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In this edition...
A decision by the EMEA for Pharmaxis' Bronchitol is expected this quarter. This will be a pivotal event for the fully integrated pharma company, and our view is that a thumbs-up is highly likely. pSivida's partner Alimera is set to resubmit its NDA for Iluvien for diabetic macular edema, with an outcome anticipated by years' end. Phosphagenics expects to launch its cellulite cream product this month. The cream incorporates Metabolic Pharmaceutical's AOD9604. Tissue Therapies is raising capital, this time with the purpose of increasing manufacturing capacity and control. To conclude, we profile private company Biogenerics Australia, which is aiming get the first bio-similar to Amgen's Neupogen approved in the US.
The Editors
Companies Covered: PVA, POH, PXS, TIS, Biogenerics Australia

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - May '10)	49.2%
Year 10 (May '10 - Current)	47.6%
Cumulative Gain	**328%**
Av Annual Gain (9 yrs)	**18.5%**

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Bioshares

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Edition 404

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

Pharmaxis European Approval for Bronchitol – Strong Likelihood of Success

Pharmaxis (PXS: $3.05) will hear back from European regulators this quarter regarding the approval of its cystic fibrosis drug candidate, Bronchitol. Europe is a major market for Pharmaxis, worth up to $500 million a year, hence the interest in the company and the interest in the decision from regulators. CEO Alan Robertson is very confident the drug will gain approval. *Bioshares* would be very surprised if it didn't gain approval.

The drug, which was launched recently in Australia, has now been tested in 600 patients in two global Phase III trials at 93 hospitals. It has been shown to be very safe and improves lung function in patients by 8% in the first year of treatment, when lung function would normally be expected to decrease by 2%.

Robertson believes that all patients with CF will at least try this drug. Up to 60% of patients may stay on treatment, which if the price is matched with that of Pulmozyme in Europe of $13,000, represents a realistic sales figure of around $300 million a year. It's a reasonable assumption given the 65% Pulmozyme usage in the Pharmaxis Phase III trials.

Pharmaxis expects to be selling the drug in the second half of this year, at least into the UK and Germany (in Q3), where reimbursement does not need to be negotiated as there is free pricing in those countries. However in the UK it is still waiting to hear back from NICE which will make a recommendation about the cost effectiveness of the Bronchitol. There are around 16,000 people in those two countries living with CF, which represents an addressable market there of $208 million a year.

The UK team is operational with 11 staff and one product manager has been installed in Germany. The German team will be ramped up as required. In the UK people with CF are treated at only 55 clinics. In Germany the number is 131 clinics, but nine hospitals treat 36% of the 8,000 Germans with CF. In the US, 30,000 people with CF are managed through only 150 CF centres. It is this narrow distribution channels that has allowed Pharmaxis to build what's called a fully integrated pharmaceutical company, where it designs, develops, manufactures (in Sydney) and sells the drugs. The company has 18 staff in the US, which is also selling the Aridol product.

– Cont'd over

– Pharmaxis continued

In the rest of Europe, Pharmaxis expects to be selling its drug from the fourth quarter of this year if all goes well, through its contract sales force from **Quintiles**. Robertson says the awareness of the drug amongst the CF community is currently around 80%.

Bronchitol was launched in Australia recently. The company is in discussions with the government's Australian Pharmaceutical Advisory Committee to get the drug put onto the PBS for reimbursement. It is available to patients through some hospitals and through patient familiarization programs.

In the US, the company is looking to file its drug for approval by the end of the year, and if all goes well, to get that drug approved by mid 2012. The competing drug Pulmozyme sells for $22,000 per year's treatment, equating to an addressable market of $660 million a year in the US.

Bronchiectasis – An Even Bigger Market

Bronchitol is also in Phase III trials for the treatment of bronchiectasis, which is a broad ranging condition that describes a deterioration of the lungs. There are around 600,000 people with bronchiectasis, which represents a market size eight times greater than for CF.

For Pharmaxis the dilemma has been how to maintain the price for Bronchitol for CF when it may be difficult to justify for a less serious condition like bronchietasis. Pharmaxis has decided it will seek to maintain the price, but focus on the moderate-severe patient sub-category in broncieactasis, which makes up around 45% of 600,000 patient pool.

