

In this edition...

We have prepared our annual clinical trials survey. There are currently 11 Phase III trials underway or in the planning by Australian biotechs, an impressive result. However perhaps not surprisingly, the number of clinical trials underway or in the planning was well down on last year's figure, now 55 compared to 82 in 2008.

We also provide a major update on CathRx, which has recently secured some funding, although at quite a price. And Cytopia has announced its second clinical program to proceed.

The Editors

**Companies Covered: CYT,CXD,
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 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - Current)	7.4%
Cumulative Gain	108%
Av Annual Gain (8 yrs)	14.7%

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Blake Industry & Market Analysis Pty Ltd
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence
No. 258032

Enquiries for *Bioshares*
Ph: (03) 9326 5382
Fax: (03) 9329 3350
Email: info@bioshares.com.au

David Blake
Ph: (03) 9326 5382
Email: blake@bioshares.com.au

Mark Pachacz
Ph: (03) 9671 3222
Email: pachacz@bioshares.com.au

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

Extract from Bioshares –

Cytopia to Move CYT387 into Clinic

Cytopia is broadening its clinical pipeline with its second clinical program expected to start in the second half of 2009. The lead candidate, CYT387, will be trialed in around 30 patients with myelofibrosis. The trial will be conducted at the prestigious Mayo Clinic under the study chair Dr Ayalew Tefferi, who is a key opinion leader in this field.

CYT387 inhibits the JAK2 signalling pathway in cells. This pathway is linked with various cancers and inflammatory disorders. The JAK2 inhibitors are the backbone of the company, with the company founded on the proprietary position around inhibition or modulation of this biological pathway in cells.

The disease Cytopia is tackling in this clinical trial fits into a broader category of myeloproliferative disorders. The estimated market size for these disorders is around US\$500 million with no currently effective treatments on the market.

The Phase I/II trial will be an open label trial, likely in around 30 patients. Trial results should start to become available in the first quarter of 2010, with results expected to be seen within four weeks of treatment. The Phase I and Phase II part of the trial should be completed by the end of 2010. The company estimates the trial will cost only \$1 million to conduct. Costs of the trial are reduced because the candidate is an oral formulation, and that the trial can be conducted at the one centre in the US, which treats a large number of patients with this disease.

If positive results emerge, the company will look to expand into other myeloproliferative disorders and look to move into a Phase II/III trial for myelofibrosis. With no effective therapies on the market, this program has the potential to move rapidly through the clinical trial process. There are currently three other companies with clinical programs working on the same target.

Incyte Pharmaceuticals is trailing its JAK inhibitor on a number of myeloproliferative disorders and inflammatory conditions (included rheumatoid arthritis). Its myelofibrosis trial is currently at the Phase II/III stage of development. SBio from Singapore started its Phase I/II trial in myelofibrosis in Australia at the end of last year with its JAK2 inhibitor. And Targegen Inc is currently conducting its Phase I/II trial in myelofibrosis in six centres in the US.

Myeloproliferative disorders are a nascent market and are eligible for orphan drug status. Cytopia's expertise developed over the last decade in developing JAK2 drug candidates places this Phase I/II program is the company's sweet spot.

Cont'd over

Glioma trial update

Cytopia is currently conducting a Phase I/II trial in patients with Glioma with its lead, CYT997. Three sites in Australia are recruiting patients, with additional two Australian sites and one international site expected to be added. Around 30 patients are to be enrolled. Some efficacy results from this trial are expected to be reported by the company in the first half of 2010.

Funding requirements

Over the next five months the company will need to address its funding requirements, with sufficient funds at the moment to take the company to the end of March 2010. Funding options include a partnering deal or an equity raising.

Recommendation

Cytopia's share price has fallen by over 90% from its high three years ago. Whilst many of the leading biotech company share prices have bounced back this year, Cytopia and many smaller biotechs have ongoing funding challenges recognised by investors which has caused the sell-off in such stocks. Cytopia is now capitalised at only \$6.4 million. At some stage this stock has the potential to generate a multiple fold return, once funding issues subside, equity markets stabilise and certainly when and if a clinical breakthrough is achieved. Adding a second clinical program to its pipeline significantly increases the possibility of the latter occurring.

Bioshares recommendation: **Speculative Buy Class B**

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, Cytopia, Arana Therapeutics, Starpharma Holdings, Cogstate, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical

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