#### In this edition...

It's been an up and down week for Sirtex Medical this week, with legal action from the University of Western Australia advancing and the company's founder stepping down as chairman. It also posted some impressive financial results for the last year. With the company looking a strong contender to become a Bioshares 500 company in coming years, we thought it was worthwhile to take a close look at the reasons behind this ongoing dispute.

We also look at the transformation set to take place at Avastra, pending share-holder approval, and with Alchemia having entered a trading halt during the week, we look at likely developments that may have triggered the halt.

# The editors Companies covered: AVS, ACL, BTA, CGS, PTD, PXS, 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)	-10.0%	
Cumulative Gain 150%		
Average Annual Gain	22.2%	

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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

25 August 2006 Edition 181

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

# Avastra Transformation in Progress; Consolidation of US Sleep Centres Set To Begin

Avastra (AVX: 28 cents) listed on the ASX in June 2004 to commercialise its Bioweld technology, a novel technology that used lasers and an albumin (protein) construct to join blood vessels. The technology was initially promising but it could not be progressed after some unusual preclinical and clinical results were revealed . The cash box listed entity was left with \$3.7 million at the end of the last financial year and a proposal will be put to shareholders next Tuesday to significantly change the direction of the company. At current prices, Avastra is capitalised at \$8.4 million.

### **New direction**

At an EGM next week, shareholders will vote on transforming the company to a specialist sleep diagnostic service provider, but with the principal place of operations located in the US. This is a continuation of a trend taking place in the listed Australian biotech sector. The ASX is a receptive exchange for microcap biotech/life science stocks. US investment bankers have been evaluating and using listed Australian vehicles to house particular kinds of US business assets in preference to using small US listed entities that experience high costs for complying with the Sarbanes-Oxley legislation in the US.

US-based investment bank, Montgomery Pacific, is behind this strategy, having successfully handled the acquisition of a US blood collection business for LifeTherapeutics last year. This approach gives Australian investors access to US assets that are housed in Australian listed entities.

Montgomery Pacific and **Queensland Investment Corporation** are involved in two such transactions. The second is with the listed life science company **Resonance Health**, which will seek to acquire pathology assets in the US, pending shareholder approval. Australian investors are very familiar with consolidation plays in

the local healthcare centres. Consolidation in the childcare sector has been very successful as has consolidation of the Australian pathology and radiology industries.

# The US sleep centre market

One of the other reasons for creating this investment vehicle through an Australian listed entity is that Australian investors are very familiar with the sleep treatment market through one of the countries largest medical device companies, **Resmed**.

In the US there are about 1900 independently owned sleep centres although there has been relatively little consolidation to date. The largest player owns 90 centres in the US. Of the independent operations, the Avastra consultants have identified 1100 sleep centres, 500 of which are in desirable locations and 100 of those fit the requirements of the type of sleep centre Avastra is considering acquiring, if it receives shareholder approval for its change of direction.

One of the vital aspects to this investment is the company's ability to attract a CEO with extensive experience in consolidation plays in the US healthcare sector and someone who has an intricate knowledge and experience of the complex US healthcare

Cont'd over

reimbursement system. George Suda is the incoming CEO for Avastra. He worked for 12 years for **Apria Healthcare** in the US, a US\$790 million company that is a provider of home healthcare and service products. Suda led the acquisitions of over 200 businesses by Apria.

# Rational for consolidation of US sleep centre market

The rational for any consolidation always includes efficiencies of scale. Avastra plans to acquire only profitable sleep centres in the US and improve their operation through more streamlined interaction with insurance groups, the importance of which can not be downplayed, better links to sleep physicians and improvement of general management of these businesses. The aim to is build a critical mass where value can be added, including the addition of new sleep centres to existing businesses. Existing management will generally be locked in to employment contracts with the company (for five years).