There are no drugs approved for the treatment of bronchiectasis, with Pulmozyme having failed to show efficacy. Pharmaxis has completed one Phase III study with positive outcomes. In a conference call this week, Robertson referred to an email from one patient with bronchiectasis who had been advised to hang upside down to remove the excess mucous from her poorly functioning because there are no treatment options.

Aridol

The lung function test, Aridol, is now selling into major markets, including the US where it was launched in February this year. The company is starting to get some traction with this product, although remembering it is a niche market opportunity that does not have the large potential of Bronchitol. Sales for the quarter were $318,000, which was a significant increase over the previous quarter ($157,000) but a minor increase over the previous corresponding period ($282,000). There is a very good opportunity in the US, where allergists are showing a strong interest because they can make a good business from the product. In South Korea, 14 major hospitals are using the test and there is good reimbursement in that country.

The market for Aridol is small at the moment, maybe only around $10 million, but there is the potential to expand the market to around $50 million a year. Two studies recently showed that the level of asthma drugs given can be accurately reduced without detrimental affect to patients (adults and children) by calibrating disease symptoms response using Aridol.

ASM8

The company's asthma drug candidate, ASM8, which it gained from its Topigen acquisition, is in Phase II studies in patients with asthma who do not respond well to existing therapies. That trial will report in the second half of this year.

Financials - Capital Raising Antipated

The company ended the March quarter with $56 million in cash. In our view, it's likely the company will look to raise cash following approval in Europe of Bronchitol. Given the company's market capitalisation, a $50 million raising would not cause any significant dilution.

Summary

Pharmaxis remains one of the top tier biotechs in the sector. Its drug is the first to have been approved for the treatment of CF in 18 years, and we are confident European and US approval will be achieved. People with CF have a much shorter life expectancy because of loss of lung function, something that Bronchitol has shown to improve substantially.

In Australia the drug has been approved either to use alone, as an add-on therapy to Pulmozyme, or for people who are intolerant to Pulmozyme or have an inadequate response to Pulmozyme. In likelihood, due to its ease of use, Bronchitol should also take market share away from Pulmozyme.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Bioshares will take a short break over the Easter/ Anzac Day long weekend.

The next issue of ***Bioshares*** (405) will be emailed to subscribers on Monday May 2, 2011

Bioshares is published 48 times a year.

pSivida Edges Closer to Iluvien Approval

pSivida (PVA: $4.20) is another company nearing the end of its lead product development program. Its drug, called Iluvien, is a depot injection of a corticosteroid (fluocinolone acetonide) for the treatment of diabetic macular edema. The program has been licensed to listed US biotech, **Alimera Sciences**.

Alimera filed the drug for approval last year, and was awarded an accelerated review because of the unmet clinical need in this area. If December last year the company was issued with a Complete Response Letter (CRL) from the FDA, which meant that the company's New Drug Application could not be approved in its current form.

Reasons for FDA's CRL response

There were a number of reasons why the FDA did not approve Iluvien at first pass. Firstly, there were some deficiencies at the company's third party manufacturing facilities which did not comply with cGMP. These should be resolved reasonably quickly and should not be major issues.

The FDA also wanted additional information on the control groups and some specifications regarding packaging, manufacturing and sterilization. These also should not be major obstacles.

The FDA did not request additional studies to be conducted. The submission was based on data on patients who had the Iluvien implant for 24 months, which was the agreed timeline. However, the company was very close to having 36 month data available which the FDA has now requested to see, to assess both the safety and efficacy after three years.

Phase III Study Results

pSivida's partner Alimera conducted two Phase III trials which involved 561 patients in the low dose arm that comprised the full evaluation set. Both trials showed statistical significance at 24 months (p=0.029 and p=0.03), at 30 months (p=0.011, p=0.002), and at 33 months (p=0.042, p=0.046) but not at 36 months (p=0.106, p=0.086). A p-value of less than 0.05 is the target, which represents a 95% probability that the result was not merely achieved by chance.

That the results were not statistically significant at 36 months should not be an issue given the primary endpoint was the percentage of patients, who achieved a 15 letter improvement on the eye chart (equivalent to three lines) at 24 months. At 24 months, Iluvien delivered the required result in 26.8% and 30.6% of patients in the two trials, compared to a 14.7% and 17.8% improvement in the control groups.

