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In this edition...
Dependency is a theme for this edition, where our focus turns to companies which supply services or derive research collaboration income from large pharmaceutical companies, or even small R&D oriented biotechs. Big Pharma cut 50,000 jobs in 2010 and 20,000 in 2011 and more have followed in 2012. Some small companies, lead by Cogstate, have weathered the storms in big companies better than others, such as Phylogica, although the difference between the two is that Cogstate sells a test that has become more widely accepted in CNS trials whereas Phylogica is still seeking validation of its peptide platform.
An oversubscribed fundraising has de-risked Avita Medical's funding position. The company is developing a next generation version of its ReCell spray-on-skin kit.
Companies Covered: AVH, ACG, BTA, CGS, IDT, PYC

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - current)	-13.0%
Cumulative Gain	**200%**
Av. annual gain (11 yrs)	**17.8%**

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Bioshares

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Global Pharma Restructure Takes its Toll on Local Service Companies

There are a number of companies in the Australian biotech sector that focus their business on providing services to pharmaceutical and biotech companies. These include **Atcor Medical**, **Cogstate**, **IDT** and **Phylogica**.

One issue with all of these companies is that revenue from biotech and pharmaceutical companies is generally lumpy. Major structural changes occurring within the large pharmaceutical companies over recent years are affecting the time it takes to get pharmaceutical companies across the line.

In 2010, there were around 50,000 jobs cut in the global pharmaceutical industry. Last year that number was reduced to around 20,000 job cuts. However, the restructuring continues.

Driven by patent expiries (generic competition), a failure to replace patent expiring drugs with new blockbuster drugs, government intervention on pricing, and cost cutting from mega mergers are all reasons for the continued job cuts in the global pharmaceutical industry.

In June this year, **Roche** announced it would cut 1,000 jobs, closing the R&D facility where valium was discovered in New Jersey. In July **MedImmune** announced 200 job cuts, cutting its Californian sites to merge its infectious disease and vaccine R&D facilities. In February **AstraZeneca** announced 7,300 job cuts, continuing on from 2011 restructuring. In 2011, **Merck** laid off 13,000 employees after its **Schering-Plough** merger. In the same year **Pfizer** closed its UK Kent R&D facility, axing 2,400 jobs, and **Novartis** cut 2,000 jobs last year.

Sanofi plans to cut 900 jobs in France in a controversial dispute with labour unions. Sanofi's CEO said recently that its French research facilities had not come up with a new medicine in 20 years. The restructuring is a part of a plan to make its R&D more efficient, following its $20 billion merger with **Genzyme** last year.

It is no surprise the local service companies experience inconsistent demand with this restructuring underway, which has also often delayed contract negotiations with global pharmaceutical customers.

Atcor Medical – A Better Year Expected

Atcor Medical (ACG: 7 cents) has had a very good start to the new financial year, signing two large pharmaceutical contracts. The first was for $1.1 million (in August) and the second for $3.2 million (in October), the largest the company has signed to date.

For the first quarter, the company generated a positive operating cash flow of $260,000,

Cont'd over

increasing its cash balance to $1.3 million. This was largely due to increased receipts from customers to $2.56 million for the quarter.

Atcor sells the Sphygmocor test for measuring central blood pressure, which delivers a measure of arterial stiffness; the more flexible the arteries, the healthier the person. Atcor markets its device (which sells for around $13,000) to pharmaceutical companies for use in clinical trials and also for research purposes and to specialists. It also leases the device.

Over the next three years, pharmaceutical sales, which make up around 55%-60% of total sales, are expected to be the driver for the business. After that, sales to medical practitioners should play more of a dominant role to the business. One big driver for that to occur would be if a new drug is approved that requires a central blood pressure test to prescribe the new therapy.

The $3.2 million trial is in an undisclosed disease area, but one where Atcor has been involved in previously. Most of the sales from that contract are expected to be recognised in this financial year, although payment is expected in this and the next financial years. This trial is using the earlier version of the Sphygmocor.

Next Generation Product – Sphygmocor XCEL

The company is now selling a new version of the Sphygmocor test, called the Sphygmocor XCEL, outside of the US (FDA approval is pending). This device uses a cuff, similar to taking standard blood pressure, making it easier to use. The more user friendly version is making the product easier to sell, according to the company.

Last financial year Atcor made a loss of $1.3 million. The company has reduced its cost base recently and the good start to this year may see the company mover closer to a cash flow positive position. That is still a goal for the company. Whether it achieves it or not this year depends on how strong the year is. We do not anticipate a capital raising in the short term.

Atcor is capitalised at $11 million.

