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In this edition...
The reporting of cash flow and also earnings figures are behind many of the company analyses in this week's edition. Product sales from global pharmaceutical giant GlaxoSmithKline for the June quarter matter to not one but two local companies, Alchemia and Biota. This week the news is positive for Biota and dampened a little for Alchemia.

We also note Sirtex's healthy growth in receipts with a welcome profit on the cards. And reflecting Sirtex and Optiscan's history, we argue that Clinical Cell Culture may be set to follow a well trod path that sees a rebound in its stock price down the track.

The editors

Companies covered: ACL, AVP, BTA, CCE, GTG, OIL, SRX

	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)	-13.2%
Cumulative Gain	**141%**
Average Annual Gain	**21.7%**

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).

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

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Edition 177

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

Clinical Cell Culture – Now For the Hard Yards

The commercialization path that Sirtex Medical and Optiscan Imaging have undertaken are helpful case studies when looking at another medical device company, Clinical Cell Culture (CCE: 12 cents).

As with most technology developers that are listed on the ASX, an initial public euphoria in an emerging technology sends the share price soaring. This is then generally followed by disappointment as sales take longer (much longer) to materialise than earlier anticipated and the share price plummets. This creates a value proposition as the stock is oversold and the real business is being formed. Sirtex Medical has completed the three phases of this cycle, Optiscan Imaging has now entered the third phase, with sales orders being placed by Pentax, and Clinical Cell Culture (C3) has just entered the third phase with regulatory approvals having been largely received (excluding the US) and the business of building a reliable sales stream is in process.

C3 has developed three products that are termed 'spray-on' skin and are used to treat wounds including burns and in plastic surgery procedures. The company's products are approved for use in 33 countries, with most recently approval being received in Australia and Canada.

The company's lead product, called ReCell, is a device used in the surgery that allows small wounds to be treated almost immediately (30 minutes) after taking a biopsy, giving the surgeon spray-on skin for small wounds. The largest market for this product is in plastic surgery application.

The problems C3 has encountered over the last 12 months have been due largely to attempting an aggressive global rollout of its products. This has resulted in failed approval in Australia (initially) and in the US. Also the use of the ReCell product has been successful in some regions (such as Italy and the UK) and poor in other countries (such as Spain and Japan) because education and supervision of the clinicians has been inadequate.

C3 is waiting to begin trials with ReCell for US regulatory approval. Seven trial sites have been nominated in the US, Germany and the UK which will enroll 71 patients. The trial will not only allow the company to file for regulatory approval in the US but will also generate some helpful, independent data for the ReCell product. The trial will start by October this year and will compare ReCell with meshed skin grafts for second degree burns. If all goes well, approval from US regulators can be expected in late 2007.

To improve sales in existing markets, C3 will need to optimize its distribution arrangements and re-launch products in countries where initial entries have been poor. Problems in using the ReCell device have been due to the use of incorrect bandages, wrong biopsy sites and insufficient dermabrasion of the wound site.

The company's co-founder, Fiona Wood, is actively involved with the company. She has resumed her board position, and is involved in investigator site visits, conference calls with users, and re-launches of the products into poorly performing countries.

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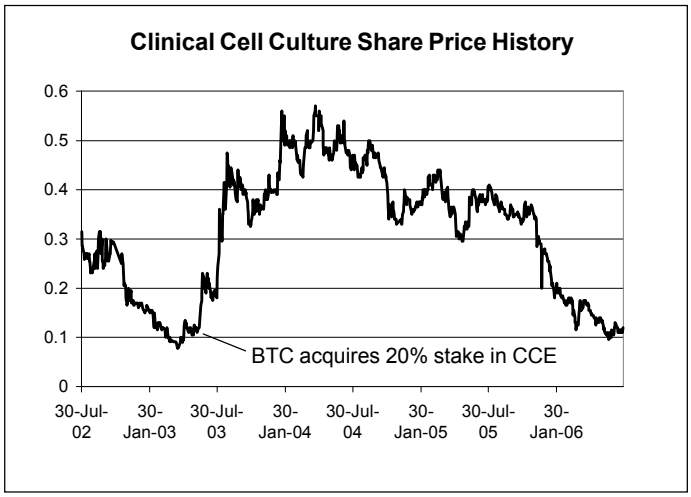


Summary

C3 is capitalised at $25.6 million with $8.6 million in cash at 30 June this year. The company generated $1.3 million in receipts from customers in the last 12 months, a marginal increase over the figure for the previous corresponding period ($1.2 million). C3 has a monthly burn rate of $0.8 million per month and will need to raise funds in the next six months.