According to CEO Paul Ashton, the result was better in the more severe patients, with a 45% improvement in patients with 20/100 vision (which means those patients who can see the same at 20 feet as people with normal vision can see at 100 feet).

The efficacy result looks unambiguously positive. With respect to safety, which will be an important aspect to clear with the FDA, 35% of patients developed intra-ocular pressure as a result of the treatment. In most of those cases the issue was resolved with the application of eye drops. However, 3.7% of patients had to undergo an 'incisional surgical procedure' at two years and 4.8% at three years. The efficacy over the safety with be the key risk/benefit that the FDA will need to assess, with an advisory panel meeting likely prior to approval.

Alimera to Resubmit NDA

It is expected that Alimera will very shortly resubmit the New Drug Application with the FDA. The review should occur within six months of refilling, with a result expected by year's end.

Upon approval, pSivida will receive a US$25 million milestone payment and is eligible to receive a 20% profit share from product sales. Alimera and pSivida jointly own the trial data and the FDA submission. If Alimera were to be acquired, which is likely given the high level of venture capital ownership of that company, it's likely that pSivida's interest would also be acquired.

Alimera is capitalised at US$246 million and pSivida has a market capitalisation of $91 million.

Market Size and Competition

The target market size in the US for Iluvien is around one million people a year, and more specifically 1.3 million eyes. US analysts estimate sales of Iluvien to reach anywhere between $250 million to $800 million a year.

The main competition to Iluvien is **Genentech**'s Avastin, which has been reformulated as a smaller dose and is called Lucentis. Two Phase III trials have been completed with Lucentis, where 45.7% of patients received an improvement of 15 letters at three months compared to 12.3% in the control group. While it's a better result than for Iluvien, Lucentis needs to be injected monthly into the eye. The data will similarly be considered at 36 months.

Although Lucentis is expected to gain a leading market share, there should still be a significant market opportunity for Iluvien, particularly for those people who are not comfortably with receiving a monthly injection into the eye.

pSivida is also working on a sustained release version of the active Lucentis drug for when it comes off patent, although that program is in the early stages of development.

Summary

pSivida had just under US$15 million in funds at the end of last year and has since raised a further US$10 million. We rate the chance of Iluvien being granted approval by the FDA by year's end as strong, which will trigger a $25 million milestone payment. The company is now in a more comfortable position and if all goes well, should see strong share price performance this year. Substantial shareholders include the **Orbis** funds management group, which owns approximately 15% of the company.

Bioshares recommendation: **Speculative Buy Class B**

Phosphagenics Ready to Launch Cellulite Treatment in Australia

Phosphagenics (POH:14.5 cents) announced that it will launch its cellulite treatment cream this month in Australia. The product contains the compound from Metabolic Pharmaceuticals, AOD9604, that failed as a treatment for weight loss.

AOD9604 is a fragment of the human growth hormone. The logic as to why this drug candidate should have worked was always clear, however, trying to deliver the peptide drug as a tablet didn't work, with the peptide consumed by digestive enzymes.

Phosphagenics CEO, Esra Ogru, and its chief scientist both used to work for Metabolic, so know the compound well. Last year Phosphagenics licensed the compound from Calzada (formerly Metabolic Pharmaceuticals) to use the compound as a topic agent in cosmetic applications. Phosphagenics will pay Calzada a 3.5% royalty in return from any product sales. It has cost Phosphagenics less than $300,000 to formulate this new product.

The compound has been shown in laboratory testing to promote the breakdown and release of stored fat cells. That the compound could not be developed as an oral tablet does not mean it doesn't have an effect on fat cells in the body. Earlier clinical trials when the compound was injected showed it did have positive weight loss effect and there have been accounts of body builders importing the peptide from China and injecting themselves to reduce body fat to very low levels.

The product, called BodyShaper Cellulite Contour Crème, includes AOD9604, other standard additives for a cellulite crème, including caffeine, and the company's trandermal delivery system called TPM, which includes a phosphate derivative of Vitamin E that enhances absorption of compounds through the skin. The delivery system will help get the peptide into the skin to disrupt the fat cells.