# Initial acquisitions identified

Avastra has identified two sleep centre businesses, the first of which has four sleep centres in California and the second owns six centres in Portland, Salt Lake, Houston and Phoenix. The two businesses being acquired generate revenue of \$6 million and are both profitable. Avastra has signed letters of intent with these companies and the transactions are likely to proceed if the resolutions are passed at the forthcoming EGM.

## Risks

Sell down by existing shareholders

As with any backdoor listing, there is always the strong likelihood that investors in the company who bought stock because of the interest in the previous (failed) technology will sell out as the new business progresses as the share price starts to increase.

Expected price weakness following anticipated rights issue

A rights issue is expected in coming months, which may also see a weakness in the share price in the short term, although if the rights issue proceeds, existing shareholders are expected to receive entitlements to purchase more shares at the rights issue price, which is likely to be a discount to the trading price.

Resolutions need to be passed at EGM

This change of direction for Avastra needs to be passed at an EGM next week. If the resolutions are not passed, there is a possibility cash will be returned to shareholders.

Sufficient capital to conduct acquisition strategy

Following the planned placement, Avastra will have just over \$6 million in cash, which presumably will be sufficient to fund the first two acquisitions, and further funds may be raised in a future rights issue. Although any acquisitions will generally be paid in mostly cash and some scrip three to five years after acquisition, the company will need to have secured its funding of future payments before any acquisitions can be made. The company's consolidation strategy would be weakened and limited by its access to funding and any future expansion will be strongly influenced by the success of these early acquisitions.

Business integration risk

The greatest risk for the company relates to its core proposed business, that of integrating many smaller businesses into the one company. This risk is reduced with the appointment of an experienced CEO who has extensive experience in the health service industry in the US and in leading acquisition teams.

# **Summary**

The change in direction appears to offer a viable business strategy for Avastra. In simple terms, the company will seek to acquire small profitable businesses and improve those businesses through economies of scale and more streamlined operating systems. The main risks are in the core area of business integration and in successfully negotiating the legal requirements in the proposed corporate transition.

Investors interested in this stock should read the Explanatory Memorandum of the company EGM found on the ASX website under company announcements.

Bioshares Recommendation: Withheld, pending EGM results.

**Bioshares** 

# Alchemia Trading Halt

Alchemia went into a trading halt during the week and is expected to resume trading on Monday pending an announcement. It's believed there has been a significant development in the company's R&D program. One of the more likely reasons for the trading halt is a commercial development with the company's programs in later stage development gained from Alchemia's recent acquisition of Meditech Research.

At the top of this list would be an arrangement to commercialise the HyCAMP technology currently in Phase II clinical trials. The first possible partner for this program would be **APP**, with which Alchemia has already formed a commercial relationship to sell generic Arixtra in the US. APP has a specialist oncology business that sells Abraxane, a proprietary version of paclitaxel.

Second in line would be **Pfizer**, which sells irinotecan, branded asCamptosar. HyCAMP, combines hyaluronic acid with irinotecan, and it could offer Pfizer a valuable product extension, with the patent on irinotecan expiring on February 20, 2008.

Pfizer recorded sales of US\$910 million for Camptosar in 2005, an increase of 64% from the 2004.

**Bioshares** 

# Sirtex Medical – Litigation Proceeds as Company Delivers on Stellar Growth

On August 22, **Sirtex Medical** announced to the market that it had issued in the Federal Court a set of cross claims against Sirtex founder and former executive chairman and current director Dr Bruce Gray, and also the **Cancer Research Institute Inc** (CRI). This cross claim relates to a proceedings initiated by the **University of Western Australia** against Dr Bruce Gray, Sirtex Medical and the Cancer Research Institute.

In common parlance, UWA is a suing Dr Bruce Gray, Sirtex Medical and the Cancer Research Institute, and Sirtex is countersuing Dr Bruce Gray and the Cancer Research Institute. Without the benefit of reading Sirtex's cross claim against Dr Gray and the CRI, we assume the claims are contingent on the outcome of the case the UWA has brought against Dr Bruce Gray, Sirtex Medical and the CRI.

