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In this edition...

The field of stem cell technology and therapeutics has the capacity to deliver some of the greatest medical breakthroughs of the 21st Century. One company that is positioning itself to be a central player is Stem Cell Sciences, a company that has its origins in Australia and now has operations in four continents around the world.

M&A continues in the sector, a very healthy sign. Two microcaps, Visiomed and Clinical Cell Culture look set to merge, perhaps a sign of what may be ahead for other smaller biotechs that fail to deliver.

We also update readers on progress at Living Cell Technologies, which has enjoyed some early clinical success, Cytopia and Biodiem.

The editors

Companies covered: BDM, CCE, CYT, LCT, STC, VSG

	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)	-6.2%
Cumulative Gain	**206%**
Av Annual Gain (6 yrs)	**26.8%**

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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) 9671 3633
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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Bioshares

12 October 2007
Edition 236

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

Stem Cell Sciences – Positioning for Global Stem Gell Growth

Stem Cell Sciences (STC: 65 cents) listed on the ASX in April this year raising $12 million through the process. This listing follows on from an earlier listing on the AIM stock market in the UK in 2005 when it raised $13.8 million. However, since listing on both exchanges, the company's share price has slowly declined each time. The decline has as much to do with the uncertainty of where the stem cell field is heading (or how quickly), a lack of commercial validity (there a few stem cell therapies on the market), as it does with a multi-faceted business plan that investors may find difficult to assess.

Stem Cell Sciences (SCS) is not a biotech company developing the next blockbuster pharmaceutical product. The company is all about positioning itself centrally in the emerging therapeutic field of stem cells which offers arguably some of the great medical breakthroughs of the 21st century.

Core expertise – growing stem cells

The company's core expertise is in producing (growing) stem cells and also in differentiating stem cells, for instance producing neural stem cells from more fundamental cells such as embryonic stem cells. The company's argument is that all stem cell applications both now (stem cells used for drug screening) and in the future (for stem cell therapeutics) will require a high level of expertise in growing these cells reproducibly on commercial scale.

Stem Cell Sciences was formed in Melbourne in 1994. In December last year the company commissioned its commercial stem cell manufacturing facility in Cambridge, England, and interest from major pharmaceutical groups has grown considerably since the facility was opened.

In-licensed adult stem cells

To support and build on its core area of expertise, the company's approach is to work with leading academic stem cell groups around the world, in-license IP, and out-license or partner major stem cell development programs or technologies. In 2005, the company in-licensed patented technology from the **Universities of Edinburgh** and **Milan** to derive and grow pure adult neural stem cells (or brain cells). This technology is being applied to therapeutic programs in treating neurological diseases or injuries such as Parkinson's disease, stroke and spinal cord injury. This first therapeutic program using these cells is expected to move into clinical trials in about three years time for the treatment of age-related macular degeneration.

Last year the company and its joint venture partner in Japan, **SCS KK**, in-licensed stem cell technology from the **University of Nice,** giving it access to adipose (fat) derived stem cells. These stem cells will be applied for therapeutic applications such as the treatment of Duchenne Muscular Dystrophy. SCS signed a second separate in-licensing agreement

with the university to investigate use of the cells in treating osteoporosis and obesity. The novel adult (although in fact derived from children) cells were discovered by the University of Nice. They are easily grown and produce bone and fat cells at a very high efficiency.

Therapeutic development partnerships/out-licensing

SCS KK is leading the muscular dystrophy program in Japan, which is expected to move into clinical trials in 2009. Both SCS KK and Stem Cell Sciences will be working with the University of Nice and the **CNRS** in France to advance therapeutic programs related using these cells. In November last year, Stem Cell Sciences started preclinical studies on repairing spinal cord injury with the **Regenerative Medicine Institute** in Ireland. That program is scheduled to move into clinical trials in 2011.

The next commercial step is then to out-license the technology to larger pharmaceutical groups once they have been sufficiently advanced. The company also has intellectual property assets in the embryonic stem cell area although therapeutic programs with these cells will be considerably further from clinical application and development.