Bioshares recommendation: **Speculative Hold Class B**

Phylogica – Deals Delayed by Pharma Restructure

Phylogica (PYC: 2.5 cents) has been the most affected by pharma restructuring, of the Australian biotechs which rely on pharmaceutical companies to generate income. It has missed the milestones it set itself in negotiating new deals because of the major reorganisation that is occurring in the pharmaceutical industry.

Pharmaceutical companies have now more investors on their registers looking for yield not growth, resulting in major changes to the way pharmaceutical companies conduct their R&D.

VP of Corporate Development at Phylogica, Nick Woolf, said the company have two late stage deals it was negotiating that have now been delayed because its potential partners have gone through a restructure.

While it has not ended discussions, one of the potential deals is being completely restructured with revised targets.

Woolf says the company has 25 discussions underway with four at the later stage. One of the next stages is also for one of the company's existing collaborations to move to a full licensing deal, where the partner commits to progressing a drug candidate into clinical evaluation.

Phylogica currently has four major collaborations with **Roche**, **Pfizer**, MedImmune (**AstraZeneca**) and Janssen (**Johnson & Johnson**).

Roche is interested in Phylogica's peptides that can help get drugs across the blood-brain-barrier. The option to progress those peptides expires in December, so a decision from Roche is expected by then to decide whether it wants to license the technology.

Pfizer is evaluating Phylogica's peptides for use in vaccines. The option to look at these compounds is expiring in December. Potential milestones are approaching in this collaboration.

If either program moves to a licensing arrangement, then larger milestone payments can be expected (our estimate is between $2-$3 million). This will be a major validation of the Phylogica technology platform if these deals progress, according to Woolf.

The collaboration with MedImmune is progressing, the objective to develop an antibiotic against *Pseudomonas aureginosa*. Woolf said the relationship with that company is excellent.

Janssen is also looking to use Phylogica's peptides to penetrate cells. That relationship is also progressing well and there is the potential for a second deal.

Funding

At the end of June Phylogica's cash balance was $2.8 million. The company expects to receive an R&D tax credit shortly of $1.9 million. It has also entered into a convertible note financing arrangement to raise up to $1.6 million. The notes can be converted into shares at a large premium to the company's share price, at 5.3 cents. However that conversion price falls by 40% if the company does not complete another Janssen size deal by November 2013, or by 35% if it strikes one Janssen type deal (or cumulative deals in size). The Janssen deal was Phylogica's largest, bringing in $1.2 million in the first two months.

Phylogica is capitalised at $11 million.

Bioshares recommendation: **Speculative Hold Class B**

IDT – Looking for Growth Through M&A

IDT (IDT: 21 cents) conducts contract manufacturing of drugs for pharmaceutical companies. It has struggled to compete against lower cost manufacturing. At its peak in 2008, IDT generated revenue of $31.5 million and a net profit of $7.1 million.

Cont'd over

In 2012, the company generated revenue of only $10 million (down 68% from 2008) and recorded a loss of $1.8 million. The company expects to generate a loss on the first half of this financial year but expects a stronger second half.

IDT invested $1.1 million in R&D in FY2012. It is looking to change its business model to also incorporate its own product development. The company is also actively seeking to merge with or acquire another business

Bioshares recommendation: **Not Formally Covered**

Cogstate Signs Record Contracts for FY2012

The most successful Australian biotech servicing the international pharmaceutical sector is Cogstate (CGS: 40 cents), having largely dodged the impact from global pharma restructuring. The company has steadily built up its sales from nothing in 2004 to $12.1 million in FY2012, up 45% over the previous year, with only one year in the last eight where revenue had fallen.

In terms of contracts signed, in US currency with the US being where most of the company's revenue is generated, sales contracts signed have increased each year and reached a record $14 million in FY2012, a 50% increase over last year.

Cogstate signs between 20-30 contracts a year. Although the increase in the business has helped smooth out the revenue peaks and troughs, there is still some variability in quarterly sales depending on when the larger contracts are signed and when they commence. A large contract for a Phase III trial is worth approximately $4 million in revenue and can be spread over a four year period.

The first half of this financial year is forecast to be lower than expected, at around $5 million said CEO Brad O'Connor at this year's AGM, with the company expecting to record a loss of between $1.0 - $1.2 million. However that same amount equates to what Cogstate is investing in its dementia screening program and in Axon Sports.

In the last two quarters the company has generated a net cash outflow of $1.8 million. However the company is forecasting a stronger second half, with $8.5 million in revenue already secured for this financial year from existing contracts.