In their announcement of the 22nd, Sirtex stated that it and Dr Gray will maintain their denial and defence of the allegations made by UWA, even while the proposed cross claim is submitted to the Federal Court. The essence of the cross claim is that Sirtex was mislead by Dr Gray and the CRI and that they (Dr Gray and the CRI) also breached warranties.

# Why is the UWA suing Dr Bruce Gray, Sirtex Medical and the Cancer Research Institute?

According to "Reasons for judgement on motions to strike out further substituted statement of claim and application" [Federal Court, Justice French, 17 March 2005, Perth] the

"substance of the claims against Dr Gray was that while an employee of the University he had developed technologies for the treatment of cancer, lodged patent applications in respect of them and assigned to Sirtex his rights in relation to them. The assignments were said to have been done without the knowledge or consent of the University and to have taken place during Dr Gray's period of employment with the University and in breach of his Employment Conditions. In August 2000, Sirtex was admitted to the official list of the Australian Stock Exchange and Dr Gray is said to have received in excess of 19 million shares and 114,000 options in the company.

It was alleged in the statement of claim that Dr Gray had failed to comply with the Patents Regulations of the University and their successors, the University's Intellectual Property Regulations."

# What is UWA seeking by suing Dr Bruce Gray, Sirtex Medical and the Cancer Research Institute?

The same Federal Court document of March 17, 2005, also recorded that "the University asserted that it was entitled to the initial shares and options issued to him and to any consideration received by him flowing from the sale of any of them. It claimed to be entitled to have Sirtex rectify its Share Register and the Register of Options. Alternatively, it was said that Sirtex held the patents assigned to it on trust for the University. The University was said to have suffered damage by reason of the conduct of Dr

Gray and Sirtex. Orders were sought for the transfer of shares in Sirtex, rectification of the Sirtex Registers, declarations of trust, an account of profits, the appointment of a receiver to Sirtex, damages pursuant to s 175(2) of the Corporations Act 2001 (Cth), and damages generally, including equitable damages."

The UWA has argued that it is entitled to the initial shares and options at the time of listing of Dr Gray and the CRI, and to patents assigned to Sirtex.

## When was the dispute initiated?

The legal dispute commenced on 21 December 2004, when the UWA filed its first set of claims, which have subsequently been amended (substituted).

# When will the court case actually take place?

The court case has been scheduled to commence on March 12, 2007, and several weeks have been set aside for the hearing.

# What are the implications for Sirtex investors?

A worst case scenario is that the Federal Court finds in favour in the UWA, regarding its major claims, such that it is awarded Dr Gray's shares in Sirtex and the Cancer Research Institute's shareholding. Dr Gray currently holds 17.47 million shares (31.34 % of 55.75 million) and the CRI owns 4.7 million shares (8.55%).

This would certainly make the UWA the major shareholder in Sirtex, with a capacity to control the direction of the company.

If it was found that certain patents, especially those relating to the Sir-Spheres invention - a device used for the treatment of liver cancer - were incorrectly or improperly assigned to Sirtex, the assignment could in all likelihood revert to the UWA. If that were the case, Sirtex would need to seek a license to these patents. Securing such a licence might entail the payment of a fee and royalty consistent with the licensing of a medical technology in its early stages of development. Such a royalty may be in the order of 1% to 3% but that is conjecture on our part. From an investment point of view this would place Sirtex in a position not that different to many other listed biotech company that has inlicensed technology and have milestone and royalty payment obligations.

If the UWA did become the major shareholder in Sirtex, then an obvious question would be whether it would prefer to sell its holding in full, reduce its holding, or maintain its holding and maintain an active interest in the welfare of the company. Its decision on how it might treat a holding could impact on the degree of damages it might wish to seek, if indeed is it entitled to seek damages as part of its claim.

