

In this edition...

One of the key measures of activity in the biotech space is the total number of clinical trials underway or in the planning. Right now, according to our annual clinical trial survey, that number is 82, which is probably slightly understated due to the use of our survey methodology. This is a healthy number, and an even more healthy number is the 22 Phase III trials underway or in planning. That is good news for biotech investors who wish to invest in a relatively less risky biotech opportunities.

Once again the data shows a biotech sector in good shape, with strong newsflow expected for the remainder of 2008 and well into 2009.

The editors

Companies covered: AAH, Clinical Trials Survey

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (from 4 May '07)	-36%
Cumulative Gain	107.0%
Av Annual Gain (6 yrs)	26.8%

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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 2008

There were 82 clinical trials underway or planned by Australian drug developers and medical device firms as of April 2008, according to the *Bioshares* annual clinical trial survey of Australian life science companies. At the time of our last survey in March 2007, there were 72 clinical trials underway or planned.

According to the survey there were 22 Phase III clinical trial programs underway or in planning and 27 Phase II trials underway or in planning.

The results from at least eighteen clinical trials, including several preliminary results, are expected to be announced over the course of 2008. In contrast, 2009 should see at least 24 clinical trial results announced. These figures are stated as expected minimums because a number of companies have not declared the periods in which they might announce the results of 31 clinical trials.

For this survey, 25 companies were surveyed, although data pertaining to the clinical programs of several companies were sourced from company publications and announcements. Activity figures obtained from this survey understate the actual number of trials underway or planned as the survey excludes companies conducting post-marketing trials. Some companies also elect to not include all clinical trial activity in their survey responses.

A summary of the clinical trial survey can be found on page 2 and 3, with a more complete survey report found in **Appendix A**.

2008 – Selected Trials to Monitor

Forthcoming trial result announcements to look out for include include **Arana Therapeutics** trial of its domain antibody ART621 which is being evaluated in a Phase IIa trial in patients with psoriasis (2008 Q4). This is a repeat dose and pharmacokinetics study that will aid the company in the design of a larger study of the same compound in rheumatoid arthritis. The study will also supply information that the company can apply to the marketing of a data package to potential partners.

Pharmaxis expects to announce results of a Phase II study of Aridol, its lung function diagnostic in COPD patients in 2008 Q3. This is a new indication for Aridol. Pharmaxis also expects to publish 12 month safety data for Bronchitol for bronchiectasis patients mid-year in support of its marketing authorization application with the TGA.

Interim data is expected from **Cytopia**'s CYT997 being tested in multiple myeloma patients in 2008 Q3 (final, 2008 Q4) and **Clinuvel Pharmaceuticals**' CUV1647, which is being evaluated in patients with absolute sun intolerance, is expected in 2008 Q4.

Finally, **Antisense Therapeutics**' final report on its Phase IIa trial of ATL1102 in multiple sclerosis patients is expected mid-year.

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Bioshares 2008 Clinical Trials Survey – Clinical Trials Where Companies Have Advised Period in which Results will be Announced