The company has installed a new CEO, Bob Atwill, originally from the UK who is now based in Canberra. Atwill has considerable medical device experience. A fresh approach by the company, as represented through the appointment of Atwill, in correctly the company's mistakes may yield significant results.

Bioshares recommendation: **Speculative Buy Class B**

Biota Holdings – Relenza Sales Forge Ahead

The GSK quarterly results are becoming compelling reading for Australian biotech investors. Not only is there important data included in each quarter on Arixtra, which is relevant to Alchemia, but results are included on Relenza sales, which are directly relevant to Biota Holdings (BTA: $1.29).

For the financial year just passed, Biota will receive approximately $5.1 million in royalties. This figure is ramping up quickly, with Relenza sales increasing by more than 100% in the last quarter over the first quarter of this year, from US$13 million to US$30 million. By year's end, GSK is expected to have a manufacturing capacity of 15 million courses a year, which equates to estimated annual sales of US$300 million as a minimum. This capacity may double in 2007.

If this holds true, Biota will stand to receive royalties in CY2007 in the order of $23 million and $46 million in CY2008. Biota's patents run out in 2011, which gives the company an estimated expected royalty stream over this period of at least $200 million. Biota is currently capitalised at $230 million and had $51 million in cash at the end of last year. It appears the market is assigning little value to the potential windfall from its litigation case with GSK and its currentl preclinical and clinical pipeline.

Bioshares recommendation: **Buy**

Sirtex Medical Continues to Grow Sales and Return Profit

Sirtex Medical (SRX: $2.32) released its quarterly cash flow numbers this week. Sirtex is selling a liver cancer treatment throughout the world that uses ceramic spheres coated with short half life radioactive yttrium-90 particles. In the 12 months to 30 June 2006, the company received $21 million from customers for its products and generated a net operating cashflow of $4.2 million.

In the last quarter, receipts from customers increased to $5.7 million, up 14% on the previous quarter and up 83% on the previous corresponding period. Net operating cash flow for the last quarter was down from the third and fourth quarters of last year, at $839,000, although the company did pay income taxes of $366,000 in this last quarter.

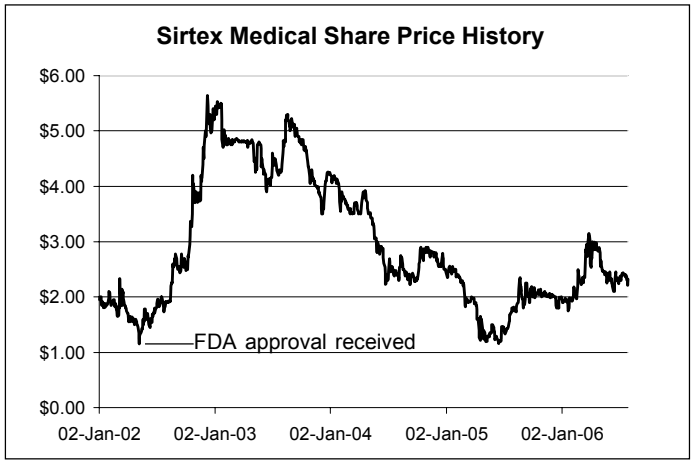
Sirtex Medical Cash flow figures

	Receipts from customers ($M)	Net Op. C/F ($M)
Q2 2005	3.1	-0.62
Q3 2005	4.9	1.1
Q4 2005	5.4	1.7
Q1 2006	5	0.84
Q2 2006	5.7	0.84

Sirtex has increased its staff and advertising costs during the year to build its sales over this period. In the last 12 months it sponsored seminars for its users – interventional radiologists and surgeons – in Spain and the US, and it has recently added a CEO for its US subsidiary.

Over the last 12 months, Sirtex's treatment has become reimbursable by private health funds in Australia (costing the patient $792 with overall product cost of $8,000), and is now covered by public funding in Australia as well (on an interim basis) for patients with secondary liver cancer from colorectal cancer. Sirtex Medical is capitalised at $122 million and had $10.8 million in cash at the end of June this year.

Bioshares recommendation: **Buy**



The Lovenox Market Will Take Time to Crack

GlaxoSmithKline (GSK) released its quarterly sales results this week, which included sales numbers for Arixtra, a synthetic heparin product. This is an important sales figure for Alchemia shareholders to monitor, with Alchemia due to release its generic Arixtra product into the US in 2008.