Current revenue streams

Cell growth media

Stem Cell Sciences has developed several media products used to grow stem cells. To date, these have been licensed to **Chemicon International (**now **Millipore)** and are sold under the SC Proven product label range. In October last year the company appointed **Millipore Corporation** as a distributor of its second media product 'hEScGro', a serum-free media used to grown human embryonic stem cells, hESCs.

Out-licensing income for R&D

Another current income stream for the company has been licensing access to the some of the proprietary stem cell technology on a non-exclusive basis. To date, the company has out-licensed IP to Lexicon Genetics, Deltagen and Merck.

Stem Cell Production

A third income stream for the company is the customized production of stem cells at the company's Cambridge facilities. The company generated a modest income in the 12 months to June of $1.9 million from these sources.

European grant syndicates

Stem Cell Sciences has been very successful in accessing European grants to fund its R&D through stem cell syndicates. The grants, arranged through commercial and academic partnerships are important not only for the funding, but also for the access to the developments that emerge from these co-operative structures, such as the neural stem cell technology in-licensed by Stem Cell Sciences.

The grants are provided by the European Union's Sixth Framework Program, which is designed to support and build European research across the European Union in specific research areas in a collaborative manner. Stem Cell Sciences was recently part of a 2.4 million Euro grant under this program with three other commercial groups and four academic groups (0.42 million Euro is allocated to Stem Cell Sciences). The program, called Neuroscreen, will use Stem Cell Science's neural stem cells to develop assays for the cells that may be useful in the future to screen drugs to treat diseases such as Alzheimer's disease, stroke and epilepsy.

Risks/Challenges

The field of stem cell research and development is in its *commercial* infancy especially as the science continues evolve. The company description of this situation is that "we are at the end of the beginning of stem cell research". The commercial path for these technologies is as novel as the underlying technology. This helps explain the hesitancy of investors to forcefully back stem cell focused biotech companies.

With the technology complex and the path to market somewhat unknown, Stem Cell Sciences faces the challenge to add clarity to its commercialization model. Companies in the field such as **Mesoblast**, that have been able to provide a clear investment proposition with a rapid translation into clinical studies have received strong support from investors. However, that company also is not without significant technology and commercialisation development risks.

Over the medium term, Stem Cell Sciences will add tangible value by building its revenue generating businesses. However, at present this is a modest income stream. And clinical validation through its therapeutic programs is at least three years away, which makes the company a longer term, but potentially attractive, investment prospect.

Summary

Stem Cell Sciences is supported by high quality science and is looking to be one of the central players in the emerging field of stem cell technology. Its expertise in growing stem cells for use by pharmaceutical companies for drug screening, and in selling cell culture media to grow stem cells has the capacity to earn a solid income stream poetntially growing to over $50 million a year.

Stem Cell Sciences is capitalised at only $22 million with $13 million in cash at June 30, offering investors an excellent exposure in their portfolios to this field. The company has challenges moving forward in clarifying its commercial pathway, particularly in its therapeutic development programs.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Correction:
On page 2 of Bioshares 235, in the paragraph beginning **'Progen Pharmaceuticals** released data from its Phase II trial of PI-88 in combination with the taxol drug docetaxol...' , the sentence 'The trial did meet its endpoints' is incorrect and should read: 'The trial did not meet its endpoints.' Also, 'Docetaxol' should read 'Docetaxel'.

Clinical Cell Culture and Visiomed Group Announce Merger

Consolidation in the listed Australian biotech sector continues apace, with West Australian businesses **Clinical Cell Culture** (CCE: 3.6 cents) seeking to acquire **Visiomed Group** (VSG: 2.1 cents). These two companies have fallen out of favour in recent times, having failed to meet expectation regarding sales performances. However, for Visiomed that situation may be about to change with that company beginning to report an improved sales performance.

Clinical Cell Culture (C3) is the developer of a novel skin tissue repair technology that is based on the harvesting and culturing of a patient's own skin cells. The company has achieved registrations for its ReCell kit in many markets around the world, but not the USA. ReCell is designed for the treatment of small burns and tissue damage (2%-4% of body area). Its rapid burns treatment products (CellSpray and CellSpray XP) have also received registrations in a number of jurisdictions. C3 is headquartered in Cambridge, UK.

