should be on the market in the US in 2007.

We expect Vivus will seek a larger marketing partner for this product in the US and Acrux will look to find a marketing partner for Europe and other regions. Acrux has several other products in clinical development that utilise its delivery technology.

Acrux is capitalised at $105 million and holds $23 million in cash.

Acrux – Key points

- Low 'molecule' risk as transdermal delivery technology is applied to currently approved drugs
- Potential market entry for Evamist in 2007 in US
- Extensive pipeline, with fentanyl pain drug application very attractive

Bioshares Recommendation: **Speculative Buy Class A**

Psivida

Psivida (61 cents) has leap-frogged its commercial development status through the acquisition of Control Delivery Systems in the US at the beginning of this year. The company now has two products on the market for the treatment of treatment of chronic back-of-the-eye disorders. Both products are sold by **Bausch & Lomb** and Psivida receives a royalty from sales. Retisert was approved last year for the treatment of uveitis. This product is fully reimbursed by Medicare in the US (US$18,000) and Psivida receives a double digit royalty. The second product, Vitrasert, is a sustained release antiviral treatment although is generating negligible sales.

Psivida is funding the development of a third product, Medidur, which uses the same pharmaceutical as Retisert (fluocinolone acetonide) in an improved delivery system for the treatment of diabetic macular edema. Psivida is co-funding with its partner, **Alimera Sciences**, a 1,000 patient Phase III trial.

Applying the company's internally developed biosilicon technology, Psivida is currently conducting two Phase II trials with its BrachySil product in patients with inoperable liver cancer and pancreatic cancer.

Psivida is capitalised at $267 million with $44 million in cash including the current capital raising underway.

Psivida – Key points

- Established a well staged portfolio of drug delivery products and technologies
- Retisert product has competitive potential against Lucentis and Avastin, for macular degeneration (eye diseases)
- Macular degeneration markets are significant and growing

Bioshares Recommendation: **Speculative Buy Class A**

Aspiring Tier-1 Biotechs

Companies we view as aspiring to reach this Tier-1 category, with products due to enter pivotal Phase III trials over the next 12-18 months, include **Neuren Pharmaceuticals**, **Avexa**, **Progen Industries** and **Metabolic Pharmaceuticals**. **ChemGenex Pharmaceuticals** is also a company on the verge of becoming a Tier-1 biotech, with a registration trial in oncology currently underway.

Neuren's Phase III trial for its neuro-protectant compound, Glypromate, is due to begin in the second half of this year in 500 patients undergoing coronary artery bypass surgery. It had approximately $10 million in cash at the end of March this year. Avexa is currently completing a Phase IIb trial for its HIV drug. If that result is positive (results are due in August), Avexa will launch into a 800 patient Phase III trial. The company currently has $24 million in cash and would be expected to undertake a large capital raising to fund its Phase III trial as one option. (The second would be to partner with a larger biotech/pharmaceutical company).

Chemgenex Pharmaceuticals is currently completing a capital raising that should see the company with $15-$20 million in cash. It is currently conducting a registration Phase II/III trial with its lead compound, Ceflatonin, for the treatment for Gleevec-resistant chronic myeloid leukemia. The trial should be completed by year's end and the company may be in a position to register the drug in 2007. A more robust financial position would place the company in a Tier-1 category.

Progen is set to embark on a Phase III trial in mid 2007 that could involve as many as 1,000 patients with primary liver cancer, testing the company's angiogenesis inhibitor, PI-88. Progen is currently capitalised at $133 million with an estimated $16 million in cash.

And Metabolic Pharmaceuticals is another biotech that is attempting to launch into the Tier-1 category. The company has recently completed enrolment of a 500-person Phase II study for its weight loss drug, AOD9604. Results are expected early next year and if positive, the company will likely seek to license the compound to a major pharmaceutical company. The company has cash assets of $25 million.

Other Current Tier-1 Biotechs

Other companies we would group, from time to time, as Tier-1 biotechs that are not conducting late stage trials but with products on the market or with entitlements to a current royalty stream are **Sirtex Medical**, **Peptech** and **Biota Holdings**.

Five Tier-1 Companies: Financial Data and Lead Product Information

Company	**Alchemia**	**Pharmaxis**	**Peplin**	**pSiVida**	**Acrux**
Code	ACL	PXS	PEP	PSD	ACR
Date founded	2-Nov-95	29-May-98	7-Dec-99	8-Dec-00	19-Mar-98
Date listed	23-Dec-03	10-Nov-03	22-Sep-00	18-May-01	29-Jul-04
Years established before listing	8	5	0.8	0.4	6
Years established	11	8	6	5	8
CMP	$1.29	$2.09	$0.73	$0.61	$0.78
Capitalisation ($M)	$174	$367	$135	$267	$105
Cash (latest period; estimated) ($M)	$31	$103	$52	$44	$23
PEP, PSD: assumes current capital raisings are completed					
Technology Value ($M)	$143	$264	$83	$223	$82
Funding - IPO onwards ($M)	$47	$124	$87	$76	$28
Staff (EFT) (Num.)	50*	65	7**	55	41
** est.** at Jun 30, 2005*					