The result has mixed implications for Alchemia. Overall Arixtra sales in the quarter increased by 26% over the previous quarter to US$24 million, from US$19 million in the March quarter. Over the previous corresponding three month period in 2005, sales increased by 167%. Annualised sales in that June 2005 quarter were running at US$36 million. In the 2006 June quarter, annualized sales were US$96 million.

The disappointing aspect for Alchemia was that US sales fell marginally in the last quarter, to US$11 million from US$12 million in the previous quarter. The US market is the most significant to Alchemia at the moment because that is where its partner, APP, will first launch the Alchemia product in 2008.

Alchemia recently appointed Peter Smith, formerly CEO of **Amrad Corporation** (now **Zenyth Therapeutics**), as Director of Commercialisation. Smith's role first and foremost is to look at commercialising the generic Arixtra product into other world markets, including China, India, Europe, South America and Australia.

Alchemia can launch its drug into Europe in 2012 and in some Eastern European regions in 2009. It's expected its generic Arixtra will be launched in Australia possibly within the two years, and a direct sales force option is being considered. The Lovenox market in Australia is estimated at $50 - $60 million a year.

The difficulty GSK has in building Arixtra sales is due to the stranglehold that **Sanofi Aventis** has with its Lovenox product, that generates annual global sales in excess of US$2 billion. Sanofi Aventis protects this market very closely. It's rumoured that the company gives away more Lovenox at present than the quantity of Arixtra that GSK sells.

Another impediment for GSK is that it only has approval for 70% of heparin indications for Arixtra. The remaining 30% is for Acute Coronary Syndrome. GSK is expected to get FDA approval for ACS for Arixtra in 2008. It's an important drug sector for GSK and Alchemia, as ACS is the indication that Arixtra has shown clear safety advantages over Lovenox in a 20,000 patient study. It appears that hospitals are reluctant in switching over to Arixtra if it is not approved for all heparin indications.

The latest GSK figures also suggest that GSK is focusing on regions outside of the US, where it has longer market exclusivity. Given that a generic competitor will launch in the US in 2008 (APP/Alchemia), it's logical that GSK will concentrate its marketing efforts in markets where it will receive greater protection. Alchemia may experience some short term market weakness based on the recent result although remains a long term **Speculative Buy Class A** stock.

Leading US Teaching Hospital Adopts the Optiscan Technology

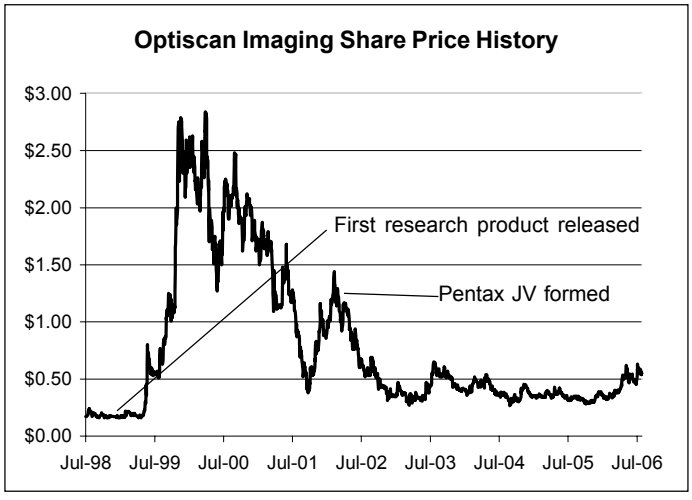
Optiscan Imaging (OIL: 55 cents) had some positive news to announce recently relating to its main product on the market, the ISC1000 endomicroscope. **Mainz Hospital** in Germany and **Johns Hopkins Hospital** in the US have formed a formal collaboration to work on the Optiscan/Pentax endomicroscope.

One of the two main objectives from this collaboration is to improve the detection of early stage cancers using the Optiscan/Pentax product. Johns Hopkins is one of the leading teaching hospitals in the US. It's a signal by one of the leading hospitals in the US that views the Optiscan/Pentax endomicroscope product as a technology that deserves more widespread clinical adoption for cancer diagnosis. Johns Hopkins will become a leading US centre of endomicroscopy. This is an important stepping stone in the Optiscan technology being adopted as a routine technology for use by gastroenterologists worldwide.