Company	Drug Code/Name [Trial Code]	Phase	Expected qtr results ann.	Disease or Medical Condition
2008 - Q2				
Novogen (NRT)	NV196-0001	Phase I	2008 Q2	Advanced malignancies
Pharmaxis (PXS)	Bronchitol [DPM-CF-202]	Phase II	2008 Q2	Cystic Fibrosis
QRxPharma (QRX)	Q8003 Study 007	Phase III	2008 Q2	Bunionectomy patients
Acrux (ACR)	Nestorone MDTS	Phase I	2008 Q2 /Q3	Contraception
2008 - Q3				
Progen Pharmaceuticals (PGL)	PI-88 [CFZ101]	Phase I	2008 Q3	Hepato-cellular carcinoma
Cytopia (CYT)	CYT997 [CCL06001]	Phase I	2008 Q3	Diverse solid tumours
Mesoblast (MSB)	MSB - FR001	Phase I/IIa	2008 Q3	Delayed healing / non-union of long bone fractures
Pharmaxis (PXS)	Aridol [DPM-COPD-202]	Phase II	2008 Q3	COPD
Tissue Therapies (TIS)	VitroGro	Phase I	2008 Q3	Chronic skin ulcers
Pharmaxis (PXS)	Bronchitol [DPM-B-301]	Phase III	2008 Q3 [2007 Q3]	Bronchiectasis
Cytopia (CYT)	CYT997 [CCL07001]	Phase II	2008 Q3 interim (2008 Q4)	Multiple myeloma
2008 - Q4				
Arana Therapeutics (AAH)	ART621 [201]	Phase IIa	2008 Q4	Psoriasis
Biotron (BIT)	BIT225 [003]	Phase Ib/IIa	2008 Q4	Hepatitis C virus (HCV)
Biotron (BIT)	BIT225 [004]	Phase Ib/IIa	2008 Q4	HIV
Pharmaxis (PXS)	PXS25	Phase I	2008 Q4	Lung inflammation
Clinuvel Pharmaceuticals (CUV)	CUV1647	Phase III	2008 Q4 (interim - 70 pts)	Absolute sun intolerance
2008 - Other				
Acrux (ACR)	Nestorone MDTS	Phase I	2008 H2	Contraception
Antisense Therapeutics (ANP)	ATL1102	Phase IIa	2008 Mid	Multiple Sclerosis
2009 - Q1				
Bone Medical (BNE)	CaPTHymone	Phase IIb	2009 Q1	Osteoporosis
Biota Holdings (BTA)	CS8958 Elderly Subjects	Phase I	2009 Q1	Influenza infection
Progen Pharmaceuticals (PGL)	PI-88 [PR88205]	Phase II	2009 Q1	Metastatic melanoma
Pharmaxis (PXS)	Bronchitol [DPM-CF-301]	Phase III	2009 Q1	Cystic Fibrosis
Pharmaxis (PXS)	ACRN-asthma	Phase III	2009 Q1	Asthma
Clinuvel Pharmaceuticals (CUV)	CUV1647	Phase III	2009 Q1	Severe sun poisoning
2009 - Q2				
Benitec (BLT)	Stem Cell/AntiHIV RNAi Therapy	Phase I	2009 Q2	High risk AIDS Lymphoma
ChemGenex Pharmaceuticals (CXS)	CGX-635 [CML-202]	Phase II/III	2009 Q2	CML patients -failed imatinib -w. T315I mutation
ChemGenex Pharmaceuticals (CXS)	CGX-635 [AML-204]	Phase II	2009 Q2	AMLpatients - failed prior chemo-therapy
Giaconda (GIA)	Hepaconda	Phase IIa	2009 Q2	Chronic Hepatitis C Genotype 1 infection
Neuren Pharmaceuticals (NEU)	Glypromate	Phase III	2009 Q2	Cognitive impairment post cardiopulmonary bypass
Progen Pharmaceuticals (PGL)	PI-88 [47-01-001]	Phase I	2009 Q2	Advanced cancer patients
Pharmaxis (PXS)	Bronchitol [DPM-B-304]	Phase III	2009 Q2	Bronchiect-asis
2009 - Q3				
Bone Medical (BNE)	Capsitonin	Phase IIb	2009 Q3	Osteoarthritis
Biota Holdings (BTA)	BTA798	Phase IIa	2009 Q3	Human rhinovirus infection
ChemGenex Pharmaceuticals (CXS)	CGX-635 [CML-203]	Phase II	2009 Q3	CML patients who have failed multiple TKIs
Progen Pharmaceuticals (PGL)	PI-88 [47-01-002]	Phase I	2009 Q3	Advanced cancer patients
2009 - Q4				
Cytopia (CYT)	CYT997 [CCL08001]	Phase Ib/II	2009 Q4	Glioblastoma multiforme (glioma)
Cytopia (CYT)	CYT387 [CCL08101]	Phase I/II	2009 Q4	Myeloproliferative disorders
Pharmaxis (PXS)	Bronchitol [DPM-CF-302]	Phase III	2009 Q4	Cystic Fibrosis
2009 - Other				
BioMD (BOD)	ADAPT Pericardial Patch	Phase II	2009 End	Congenital heart disease
Acrux (ACR)	Testosterone MD-Lotion	Phase III	2009 H2	Hypogonadism
Halcyon Pharmaceuticals (HGN)	Subazole HGN04	Phase III	2009 H2	Onychomycosis of toenail
Ventracor (VCR)	VentrAssist	NA	2009 Mid	End stage heart failure
2010				
Neuren Pharmaceuticals (NEU)	NNZ-2566	Phase II	2010 Q1	Traumatic brain injury
Neuren Pharmaceuticals (NEU)	Nefiracetam	Phase IIb	2010 Q1	Post stroke apathy and depression
Avexa (AVX)	Apricitabine [301 & 302]	Phase III	2010 Q2	HIV
Bone Medical (BNE)	Capsitonin	Phase III	2010 Q2	Osteoporosis
Biota Holdings (BTA)	CS8958 Multiple Dose	Phase I	2010 Q2	Influenza infection
Progen Pharmaceuticals (PGL)	PI-88 [PR88302]	Phase III	2010 Q4	Hepato-cellular carcinoma
2011				
Ventracor (VCR)	VentrAssist	NA	2011 End	End stage heart failure