Lead Product Code or name	**Sodium fondaparinux**	**Aridol**	**PEP-005 Topical Gel**	**Retisert**	**Evamist**
Description	Sythetic version of a fragment of heparin	Inhaled dry powder formulation of manitol	Small molecule inhibitor of Protein Kinase C	Sustained release Fluocinole Acetonide	Transdermally delivered estrogen (a hormone)
Indication/s	Anti-coagulation therapies (various)	Identify patients with active asthma	Treatment of non-cancerous skin lesions (Actinic Keratosis and Basal Cell Carcinoma)	Uveitis,diabetic macular edema (DME), diabetic retinopathy	Treatments of symptoms of menopause
Recent Clinical Data	Acute Coronoary Syndrome (20,000 pt trial): GSK's Arixtra (fondaparinux) was associated with 47% decrease in bleeding compared to Lovenox	Phase III - up to 25% of asthma pts could have medication increased; up to 17% of pts could have medication decreased without adverse events	Phase IIa - achieved clearance of 71% of lesions	DME Trial, Phase III - 28% of pts improved visual acuity by 3 lines or more v. 15% for standard of care	Phase III - Most effective dose reduced hot flushes by 78%, in a population of women who experienced a mean total frequency of at least 56 hot flushes per week

Stock Updates

Peptech (PTD: $1.31)
Consolidation Activator

Peptech has been keen on playing a role in consolidation of the Australian biotech sector. The topic of consolidation, a term used to describe an effect of wide-spread M&A activity, has been frequently canvassed and discussed by many biotechs over the last two years. However, few have been able complete transactions, particularly in the listed biotech space.

The sector is moving to a distinctly tiered arrangement of companies. Tier-1 biotechs are those that are well cashed up, have compounds in later stage clinical trials or on the market, and capitalisations in excess of $100 million. From an M&A point of view, we expect it will become more of a buyers market for the more solid Tier-1 companies, because this set of companies will have superior access to capital. On the other hand, the Tier-2 companies will find it increasing difficult to secure investment attention and necessary funds on favourable terms.

Peptech has emerged as a clear Tier-1 biotech. The company is capitalised at $215 million and at the end of March had $42 in cash assets. Last month it announced its intention to by a private Australian biotech company, Promics, for $5 million (or $12 million if Promic's compound can advance to a Phase III trial). At the time of this acquisition, Peptech was also in advanced negotiations to make another acquisition – of a listed biotech company – although that transaction did not succeed.

With a large market capitalisation, a continuing royalty stream to 2010 (estimated to be US$80 - 100 million in total) and other potentially valuable investments or assets, Peptech is well positioned to take advantage of much awaited consolidation of the Australian biotech sector, and in the process, build a sizable biotech company with a well rounded portfolio of products in development from early to late stage with anti-inflammatory and oncology treatment applications.

In January this year, Peptech appointed Cliff Holloway as a business development manager. Holloway was formerly employed by **Pharmacopeia** in the US, also in a business development role, and in fact looked at Promics as a potential acquisition target for that company. It's of interest to note that Peptech had also considered the Promics acquisition 18 months earlier. Confirming the earlier point, as the access to capital for smaller biotechs becomes more difficult, the leading Tier-1 companies are becoming better positioned to seize on this opportunity as the divergence between Tier-1 and Tier-2 biotechs in Australia continues.

By August 2010, when Peptech's royalty stream from its TNF patents conclude, the company plans to have a much stronger pipeline of clinical programs, from pre-clinical through to a number of Phase III development programs. Peptech's other key assets include its investment in **Domantis**, which is increasing in attractivness, given the interest in the last 12 months in antibody and antibody optimisation companies. This investment could reasonably be valued in the order of US$100 million if Domantis lists in the US in the next two years, which is largely expected.

Suprelorin building in value?

Peptech's other asset of interest is that of its animal health business. It is currently generating revenue of approximately $1 million mostly from Australia. The company sells a product that helps stimulate ovulation in horses, called Ovuplant. However the key product is a pet contraceptive device (one injection lasts six months) called Suprelorin. The product is being sold in Australia and New Zealand and is expected to be launched into Europe next year and the US in 2008. The product has the potential to generate sales in excess of US$25 million. It could become a surprisingly valuable asset for the company that could be sold off once the business is better established.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Cogstate Adds GSK as Client

Cogstate (CGS: 26 cents) this week announced it had signed a contract with **GlaxoSmithKline** in the US to provide its cognitive testing platform for a Phase I clinical trial, presumably in CNS disorders. The value of the contract was not disclosed and was most likely not significant to warrant disclosure. However what was significant was that the company had added another major pharmaceutical company to its client list.