Milestones to look out for with Optiscan include:

- Negotiating a second commercial partnership for the Optiscan confocal microscopy technology as a rigid device
- Continued sales numbers to Pentax
- Sales numbers of the FIVE-1 device to drug discovery companies
- A second R&D collaboration with Pentax for the next generation ISC1000

Bioshares recommendation: **Speculative Buy Class A**



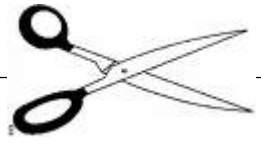
GSK Aristra Sales

	US (US$M)	ROW (US$M)	Total (US$M)
Q2 2005	5	4	9
Q3 2005	7	6	13
Q4 2005	10	4	14
Q1 2006	12	7	19
Q2 2006	11	13	24

Strategies & Issues

Set of Biotech Investment Risks

1 Product Safety
2 Proof-of-concept (Clinical)
3 Path to Approval Design
4 Cost of Goods
5 Obsolesence (Window)
6 Regulatory Process
7 Social and Legal Acceptability
8 **Freedom to operate (IP)**
9 Patent Life
10 Clinical Trial Design
11 Clinical Trial Recruitment
12 Market (Demand)
13 Marketing
14 Partnering & Collaboration (Process)
15 Distribution (& Logistics)
16 Partner
17 Supplier Dependency (Supply Chain)
18 Manufacturing (process and Scale-up)
19 Board
20 Management (Number, Depth)
21 Funding & Cash Resources
22 Developability
23 Enterprise Scale (of the Firm)
24 Opinion Leader
25 Personnel (Availability, Cost)
26 Reimbursement
27 Patient Acceptance/Convenience
28 Practitioner Acceptance
29 Competitor Reach and Dominance
30 Validity of Medical Hypothesis
31 Authenticity of Research
32 Pipeline/portfolio
33 Technology Class
34 Extent of established disease treatment knowledge
35 Competitor paradigm/landscape
36 Receptiveness of Investment Community
37 Knowledge base of co-investors (Investment)
38 Knowledge base of co-investors (Technology)
39 Type of co-investors, co-proprietors
40 Communicability of Investment Concept
41 Project Management
42 Location of Business
43 Location of Markets



Freedom to Operate: A Double-edged Sword

The Bottom Edge

Investors in biotech companies, be they drug developers, medical device firms, specialists in diagnostics, kit and instrument manufacturers or animal health companies, face many if not all of the risks presented in the table on the left. This is neither complete nor exhaustive but the existence of this list of more than forty elements that must be recognised and assessed by biotech investors is a measure of how challenging biotech investing is.

One area of investment risk worth focusing on is in the area of intellectual property, patents and know how. However, it is not enough to possess know-how or granted patents to successfully generate product revenues. What is more important is 'freedom to operate', which is the extent to which a company has accessed all the rights necessary to develop and sell a product without infringing on another company's right of exclusive practise of an invention, otherwise known as a patent.

Clarity regarding freedom to operate, the validity of patents and correct and legal ownership of patents is of great significance to investors because lack of clarity and confusion over ownership is likely to cause potential partners to not commit to collaboration, development or marketing and licensing agreements.

One company that has been beset by these issues has been the wound care company **Acuron** (AVP: 1.5 cents), which yesterday announced that it was decreasing its level of management and operational activity pending the clarification of a patent revocation action (ie challenge) emanating from a company, **Vibriant Technologies**. Although Acuron's directors have stated that they are of the view the company will be successful against Vibriant (it has previously defended itself against this company's claims in several jurisdictions before) the directors are conscious of the need to preserve capital, no doubt because patent litigation is expensive. It also consumes management time. The company also announced plans to raise additional capital so that it can pursue new and relevant opportunities. It is possible that the revocation action will not be resolved in Acuron's favour. Another possibility is that the process will be lengthy and the outcome will remain unclear.

Acuron's freedom to operate issues were recorded in its prospectus in June 2004 (see also Bioshares 82). However, the validity and title of the company's patents have been contested on more than one occasion by Vibriant Technologies. What has complicated matters has been existence of a particular prior art patent, of which the title was acquired by Acuron (according to the prospectus). The contest by Vibriant may very well be an indicator that Acurons's advanced wound care dressing system has solid commercial potential. However, the company has now adopted a more pragmatic view about the prospects of its main asset in the face of limited cash resources. At June 30, 2006 the company had $1.5 million in cash assets.