That the compound was never approved for use as a pharmaceutical, was never measured in the blood stream and had a clean safety record in over 1000 people, allows small amounts of the compound to be added for a cosmeceutical application.

Up to 40% Improvement in Appearance

In a trial involving 30 women, which is ongoing, application of the cream twice daily, to only one leg, was shown to improve the appearance of cellulite by up to 40%, with 86% of the women noting a visible improvement in appearance of the cellulite. Whilst the studies are not anywhere near as robust as those for pharmaceutical drugs, it may be enough to generate sufficient interest in the product from consumers. Cellulite in the body is related to an excess of estrogen in the body.

Phosphagenics is planning to get the product into 2,000 outlets in Australia by year's end. It will sell for $99 for one month's treat-

Cont'd over

Tissue Therapies – Beefs Up Bank Balance Pre-Licensing

Tissue Therapies (TIS: 58 cents) has announced a capital raising. The company expects to raise a minimum of $12 million and possibly as much as $15.1 million. The company had $3.1 million in cash at the end of last year. The capital raising will be conducted at a significant discount – 50 cents a share – to its share price which has been trading close to 70 cents in recent weeks.

The funds will place the company in a stronger position to complete licensing negotiations, with the company only having an estimated six months cash remaining prior to the raising. The company has also taken the opportunity to maintain control of clinical trials, registration and reimbursement for all regions, with some of the funds going towards those added costs.

To Increase Manufacturing Capacity

Around $4 million will go towards increasing manufacturing capacity by around five-fold. The company has conducted a thorough market review to better gauge the potential of its wound healing products. That addressable market size is now estimated at $14 billion and is growing at 25% year. It is expected to reach $30 billion by 2014. The main reason for the escalating growth is the diabetes epidemic and the associated, difficult to heal diabetic ulcers.

The expected sale price of the Vitrogro wound healing product will be around $100 per patient per week. Health economics studies suggest a saving of $260 per wound which should easily justify a product price of around $100.

Of benefit also is that it will not be a big ticket expenditure to hospitals, which will allow more take-up by hospitals, particularly if the length of hospital stay is shortened, which should make the product particularly appealing.

Tissue Therapies is seeking to negotiate a licensing deal for double digit royalties and to maintain manufacturing and charge a manufacturing cost. If this product does well, there is the potential for it to become a billion dollar product, from which Tissue Therapies should receive in excess of $100 million a year. But there still remains a lot of work to be done before that occurs.

Licensing Discussions Continue

Tissue Therapies is continuing with licensing discussions. There are four major groups with which it is negotiating marketing rights to the technology. There is now less urgency to have a deal completed in coming months following the capital raising. The company will likely wait until the results from the European trials come in, by June. With more data available, the value of the product should increase. Our expectation is that a licensing deal will be transacted in the second half of 2011.

Investors should not expect a large deal, given the low unit sale price and the level of sales infrastructure that will be required to sell the product.

Tissue Therapies is aiming to gain approval for Vitrogro in Europe

Cont'd over

Bioshares Model Portfolio (15 April 2011)

Company	Price (current)	Price added to portfolio	Date added
Bioniche	$1.28	$1.35	March 2011
Somnomed	$1.28	$0.94	January 2011
Phylogica	$0.066	$0.053	September 2010
Sunshine Heart	$0.050	$0.036	June 2010
Biota Holdings	$1.36	$1.09	May 2010
Tissue Therapies	$0.58	$0.21	January 2010
QRxPharma	$1.81	$0.25	December 2008
Hexima	$0.45	$0.60	October 2008
Atcor Medical	$0.12	$0.10	October 2008
Impedimed	$0.67	$0.70	August 2008
Patrys	$0.13	$0.50	December 2007
Bionomics	$0.67	$0.42	December 2007
Cogstate	$0.19	$0.13	November 2007
Sirtex Medical	$5.32	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.96	$6.60	September 2007
Starpharma Holdings	$1.30	$0.37	August 2007
Pharmaxis	$3.05	$3.15	August 2007
Universal Biosensors	$1.35	$1.23	June 2007
Acrux	$3.30	$0.83	November 2004
Alchemia	$0.72	$0.67	May 2004

Portfolio Changes – 15 April 2011

IN:
No changes

OUT:
No changes

– *Tissue Therapies cont'd*

around November this year, after the results are in from the current UK trial (around mid year) and after stability data has been received.