O'Connor sees a lot of growth still ahead in the company's clinical trials work. The company has signed $6.5 million in contracts in this financial year. It has also hired some higher level managers from the pharmaceutical industry. Its sales team has increased now from one to four and its overall staff count has increased form around 30 to 73 this year, with another 12 staff additions planned.

This will increase the company's operating cost base with a breakeven point now being between $12-$13 million in sales. Sales will start to build this financial year from the dementia screening product with Merck in Canada, and sales from its Axon Sports subsidiary.

Cogstate's Memory Test Helps Diagnose Alzheimer's Disease

Cogstate's involvement with the AIBL study (Australian Imaging, Biomarker and Lifestyle Flagship Study of Ageing) is starting to pay off. The AIBL study in Melbourne was started in 2006, following more than 1,000 people over the age of 60 who have Alzheimer's disease, cognitive impairment and health volunteers. A paper just published in the journal Neurology showed that Cogstate's test for memory in conjunction with amyloid plaque imaging of the brain allows early detection of Alzheimer's disease.

Most studies to date have looked at people with cognitive decline and then looked at whether those people have an amyloid plaque build up in the brain, which is a hallmark of Alzheimer's disease. In this study, 141 healthy people with no unusual memory or cognitive decline were followed for 18 months. At the start of that study each person was imaged for plaque build up in the brain.

What the study found was as follows: people with amyloid plaque build up in the brain showed a declining memory function over an 18 month period using the Cogstate test. Those with no amyloid deposits in the brain showed no decline in memory using the Cogsate test. All those who declined at 18 months still appeared healthy.

Cogstate's test is being launched in Canada later this year by **Merck** and will be used as a tool to detect early signs of dementia, including Alzheimer's disease. Cogstate's involvement in such a leading, long-term study into Alzheimer's disease will have several flow-on effects. These include increasing the profile of the test for the Canadian market, a likely participation in similar US AIBL-type study in the future, and an increased recognition amongst pharmaceutical companies who are Cogstate's customers in the clinical trial setting.

O'Connor stated that the company is aggressively pursuing the enormous opportunity it sees in the Alzheimer's disease area in screening. A major advance is also possible for the company if its test is used in a Phase III clinical setting in the development of Alzheimer's disease drugs, which could be driven by having a product in the market in Canada that is being used to screen for Alzheimer's disease.

Cogstate is capitalised at $30 million.

Bioshares recommendation: **Speculative Buy Class A**

Biota Shareholders to Vote on Nabi Deal

Biota Holdings (BTA: $0.67) shareholders will meet next week (Tuesday October 23, 2012) to vote on the proposed merger of Biota with US company Nabi Biopharmaceuticals. The merger would create Biota Pharmaceuticals, a US entity listed on the Nasdaq but not on the ASX.

The shareholder meeting was postponed from September 25, 2012, so that shareholders could consider revised terms of the merger between the two companies.

Less Cash

The main term of the merger that was revised was that Nabi would contribute US$27 million into the merged entity instead of US$54 million as originally proposed.

The reduction in contributed cash would then result in Biota shareholders owning a greater proportion of the company, between 81.4% and 85.8%, depending the US dollar volume weighted average of Biota's share price.

The date for determining the VWAP has passed, which means that Biota shareholders will hold approximately 83% of Biota Pharmaceuticals

The merger terms were revised following shareholder pressure of Nabi Pharmaceuticals with one group in particular, Mangrove Partners LLC, opposing the merger. This group has now endorsed the merger now that more cash will be returned to Nabi shareholders.

Shareholder Approval

Biota has stated that more than 90% of proxies lodged to date have been in favour of the proposal. According to CEO Peter Cook the number of shares voted when the company made that statement was similar to the number of shares normally voted at the company's AGM, or 60-70 million shares. Biota has 182.8 million shares outstanding.

As of September 11, 2012, Biota had 11,813 shareholders with 137 shareholders holding parcels of greater than 100,000, representing 108.7 million shares.

Biota does not need to obtain 75% of all shares to gain approval for its merger proposal. The Corporations Act states that Biota needs its merger proposal to be passed by a majority in number of shareholders present and voting (either in person or by proxy) and also obtain 75% of votes *cast*.

The likelihood that the many thousands of Biota's shareholders will participate in the merger vote is low. So far 90% of votes received favour the merger. Assuming a similar voting record is sustained at the formal merger proposal meeting on Tuesday, the chances of the merger proceeding remain high.

In previous editions of *Bioshares* we recommended that shareholders vote against that merger. We continue to hold that view. The merger proposal does not support a dual listing of the stock of Biota Pharmaceuticals, a feature which we would argue disadvantages smaller shareholders by adding increased complexity and cost.