Visiomed Group develops and markets asthma spacer products including the Funhaler, for pediatric patients and the Breath-A-Tech spacer, for adult patients. The Breath-A-Tech product is licensed from **Respironics Inc**, which manufactures and sells the technology under the trade name Optichamber. The Funhaler has received European CE mark approval, Australian TGA approval and US FDA clearance. In addition the product is reimbursable in those markets as well. Visiomed is based in Perth, Western Australia..

Clinical Cell Culture History

Clinical Cell Culture was founded in 1999 by clinical researchers Dr Fiona Wood and Marie Stoner to develop innovative skin culture technologies. Pooled development fund, **ECAT Development Capital** invested in 2001, with that company eventually deregistering as a PDF, and taking 100% ownership position and re-badging it as Clinical Cell Culture in 2002. C3's share price fell significantly on February 19, 2007, after the company announced that it would not meet revenue forecasts of $5-$7 million for FY2007. In fact revenue for FY2007 came in at $1.5 million, including sales of $0.9 million.

Visiomed Group History

Visiomed's origins date back to 2000, when listed mining company **Fimiston Resources and Technology** (formerly Fimiston Mining) invested in Skin Cancer Technologies Pty Ltd, a company related to optical detection technologies developed at the University of Western Australia in Perth. Subsequently Fimiston changed its name to **Xcell Diagnostics** in July 2001, with the re-named company going on to acquire Infamed Pty Ltd in February 2002, the owner of the Funhaler technology.

Xcell also acquired in 2002 a German company **Visiomed AG** for its skin cancer diagnosis and detection technology (microDERM) and to reflect this change of focus, the company's name changed once again, this time to Visiomed. Worthwhile sales of microDERM products were not forthcoming, with the business being divested in January 2005. In October, 2006, Visiomed acquired the respiratory device company Breath-A-Tech, which was funded with an initial cash consideration of $1.8 million and 16.6 million shares, followed by deferred payments to be made in October of 2007, 2008 and 2009 respectively.

C3 and Visiomed: Financials and other data

		Clinical Cell Culture (CCC; C3)	Visiomed	Merged entity
ASX Code		CCE	VSG	
Share Price		$0.036	$0.021	
Capitalisation ($M)		**$15.3**	**$13.6**	**$28.9**
Fimiston invests in Skin Cancer Tech.			Oct-2000	
FIM name change to Xcell Diagnostics			Jul-2001	
XEL name change to Visiomed			Sep-2003	
Date CCC Founded		Oct-1999		
ECAT Dev. invests in CCC		Nov-2001		
Name change of ECAT Dev. to CCC		Sep-2003		
Cash 30/6/2007 ($M)		**$12.3**	**$2.2**	**$14.5**
Product Focus		Tissue Repair	Respiratory feedback mechanisms	
Products		ReCell CellSpray XP CellSpray	Funhaler Breathatec	
Product Sales ($M)				
2002/03			$0.2	
	C3 CY2003	$1.0		
2003/04			$0.8	
2004/05	(C3 18 mo)	$1.4	$0.6	
2005/06		$1.1	$0.1	
2006/07		$0.9	$0.8	
Total		**$3.5**	**$1.7**	**$5.2**
Net Profit/Loss ($M)				
2002/03			-$1.8	
	C3 CY2003	-$5.6		
2003/04			-$4.4	
2004/05	(C3 18 mo)	-$14.6	-$1.2	
2005/06		-$12.0	-$1.3	
2006/07		-$15.1	-$1.1	
Total		**-$28.7**	**-$7.0**	**-$35.7**
Funding ($M)				
2002/03			$0.8	
	C3 CY2003	$7.1		
2003/04			$2.9	
2004/05	(C3 18 mo)	$15.6	$1.9	
2005/06		$10.0	$2.3	
2006/07		$13.8	$4.5	
Total		**$46.5**	**$12.4**	**$58.8**

How the merger proposal came about

The concept of merger between Visiomed and C3 was initiated from discussions held between Dr Fiona Wood and Dr Paul Watt,

who were collaborating on research tasks for another Perth-based company, **Phylogica**. Dr Paul Watt, the inventor of the Funhaler, is a director of Visiomed and a director and founder of Phylogica. However, a more crucial common link between the two companies is at the board level, with Perth accountant Dalton Gooding being the chairman of C3 and a non-executive director of Visiomed.