The company is hopeful it can continue its penetration into big pharma with possibly another two pharmaceutical companies signing on by the end of this year. Currently, a large percentage of sales are generated from one client, **Pfizer**. The current trial is expected to be completed by the end of 2006. GSK uses cognitive testing services from two of Cogstate's competitors. That GSK is considering Cogstate's product is a positive for the company, with the potential for the relationship to be strengthened if GSK is pleased with the Cogstate service.

Cogstate is making solid inroads to establishing a viably business from the clinical trial application of the Cogstate product. In the last quarter, the company generated a positive cashflow from operations and we expect the company will be approaching profitability on a consistent basis over the next five quarters. Other applications for this technology include use in the workplace as a fitness-to-operate test, and for cognitive testing to people with suspected degenerative disorders. We expect these markets will be explored further as the company is generating a strong profit growth trend from its core clinical trial testing application.

Cogstate is now capitalised at $12 million and has approximately $3.2 million in cash. For this financial year we are forecasting sales of $2.2 million.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Stock Updates

Cytopia

Announcement of Licensing Deal Expected on Monday

Cytopia (CYT: $1.02) entered into a trading halt today. The company has set expectations that it will conclude a licensing deal for certain assets before the end of the financial year, so there is a very strong likelihood that the trading halt is related to an announcement that declares a licensing deal has been signed. The company is seeking to out-license its JAK3 kinase assets, which would include one or more molecules that have been advanced into, or are set for, the pre-clinical stage of development. Cytopia has developed molecules for potentially treating rheumatoid arthritis, in transplantation (which requires immmune suppression), and in lymphoma. (Kinases are proteins involved in communication in cells.)

Possible licensees for the JAK3 program include **Novartis** and **Pfizer**. Novartis is possibly more likely because it has engaged in a significant degree of licensing activity over the last two years (see *Bioshares* 152). It also has an important business and history in developing and marketing drugs for transplantation, and drugs that target kinase proteins ie Gleevec. Pfizer may also be a candidate because it has undertaken kinase targeted drug development, but has also explored the JAK3 area.

Favourable deal terms could include, for world-wide rights, an upfront payment of US$5 million per molecule family per indication, in addition to separate research payments of US$5-$7 million for a period of four years (mirroring an aspect of a deal struck between **Avanir** and Novartis in April, 2005), and an equity investment of US$20 million. Total deal value could be as much as US$200 million. Although Cytopia does not have a proprietary position over the JAK3 kinase, its strength in generating an attractive deal would, in our opinion, stem from its ability to design selective and potent molecules for the JAK3 kinase, generate relevant cell and animal model data, and modulate the kinase as necessary to achieve results in the three different disease areas mentioned above.

Cytopia is capitalised at $75 million with cash assets estimated at $5 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

	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)	-3.9%
Cumulative Gain	**168.0%**

Evogenix **Signs on CSL**

CSL signed an agreement this week to access Evogenix's (EGX: 50 cents) protein super humanisation and optimisation technology. Evogenix will be paid on a fee for service payment for the work, but also stands to receive some royalty payments if products from the collaboration get to market. The arrangement is similar to **GlaxoSmithKline**'s arrangement with Evogenix.

There are several investment points to this deal. Firstly, it illsutrates that the demand by protein drug companies to humanisation and optimisation technologies is real, and arguably growing, when access is diminishing rapidly and all the more so following **AstraZeneca**'s bid for **Cambridge Antibody Technology** (see *Bioshares* 167). That CSL is company with a local connection to Evogenix is a positive, but it is Evogenix's improved prospects in a global market place for its specialised skills and know-how that have been confirmed.

Secondly, the relationship with CSL could provide an important upside for Evogenix stock. A successful initial fee-for-service relationship may pave way the way for deeper more extensive connections. And should CSL look to build a stronger business in the protein therapeutics space, it may elect to increase its ties with Evogenix, either directly or in-directly.

Evogenix is capitalised at $65 million and had cash assets of $7 million at March 31, 2006

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Bioshares Model Portfolio (2 June 2006)

Company	Price (current)	Price added to portfolio
Acrux	$0.78	$0.83
Agenix	$0.17	$0.22
Alchemia	$1.29	$0.67
Avexa	$0.25	$0.15
Biolayer	$0.21	$0.195
Bionomics	$0.19	$0.210
Biosignal	$0.17	$0.22
Cogstate	$0.26	$0.09
Cytopia	$1.02	$0.46
Evogenix	$0.50	$0.47
GroPep	$1.55	$1.43
Optiscan Imaging	$0.51	$0.35
Neuren Pharmaceuticals	$0.54	$0.70
Pharmaxis	$2.09	$1.90
Prima Biomed	$0.087	$0.09
Sirtex Medical	$2.35	$1.95

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, Psivida, Cytopia, Biodiem, Peptech, Starpharma Holdings, Cogstate, Xceed Biotechnology, Healthlinx, Incitive

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