Cont'd over

## Summary

Litigation typically creates investment uncertainty. However the litigation between Sirtex and UWA appears to be an ownership dispute directed at the company's founder, another entity and their respective shares and is less directed at the business being conducted by the company. The dispute, for example, is not directed at the validity of Sirtex's patents, which if it were would be cause for much greater concern.

It is difficult to imagine the UWA jeopardising any property it may be found to have title to, although with such things there is always a slim possibility. Furthermore, there is a sense in which it appears that other shareholders of Sirtex are 'quarantined' from the litigation, in that the litigation is directed at events prior to the company's listing, but not to the company's activities subsequent to listing.

# Sirtex's Full Year Results

Sirtex posted impressive figures for FY2006, recording revenue of \$22.6 mullion, an increase of 91% from the previous year. The company's gross profit from the sales of its Sir-Spheres product increased from \$8.8 million in FY2005 to \$17.9 million in FY 2006. Net profit after tax amounted to \$1.8 million on the back of a previous year loss of \$2 million. Pre-tax profit was impacted by \$1.2 million in timing differences and tax losses to not brought to account as deferred tax assets. The company's gross profit margin for FY2006 was 80%.

Sales in North America increased by 95% from \$9.6 million to \$18.8 million. Sales in Asia Pacific increased 118% to \$1.4 million and sales in Europe grew by 63% to \$2.3 million.

# **Growth prospects**

The company appears to have finally made headway in the US market The prospects for strong growth exist and we expect the commissioning of Sirtex's facility in Wilmington Massachusetts to significantly increase the capacity of the company to provide a greater window for treatment scheduling for the North American market, especially the concentrated market found in the North East of the USA.

Sirtex's SirSpheres are radiated glass beads that have useful radiation half-life of 64 hours, which with the elimination of 20 hours flight time from the ANSTO facility in Sydney increases treatment flexibility significantly. It also reduces the company's reliance on international air cargo services for access to an important overseas market.

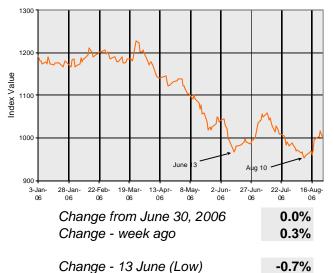
Apart from the distraction and costs associated with the litigation, the fundamentals of Sirtex's business are sound, and the company has also announced plans to scale up its assessment of additional technologies with which to strengthen its product pipeline. Sirtex is capitalised at \$118 million, with \$10.8 million in cash at June 30.

# Bioshares recommendation: Buy

An important disclaimer: The information sources used to date are Justice French's summaries and orders re **WAD292/2004** of 17 March 2005, 11 Nov 2005, 8 May 2006 and 2 June 2006. Bioshares has not been able to access the up-to-date set of claims and cross claims made by the respective parties in this dispute. If we are able to access these claims we will examine them with a view to clarifying our recommendation on this company.

**Bioshares** 





Bioshares Model Portfolio (25 August 2006)

Company	Price (current)	Price added to
		portfolio
Acrux	\$0.81	\$0.83
Agenix	\$0.16	\$0.22
Alchemia	\$0.83	\$0.67
Avexa	\$0.235	\$0.15
Bionomics	\$0.15	\$0.210
Biosignal	\$0.20	\$0.22
Cytopia	\$0.730	\$0.46
Chemgenex Pharma.	\$0.47	\$0.38
Evogenix	\$0.495	\$0.47
Optiscan Imaging	\$0.560	\$0.35
Neuren Pharmaceuticals	\$0.44	\$0.70
Pharmaxis	\$2.20	\$1.90
Prima Biomed	\$0.067	\$0.09
Sirtex Medical	\$2.12	\$1.95

# Cogstate Adds Major CNS Group to Customer List

Cogstate (CGS: 27 cents) has negotiated another clinical trial contract. While specific details of the contract were not released and are not largely material, what is of relevance is the company that Cogstate has added to customer base, **Lundbeck** of Denmark.