Bioshares 2008 Clinical Trials Survey – Clinical Trials Where Companies Have **Not** Advised Period in which Results will be Announced

Company	Drug Code/Name [Trial Code]	Phase	Expected qtr results ann.	Disease or Medical Condition
Quarter Not Stated or Not Disclosed or To Be Advised				
Acrux (ACR)	Animal health	Phase III		Undisclosed
Avexa (AVX)	Apricitabine [201E & 201EE]	Phase II (ext)	NA	HIV
Bionomics (BNO)	BNC105	Phase I		Advanced cancer, range of solid tumour types
Clinuvel Pharmaceuticals (CUV)	CUV1647	Phase II		Precursor to skin cancer
Clinuvel Pharmaceuticals (CUV)	CUV1647	Phase II		Acute anaphylactic reaction to sun
Clinuvel Pharmaceuticals (CUV)	CUV1647	Phase II		Photosensitivity associated with cancer treatment
Giaconda (GIA)	Myoconda	Phase II/III		MAP positive Crohn's disease patients
HeartWare (HTW)	HeartWare LVAD	NA	TBA	Advanced Heart Failure
Mesoblast (MSB)	MSB - SF001	Phase I/IIa		Degenerative disk disease with spondylolisthesis
Novogen (NRT)	NV06 [0034]	Phase I		Advanced malignancies
Novogen (NRT)	NV27 [0001]	Phase I		Healthy volunteers
Novogen (NRT)	NV06 [0031]	Phase I		Cervical, vaginal and vulvar cancer
Novogen (NRT)	NV06 [0025]	Phase I/II		Advanced, Disseminated, Hormone-Refractory
Novogen (NRT)	NV06 [0037]	Phase Ib		Ovarian carcinoma
Novogen (NRT)	NV06 [Yale 27640]	Phase II		Ovarian carcinoma
Novogen (NRT)	NV06 [Yale 0703002467]	Phase II		Prostate cancer
Novogen (NRT)	NV06 [0039]	Phase III		Ovarian carcinoma
Peplin (PLI)	PEP005 Topical for AK (On-head)	Phase IIb		Non-cancer skin lesions
Peplin (PLI)	PEP005 Topical for AK (Off-head)	Phase III		Non-cancer skin lesions
Peplin (PLI)	PEP005 Topical for AK (On-head)	Phase III		Non-cancer skin lesions
Pharmaxis (PXS)	DPM-PK-101	Phase I		Asthma, COPD, Cystic fibrosis
Phosphagenics (POH)	TPM/Retinoic Acid	Phase I		Acne
Phosphagenics (POH)	TPM/Insulin	Phase II		Type 1 diabetes
QRxPharma (QRX)	Q8003 Study 013	Phase I	TBD	Healthy volunteers
QRxPharma (QRX)	Q8003 Study 015	Phase II	TBD	Bunionect-omy patients
QRxPharma (QRX)	Q8003 Study 016	Phase II	TBD	Knee replacement patients
QRxPharma (QRX)	Q8003 Study 010	Phase III	TBD	Bunionectomy patients
QRxPharma (QRX)	Q8003 Study 008	Phase III	TBD	Bunionectomy patients
QRxPharma (QRX)	Q8003 Study 009	Phase III	TBD	Knee replacement patients
QRxPharma (QRX)	Q8003 Study 011	Phase III	TBD	Osteoarthritis patients
Ventracor (VCR)	VentrAssist	NA	Ongoing	End stage heart failure