Bioshares disagrees with Biota's argument that it needs to effect a US listing (through a merger) and re-domicilation because its main customer is a US organisation. Other ASX listed life science companies satisfactorily manage commercial activities in the US without recourse to a US listing.

Biota originally announced the merger as a means to 'remove the expectation of future financing'. However, the reduction in funds entering the merged entity via Nabi would place a question mark over that goal. Biota originally hired Piper Jaffray in 2011 to 'raise US$40-$50M of new equity capital to fund the development of certain key assets'.

Biota is capitalised at $122 million and retained cash of $53 million at June 30, 2012

Bioshares recommendation: **Vote Against the Merger;**
In the event of the Merger Proposal being Approved - Sell

Bioshares

Bioshares Model Portfolio (19 October 2012)

Company	Price (current)	Price added to portfolio	Date added
Nanosonics	$0.500	$0.495	June 2012
Osprey Medical	$0.31	$0.40	April 2012
QRxPharma	$0.73	$1.66	October 2011
Somnomed	$0.80	$0.94	January 2011
Phylogica	$0.025	$0.053	September 2010
Biota Holdings	$0.67	$1.09	May 2010
Tissue Therapies	$0.43	$0.21	January 2010
Cogstate	$0.400	$0.13	November 2007
Sirtex Medical	$10.00	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.65	$6.60	September 2007
Pharmaxis	$1.25	$3.15	August 2007
Universal Biosensors	$0.84	$1.23	June 2007
Alchemia	$0.585	$0.67	May 2004

Portfolio Changes – 19 October 2012

IN:
No changes

OUT:
Bionomics anticipated increased expenditure in the expensive area of antibody drug development is some cause for concern for us and the stock has been removed from the portfolio. (See last week's coverage)

Avita Medical Update

Avita Medical (AVH: $0.13) has undergone changes at the board level following a successful and oversubscribed capital raising. The company raised $6.3 million through a placement and $3 million through an oversubscribed SPP. The company also raised an additional $1.2 million through a further placement.

Octa Phillip Securities acted as sole lead manager for both the placement and the SPP. Octa Phillip Bioscience Managers committed $3 million to the fundraising and has now taken two Avita board positions, represented by Jeremy Curnock Cook and Matt McNamara. Dr Paul Watt has stepped down from the board. Further strengthening of the board is expected.

We estimate the company to hold cash resources of $18 million at the conclusion of this capital raising.

Use of Funds

The funds will be used to support sales and marketing, be applied to clinical studies of ReCell used to treat lower limb ulcers and also support the development of the next generation version of Avita's ReCell skin generation product. ReCell is a kit based product that processes skin cells harvested from a patient's healthy skin (an autologous source) into a spray-on solution for application to small wounds, disfigured skin or small burns. Each kit can, using a harvest area of 2 cm^2 supply enough material to cover a 320 cm^2 wound or burn area.

The next generation product will be a fully automated unit which will deliver cells for application 12 minutes after initiation. The system will also be more flexible, delivering different quantities of solution on a dial-up, dial down basis.

Avita expects the next generation product to be approvable by demonstration of cell-suspension equivalence to ReCell's attributes for cell suspension and that all clinical data gathered to date would sit in support of the next generation product.

The next generation product was previously discussed in *Bioshares* 396 (February 2011).

Change in Revenue Model

The next generation product will be designed to generate revenue from the sale of consumables, the use of which will reflect the size of wounds and burns treated.

US Pivotal Trial

ReCell is approved in most jurisdictions with the exception of the US, where a pivotal trial of ReCell is ongoing in burns patients. This trial is supported by funding from the US Army. Avita recently received an additional US$880,000 in funding, following on from US$1.75 million received earlier.

At the end of September, the trial had recruited approximately 75% of the required 106 patients. The study has been very slow in recruiting patients because of tight inclusion and exclusion criteria. Recruitment was originally expected to be completed by December 2011.

Summary

It is very positive to see Avita Medical successfully attend to its funding requirements. The commitment to the next generation ReCell product could be the foundation of a stepwise change in the company's revenue potential, especially if approval is gained on a simple equivalence basis. However, the time to a stepwise change in future revenues will not happen overnight and investors should be considerably patient in this regard.

Avita Medical is capitalised at $39 million.

Bioshares recommendation: **Speculative Hold Class B**

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. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

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: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, Biota Holdings, Impedimed, QRxPharma, LBT Innovations, Mesoblast, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Genetic Technologies, Calzada, Bioniche, Atcor Medical, Invion

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