Lundbeck is a large European pharmaceutical company that specializes central nervous system disorders. In 2005, that company generated sales in the order of \$2 billion. Sales of Lundbeck's Alzheimer's disease drug, Ebixa, are tracking at \$300 million a year. Lundbeck adds to the major pharmaceutical companies that are using the Costate technology, importantly the top three CNS players in the world, Johnson & Johnson, Pfizer and GlaxoSmithkline.

Cogstate provides a cognitive assessment service for pharmaceutical companies conducting clinical trials, predominantly in the CNS area. In the last financial year, the company provided its service to 18 clinical trials around the world, up from six in financial year 2005 and three in the previous year. One risk with Cogstate remains its reliance on one customer, Pfizer. In the last

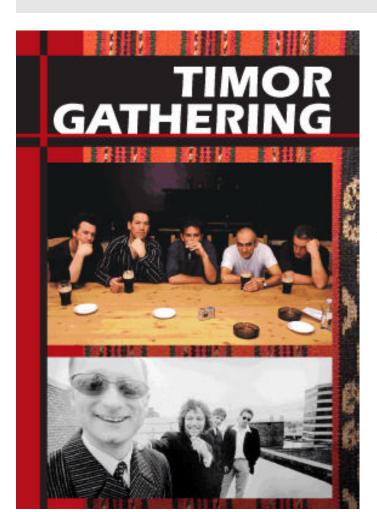
financial year, 14 of the 18 clinical trial contracts Cogstate completed were with Pfizer.

Sales in the last financial year for Cogstate were just under \$2.1 million and total revenue was \$2.4 million. The company currently has contracted revenue in advance of more than \$2.3 million.

Cogstate has also completed the divestment of its R&D portfolio, after having earlier flagged its intention to concentrate on the commercialization of its cognitive testing platform. The AT4 Alzheimer's disease program has been outlicensed to **Pacific Northwest Biotechnology** Inc for no upfront payment and an entitlement to a 1% royalty from any future sales from this program. The NLT Parkinson's disease program has been returned to **Brain Research Ltd** in Israel for no payment.

Bioshares recommendation: Speculative Buy Class B

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# TIMOR GATHERING 2006 Paul Kelly & The Boon Companions and The Hoodoo Gurus

# Sunday 8 October Athenaeum Theatre 188 Collins Street, Melbourne

Paul Kelly & The Boon Companions and The Hoodoo Gurus join forces at Melbourne's Athenaeum Theatre on Sunday 8 October in a charity fundraiser for Timor-Leste.

All proceeds will enable Australian registered charity **Life**, **Love and Health** to continue its vital work promoting health and sustainability in Timor-Leste.

This event is generously supported by the Athenaeum Theatre, EMI, Johnston Audio Services, Millmaine Entertainment, One Louder Entertainment and Ticketmaster.

Tickets on sale 28 August, from Ticketmaster www.ticketmaster.com.au Ph 136 100 and the Athenaeum Theatre Ph 9650 1500.

For more information or to make a donation visit www.lifelovehealth.com

# **Sector Trends – The Bioshares 500**

# Strategies and Issues

Within three years, it is not inconceivable that Australia will be home to at least five biotech companies (excluding the existing billion dollar life science majors of **CSL**, **Resmed** and **Cochlear**) with significant revenue streams and with individual capitalisations in excess of \$500 million. These companies, which as a group we term the Bioshares 500, will underpin the future of the Australian biotech sector and making some reasonable assumptions allows us to suggest which companies this list may include.

# Sirtex Medical

Sirtex Medical (SRX: \$2.12) has a capitalisation of only \$118 million. However it is a very likely candidate for moving into the Bioshares 500 category. The company is now a profitable business having increased revenue in the last financial year by \$11 million to \$22.6 million. It's unlikely there is a shortage of patients with secondary liver cancer and with global sales, marketing and distribution teams in place, the company is in a solid position to continue strong sales growth.