Details of the proposed merger

C3 and Visiomed have agreed to a merger by way of scheme of arrangement, which is a court mediated process that requires approval of at least 75% of shareholders. Under the terms of the proposed scheme of arrangement, Visiomed shareholders will receive five C3 shares for every seven Visiomed shares. Shoulder the merger go ahead, C3 shareholders would own 47% of the merged entity and Visiomed shareholders would own 53%.

Context

The proposed merger between C3 and Visiomed, if successful, will be the fourth merger to take place between two listed life science firms in Australia, following the merger of **Meditech Research** and **Alchemia** in 2006, **CSL** and **Zenyth Therapeutics** in 2006, **Sigma** and **Arrow Pharmaceuticals** in 2005, and recently **Peptech** and **Evogenix**. There have also been a number of companies acquired by international competitors including **Bresagen**, **Gropep**, **Vision Systems, Mayne** and now **PanBio** looks like it will be sold off to **Inverness Medical**. It's now evident that the biotech sector in Australia is slightly more rational and slightly more realistic when it comes to the difficult task of reorganising capital, assets and management.

Comments

One of the main arguments in support of the merger is that it allows Visiomed to gain access to C3's more substantial cash resources, a European marketing base, marketing and distribution resources and know-how, and financial management resources.

It appears to be a reasonable argument for Visiomed to merge with C3. However, what C3 might obtain from the merger is less clear. The best thing the merger might do is to help C3 slowly (but also much more realistically) build sales of its ReCell product and also progress the US trial of ReCell.

Why it is likely to succeed

The merger is likely to succeed because the boards of both companies have a director in common, Dalton Gooding. Typically, M&A proposals fail because boards are unable to agree on suitable terms.

Summary

One issue with the merger is that the therapeutic areas in which the two companies operate are neither synergistic nor complementary, with respiratory medicine devices standing well apart from wound repair technologies. Such a difference may mean that a more discrete business unit and branding model is adopted by the merged entity, with consequent costs and benefits.

While the merger may succeed, the future success of the merged entity depends on the board being refreshed with members who have international medical product marketing skills and experience and a strong and disciplined focus on developing and implementing realistic sales strategies.

Bioshares

Bioshares Model Portfolio (12 October 2007)

Company	Price (current)	Price added to portfolio
Acrux	$1.45	$0.83
Alchemia	$0.89	$0.67
Biota Holdings	$1.60	$1.55
Circadian Technologies	$1.27	$1.45
Clinuvel Pharmaceuticals	$0.59	$0.66
Cytopia	$0.50	$0.46
Chemgenex Pharma.	$1.04	$0.38
Optiscan Imaging	$0.43	$0.35
Peplin	$0.94	$0.83
Peptech	$1.20	$1.31
Pharmaxis	$3.90	$3.15
Phylogica	$0.25	$0.42
Probiotec	$1.26	$1.12
Progen Pharmaceuticals	$3.37	$3.52
Sirtex Medical	$4.25	$3.90
Starpharma Holdings	$0.36	$0.37
Sunshine Heart	$0.18	$0.19
Tissue Therapies	$0.49	$0.58
Universal Biosensors	$1.34	$1.23

Portfolio Changes – 12 Oct 2007

IN:
No changes

OUT:
No changes

Stock Updates

Living Cell Technologies – Good Early Results Emerge from Clinical Study

The prospects for Living Cell Technologies have improved considerably in recent weeks. The company has been given ethics approval to proceed with New Zealand trials of its porcine islet transplant, for people with type 1 diabetes. Final approval from the NZ Health Minister is now pending, ahead of trials to begin there.