The company expects to file an IND by year's end and start a trial in the US in patients with venous leg ulcers in around 200 patients. This trial is expected to take around one year to complete.

Summary

Tissue Therapies' decision to retain more of the upside with the product is positive. However that decision needs to be matched with a serious strengthening of its management team, which has been very thin to date and likely a key factor in the company missing its target dates. The company has indicated it will add two more staff by year's end to support its clinical and regulatory development.

The company has developed an attractive and unique wound healing product. We believe the product has the potential to become a billion dollar product, from which Tissue Therapies could enjoy revenues in excess of $100 million a year. However key to that outcome is the successful commercialisation of the product, with the largest forthcoming decision being the selection of the marketing partner and the terms of licensing arrangement.

Assuming the full $15.1 million is raised, the company is capitalized at $98 million.

Bioshares recommendation: **Speculative Hold Class B**

Bioshares

– *Phospagenics cont'd*

ment, which looks well priced. The product will be added to the company's Elixia range of cosmeceuticals, which also includes an anti-aging range. It currently has a team of four to sell the product in Australia and that will likely double by the end of the year. Ogru said that cosmetics are all about differentiation.

The product will also be sold in the US through **Metier Tribeca** through under that company's branding, and also direct through TV infomercials. Metier will sell 10 products for Phosphagenics. The company is also looking to appoint a European distributor in coming weeks.

Ogru believes sales of Elixia products will eventually get to a size where those assets could be to be spun out of the company. The funds from these products will all go towards supporting the company's core programs in pharmaceuticals, with the lead program being an oxycodone transdermal matrix patch, which will be moving into a Phase II trial in the second half of this year.

Phosphagenics is capitalised at $119 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Private Company Profile – Biogenerics Australia

With interest in the IPO pipeline heating up, we provide a profile on one company, Biogenerics Australia, that has indicated an intention to IPO in the not too distant future.

Biogenerics Australia is developing a generic version of **Amgen**'s Neupogen, a biologic drug better known as recombinant G-CSF (granulyte colony stimulating factor). The drug is also known as filgrastim.

Amgen's filgrastim patent in the US expires in December 2013. Sales of Neupogen totalled US$1.3 billion in 2010, in line with the previous year's figure. [In contrast, Amgen posted a 6% increase in sales of the pegylated (extended-life) form of G-CSF, Neulasta, which totalled US $3.6 billion.]

Filgrastim Used to Treat Neutropenia

Filgrastim is approved to treat neutropenia, a condition in which the white blood cell count is too low. Neutropenia can occur when certain chemotherapy drugs are administered, representing a major driver for sales.

A number of generic, or bio-similar, versions of filgrastim have already been approved in Europe, sponsored by **CT Arzneimittel**, **Hexal Biotech** (now Novartis), **Hospira**, **Teva Pharmaceuticals** and **Sandoz**. It would appear that sales have been minimal to date.

Biogenerics is aiming to register generic filgrastim in Australia and nearby territories. It has contracted Indian manufacturer **Intas Biopharmaceuticals** to manufacture the product, adopting (it would appear) Intas Biopharm's name for the drug, Neukine (recombinant Human G-CSF). Intas manages a EU-GMP approved manufacturing plant based in Ahmedebad. In addition toNeukine, Intas also manufactures Erykine (recombinant Human Erythropoietin), Intalfa (recombinant Human Interferon alpha-2b) and Neupeg (pegylated recombinant Human G-CSF). These products are not supplied to EU or US markets.

Intas had previously work with **Kwizda** to effect a launch in Europe but has since then transferred those rights to **Apotex**. In 2008, Apotex and Intas announced plans to jointly take Neukine into the US market. However, this plan has not been fulfilled due to a policy vacuum covering follow-on biologics which existed until last year.

The development of a follow-on biologics industry has been slow with quite different approaches adopted in Europe and the US. The US approach still in a state of some flux despite the passing of key legislation in 2010.