Cont'd over

The Top Edge

In contrast to Acuron, a defender of a property estate, **Genetic Technologies** (GTG: 35 cents), from Melbourne, has effected an 'offensive' licensing and litigation strategy against parties infringing its intron sequence analysis patents, known alternatively as the 'Junk DNA' patents. It must be clearly stated that this invention owned by Genetic Technologies is not 'Junk DNA'. The invention shows that non-coding DNA is in fact functional and shows how the non-coding region can be interrogated.

Genetic Technologies has perhaps secured as many as 32 licencees for its property, and successfully challenged **Applera Corporation** from which a $15 million settlement was obtained. This was paid in a combination of cash, equipment, reagents and intellectual property in December 2005. However, expectations of a lucrative stream of licensing income has not eventuated, with the revenue prospects dampened by a fact that the key patent, at least in the all important United States jurisdiction, expires in 2010.

The process has been expensive for Genetic Technologies with legal and patent expenses totalling $4.5 million in FY2005, which compares to $5.9 million in license fees received and revenue from its genetic testing business of $2.4 million. The company is likely to have spent a similar sum in FY2006, as well as received similar license income, judging by an inferential assessment of its cash flow statement for that period.

Unsustainable?

Genetic Technologies has posted sizable negative nett operational cash flows in the last two years, of -$5.8 and -$6.0 million respectively. The investment issue with Genetic Technologies is that it is difficult to see how it can sustain its business model that relies on the chasing of potential licensees when the cost is just under the return. At its current rate of spending, assuming revenues do not change, then the company will have zero cash balance in two years time. The company may need to consider a restructuring of its assets and programs.

Conclusion

Acuron and Genetic Technologies are evidence that both the prosecution and defence of intellectual property are activities requiring substantial sums of money for small Australian listed companies. If uncertainty about property entitlement emerges then a general and logical reaction for investors is to exit the stock if significant resources are not at hand to address the challenge. And should an infringement against a company's property be found to have occurred, there is no guarantee that compensation will be substantial or quickly provided.

Genetic Technologies
Cash Flow Summary ($M)

	2002	2003	2004	2005	2006
Receipts	$3.1	$6.5	$3.0	$8.9	$8.9
NOCF	-$3.3	-$1.0	-$5.3	-$5.8	-$6.0
NOCF minus Receipts	-$6.4	-$7.5	-$8.3	-$14.7	-$15.0
NICF	$9.3	$0.3	$0.0	-$1.3	-$0.2
NFCF	$0.5	$0.0	**$10.9**	**$13.2**	-$0.5
Cash End	$7.2	$5.8	$11.4	$18.4	$11.9

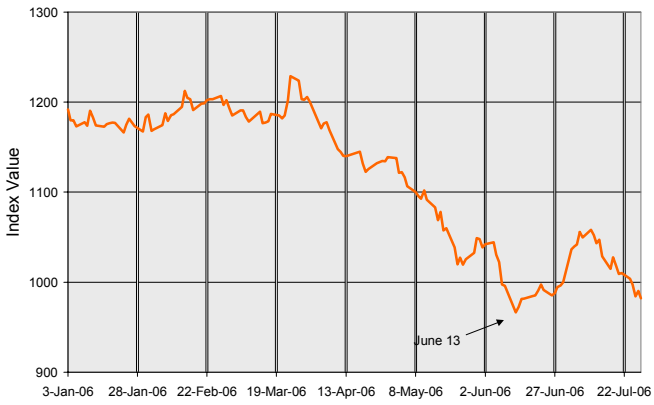
Bioshares Model Portfolio (28 July 2006)

Company	Price (current)	Price added to portfolio
Acrux	$0.78	$0.83
Agenix	$0.17	$0.22
Alchemia	$1.05	$0.67
Avexa	$0.20	$0.15
Biolayer	$0.16	$0.195
Bionomics	$0.16	$0.210
Biosignal	$0.16	$0.22
Cytopia	$0.74	$0.46
Chemgenex Pharma.	$0.44	$0.38
Evogenix	$0.53	$0.47
GroPep	$1.49	$1.43
Optiscan Imaging	$0.55	$0.35
Neuren Pharmaceuticals	$0.38	$0.70
Pharmaxis	$1.75	$1.90
Prima Biomed	$0.067	$0.09
Sirtex Medical	$2.32	$1.95

The Bioshares 20 Index

The Bioshares 20 Index

Change from June 30, 2006	**-1.8%**
Change - week ago	**-2.7%**
Change - 13 June (Low)	**1.6%**



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, Optiscan Imaging, Bionomics

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