The company announced it had secured a $2.4 million investment in the company from US-based **NaviGroup Management**. The investment group also has an option to invest a further $7.4 million over the next three months.

And the company announced positive results from the first two patients treated in a six person trial in Russia who have received its porcine islet transplant. Results with two patients have exceeded expectations, with insulin dependence being reduced by more than 25% after the first of two implants of the cells. In the planned New Zealand trial, patients will receive 50% more islet cells than that planned in the Russian trial.

The latest developments are very positive for LCT. Reducing insulin dependency, even if not completely removed, can have a profound impact on the way the disease is managed and the level of associated illnesses that eventuate from diabetes.

LCT is capitalised at $37 million.

Bioshares recommendation: **Speculative Buy Class B**

Clinical Trial Failure at Biodiem; Prominent Investors Take Stock in Placement

Biodiem (BDM: 29 cents) delivered results from its 188 patient clinical trial of its BDM-E drug candidate, being tested for the treatment of diabetic macular oedema. The trial failed to achieve positive endpoints on all parameters. However, the company believes the poor result was due to an incorrect dosage of the drug candidate in the trial. Approximately $4.5 million has been expended on BDM-E to date by Biodiem.

Positive preclinical results released earlier this year support further development of the program and there are a number of high profile investors willing to support this decision by way of a private placement. A total of $7 million has been raised by the company, including $5 million from Russian billionaire Oleg Deripaska at a considerable premium to the share price, at 30 cents a share.

Four new preclinical studies have now commenced with the compound and the company anticipates moving into a Phase I study following an IND submission with the FDA towards the end of 2008.

The financial risk for Biodiem has been significantly reduced and the company's other core program, its live attenuated influenza vaccine (LAIV) in development and partnered with **Nobilon** for markets excluding Russia and the USA, remains a potentially valuable asset for the company.

Progress with **AstraZeneca**'s Flumist LAIV over the coming northern hemisphere flu season will be a key item to monitor, with Flumist now approved for use in people from ages two to 49. This will be the first season that a refrigerated version of the vaccine will be sold (previously a frozen and more expensive version was sold) and may see an acceleration in sales. A strong performance from Flumist would be a positive development for Biodiem, which has the only other LAIV in development. Biodiem/Nobilon's LAIV is expected to move into clinical studies at the end of 2008.

Biodiem's share price rise over the last week was due to the interest in the stock from prominent high net worth individuals (the others being Hugh Morgan, chairman of Biodiem and Sir David Li, Chairman of the **Bank of East Asia**). However, with both main programs now at least a year away from the clinic and a lack of internal short term drivers in the stock, we recommend investors take advantage of the recent price surge to reduce their exposure. Note that a Share Purchase Plan will be made available to investors to invest at the same price of the placement.

Biodiem is capitalised at $22 million and holds just under $9 million in cash.

Bioshares recommendation: **Speculative Lighten Class B**

Cytopia Drafts CYT997 Phase II Plans

Cytopia (CYT: 50 cents) has revealed in its latest annual report (2007) some firmer views on the Phase II development program for it anti-cancer compound CYT997, which has completed a Phase I trial with the drug delivered intravenously, and is completing a Phase I trial with the compound dosed orally. The second Phase I trial should be completed before the end of 2007. Cytopia has stated that early data shows CYT997 is absorbed following administration. This is a very significant development for CYT997 because an orally available vascular disruption agent would confer a clear point of difference for the dug candidate against similar medicines such as Taxotere and Taxol, which are delivered by injection.

Cytopia has flagged that it will conduct several Phase II trials of CYT997, starting in 2008. Among the different forms of cancer being considered are glioma, a highly vascular and aggressive brain tumour, and multiple myeloma, a cancer of the white blood cells. Cytopia is preparing a regulatory submission for a Phase II trial of CYT997 (Oral) in multiple myeloma patients, with dosing expected to commence late in 2007.

Cytopia is capitalised at $37 million, with an estimated $12 million in cash. At current prices, Cytopia offers exceptional value.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

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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