From the \$22.8 million of sales, the company generated an impressive gross profit of \$17.9 million. The largest additional cost for the company was marketing expenses of \$8.9 million for the year. If over three years the company can increase sales to \$80 million a year, and assuming a 25% net profit margin, Sirtex will have a value of \$500 million based on a price-earnings ratio of 25 times.

# **Alchemia**

Alchemia's (ACL: 83 cents) core asset at present is its synthetic heparin product, which is expected to be launched in the US in 2008. Alchemia's partner, APP, will attempt to gain 50% of GlaxoSmithKline's market for its Arixtra product, which at present is tracking sales in the US at US\$44 million (US\$96 million globally). If Arixtra sales in the US can increase to US\$120 million in the next three years (our expectation is that sales will be significantly higher), then Alchemia should stand to receive approximately \$27 million a year in profit share. This revenue stream alone would value Alchemia close to \$500 million. Alchemia is currently capitalised at \$117 million with \$26 million in cash.

# **Biota Holdings**

Biota Holdings (\$1.27) is currently being valued by the market at \$230 million with \$51 million in cash at the end of last year. Strangely, one of Biota's valuable assets is its 25,000 strong shareholder base, which the company can readily access for further funding requirements as needed. However with an estimated royalty stream in 2007 of \$23 million in 2007 and potentially twice as much in 2008 from Relenza sales, the company may not need to approach shareholders for more cash. The company's current share price does not seem to be recognising much value from the its potentially large windfall from its present litigation with GlaxoSmithkKline, nor its development programs. Most recently the company's rhinovirus program has moved to Phase Ib clinical studies. Biota's strong cash position, its strong scrip, and its escalating revenue stream has secured a position for this company as a dominant player in the Australian biotech sector. A market capitalisation in excess of \$500 million within three years is entirely

reasonable, especially in the context of a market recognising the commercial and economic relevance of a local listed biotech sector.

# **Peptech**

Peptech (PTD: \$1.21) is capitalised at \$198 million with \$42 million in cash at the end of March this year and \$40 million in unlisted investments (Domantis). The company is expected to receive royalty income from **Centocor** and **Abbott Laboratories** over its anti-TNF patents of between \$100 – \$130 million over the next four years. The Company has a 34% holding in domain antibody company Domantis. The value of this asset could increase significantly over the next three years. Peptech has an animal health business with two products on the market, and its clinical pipeline should make strong progress between now and 2009. The company has signaled that acquisitions are part of the company's growth strategy. A market capitalisation in excess of \$500 million for the company in 2009 has a high probability.

# **Pharmaxis**

Pharmaxis (PXS: \$2.20) is the closest stock in this group to the \$500 million capitalization with a market value at the moment of \$389 million. The company had \$97 million in cash at the end of June last year. It has started selling its first product, Aridol, for measuring hyper-responsiveness of airways in patients with Asthma. The product has been released in Australia and European approval is expected shortly. Its product Bronchitol is in a 350 Phase III trial in patients with bronchiectasis and a Phase III trial in patients with cystic fibrosis is expected to begin before year's end in 400 patients. That trial will take 18 months to complete. The product could be submitted for regulatory approval at the earliest in late 2008. If the company's clinical programs progress well and sales of Aridol gain good traction, a capitalisation closer to \$1 billion by 2009 is a reasonable target for this company.

## Summary

These five companies look set to form the base of Australia's biotech sector over the next five years. Combined, the companies have a market capitalisation of \$1.05 billion with \$227 million in cash reserves. Their strong cash positions and expected revenue streams over the next three years may also see these companies as leading Australian participants in M&A both locally and internationally. And if value is not recognised locally, it is logical to expect that they would be subject to takeovers by international firms..

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### **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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