Arana Therapeutics to Co-develop ART104 with Kyowa Hakko Kogyo

Arana Therapeutics is in full flight with the development of its antibody assets. This week the company formed a development agreement with a large Japanese biotech company, **Kyowa Hakko Kogyo (KHK)**. Arana will receive a US\$4 million upfront payment as part of the deal to co-develop one of Arana's preclinical drug candidate, ART104, for the treatment of colorectal cancer.

ART104 came through Arana's acquisition of **ScanCell** in December 2006, for which Arana paid GBP2 million (with potentially a further GBP2.85 million in future royalties to pay) for 25 antibody compounds. Arana and KHK will share equally in development costs and future ownership with the exception that KHK having marketing rights into parts of Asia, should the program be successful, where Arana would receive a royalty entitlement.

KHK brings with it its own antibody optimisation technology to the program, specifically its Potelligent technology that enhances the activity of antibodies for oncology applications through reduction of fucose levels in the antibody.

KHK has had considerable success in licensing its technology recently. Last month it struck a deal with **Amgen**, where it received US\$100 million up front and up to US\$420 million in milestone payments plus royalties. The licensing deal was around access to

KHK's antibody drug KW-0761 which is being tested for inflammation and cancer. The compound is in Phase I studies and was optimised using KHK's Potelligent platform.

ART104 will be optimised using the Potelligent (and a second Complegent) platform and is expected to move into the clinic in 2010 or 2011. There is obviously genuine interest in this program from KHK, which helps support Arana's preclinical pipeline.

Bioshares recommendation: **Speculative Buy Class A**

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Bioshares Model Portfolio (24 April 2008)

Company	Price (current)	Price added to portfolio	Date added
Cellestis	\$2.45	\$2.27	April 2008
IDT	\$2.04	\$1.90	March 2008
Circadian Technologies	\$0.95	\$1.03	February 2008
Patrys	\$0.30	\$0.50	December 2007
NeuroDiscovery	\$0.15	\$0.16	December 2007
Bionomics	\$0.36	\$0.42	December 2007
Cogstate	\$0.15	\$0.13	November 2007
Sirtex Medical	\$4.00	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.42	\$0.66	September 2007
Starpharma Holdings	\$0.33	\$0.37	August 2007
Pharmaxis	\$1.55	\$3.15	August 2007
Universal Biosensors	\$0.87	\$1.23	June 2007
Biota Holdings	\$1.15	\$1.55	March 2007
Probiotec	\$1.19	\$1.12	February 2007
Peplin Inc	\$0.54	\$0.83	January 2007
Arana Therapeutics	\$1.01	\$1.31	October 2006
Chemgenex Pharma.	\$0.92	\$0.38	June 2006
Cytopia	\$0.30	\$0.46	June 2005
Optiscan Imaging	\$0.20	\$0.35	March 2005
Acrux	\$0.80	\$0.83	November 2004
Alchemia	\$0.45	\$0.67	May 2004

Portfolio Changes – 25 April 2008

IN:
No changes.

OUT:
No changes.

How Bioshares Rates Stocks

For the purpose of valuation, *Bioshares* divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

- Buy** CMP is 20% < Fair Value
- Accumulate** CMP is 10% < Fair Value
- Hold** Value = CMP
- Lighten** CMP is 10% > Fair Value
- Sell** CMP is 20% > Fair Value
(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A

These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B

These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C

These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Phylogica, Pharmaxis, NeuroDiscovery, Biotech Capital, Cytopia, Biodiem, Arana Therapeutics, Starpharma Holdings, Cogstate, Xceed Biotechnology, Incitive, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima

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