Interchangebility Pathway

What sets Biogenerics Australia's apart from many of its competitors in the bio-generics space is that prior to the introduction of the new rules set down in the US Biologics Price Competition and Innovation Act of 2009(BPCIA) (passed in March 2010), in which the new Interchangebility Standard (IS) was set down, is that it had already indentified interchangebility as a necessary pathway for developing a follow-on biologic.

Interchangebility in essence requires a 'generic' biologic to achieve the same clinical result as a reference product, showing that it is not inferior to the reference product. The implication of the IS is that clinical trials of a more advanced nature must be conducted, in contrast to simple bio-equivalence pharmacokinetic studies conducted for small molecule generic drugs.

In the lead up to the development of Neukine, Biogenerics Australia consulted with clinicians about what they would like to see that would affect their decision to use a generic version of Amgen's Neupogen. The feedback was that Biogenerics Australia should conduct a double-blind, cross-over, non-inferiority trial of Neukine, to satisfy the clinicians' fundamental concern that they were not putting patients at risk.

Biogenerics Australia was also guided by Amgen's clinical program for Neulasta (pegylated G-CSF) which demonstrated non-inferiority to Neupogen in two studies (Study 1 n=157; Study 2 n=310).

Biogenerics Australia is conducting a non-inferiority trial of Neukine in Brisbane, enrolling 115 patients, which it expects to complete at the end of this year. The company expects to gain regulatory approval to market Neukine in Australia also by the end of 2011.

Business Methods Patent

Biogenerics Australia has filed a business methods patent covering clinical trial designs for bio-generics. While patents can never provide complete protection from well-resourced opponents, the patent may afford Biogenerics Australia a degree of economic leverage for a time, if the patent is granted.

History

Biogenerics Australia was founded in 2005 by Peter Simpson, who was a one-time CEO of Biota, appointed in 1987. Prior to his role at Biota he was General Manager of David Bull Laboratories, which was acquired by FH Faulding in 1984. He was later involved with AVAX Australia, Norwood Abbey and also sat on the board of Novogen, departing that board in 2009.

Simpson holds a 50% stake in Biogenerics Australia. The company currently has 40 shareholders.

Rights Issue

The company has raised approximately $6 million in funding to date. Biogenerics Australia is seeking to raise $2.5-$3 million through a rights issue to complete its complete its registration package. It expects to conduct an IPO after the completion of the current rights issue, the conclusion of its registration trial and lodgment of a product data package with the FDA, but before any approval is given by that regulatory authority.

The company anticipates that it will enlist a marketing partner to sell Neukine in the US.

– Cont'd over

– Biogenerics Australia cont'd

Teva Pharmaceuticals' Neutroval

Teva Pharmaceuticals filed a Biologics License Application with the FDA for its bio-similar filgrastim, Neutroval, (named TevaGrastim in Europe), based on five studies in more than 680 patients, comparing Teva's product to Neupogen and placebo. The FDA sent a Complete Response letter to Teva in September 2010, seeking additional non-clinical information. Teva has also challenged Amgen's key patent covering Neupogen. An issue for Teva is that it has not chosen the Interchangebility pathway, which means that clinicians cannot substitute Teva's filgrastim for Neupogen.

According to Brian Malkin "Unlike generic drugs, there is no automatic substitution for a separate BLA. Based on the labeling for TevaGrastim, it does not appear that Teva would market Neutroval as a biobetter, i.e. an improved version of Neupogen with a better safety or efficacy profile, so Teva would likely rely on a lower cost to attract new prescriptions." http://www.fdalawyersblog.com/biologics/biosimilars-1/ Oct 8, 2010 Post.

An Observation

One observation to make regarding Biogenerics Australia is that while it may be able to import Neukine into Australia, given that the Intas facility has a TGA approval (which we assume be to the biologics manufacturing part of the Intas business, not merely the fill and finish oncology products division), it would appear that the Indian facilities have yet to approved by the FDA.

Summary

Biogenerics Australia is relying on the need of clinicians to be certain that a bio-similar drug will not be inferior to a reference product, especially in terms of safety. Hence, the development costs of bio-similars will be high relative to standard small molecule generics, which will place a brake on competition the field.

The company is a pioneer in the emerging field of follow-on biologics and we will follow its progress with great interest.

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

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