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In this edition...
Another company has moved a drug into the last phase of clinical development. Starpharma has started Phase III trials with VivaGel for the treatment of bacterial vaginosis. It joins an expanding list of drug developers in Australia that have either brought novel drugs onto global markets or entered the final, higher value-adding stage of drug development. This group of companies is one of the reasons Australian biotech is increasingly perceived as an attractive investment proposition. Pharmaxis is set to receive PBS listing in Australia for Bronchitol, with European approval just around the corner. And Atcor Medical is a stock being ignored by investors but deserves to be monitored closely.

The Editors
Companies Covered: ACG, PXS, SPL. PVA

	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 - May'11)	45.4%
Year 11 now commenced	-22.3%
Cumulative Gain	**227%**
Av. annual gain (10 yrs)	**21.2%**

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Bioshares

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

Australian Biotechs Continue Charge To Market With Late Stage Clinical Assets

One of the reasons Australian biotech sector is currently being well received is that it is aiming to create more value from drug development. **Starpharma** joins a list of mid-tier biotechs that have developed the ability to bring their drug candidates all the way to end of clinical development, with a Phase III trial started this week for Vivagel.

Biota Holdings was one of the first Australian biotechs to bring a drug, Relenza, to market for the treatment of influenza, although it was partnered very early on with **GlaxoSmithKline**. However, in marked contrast, Biota is now also in the position to bring its next generation drug, laninamivir, all the way to market in around 2016 following a contract with BARDA in the US which will fund US$231 million of the costs.

Acrux successfully brought its testosterone transdermal lotion to the market in the US last year, through its partner **Eli Lilly**, with that product having achieved over 11% total market share and may be on its way to at least a 30% market share. **Pharmaxis** is only weeks away from launching its product, Bronchitol for the treatment of cystic fibrosis in Europe. It now has approval in Australia and recently received PBS coverage locally which will give it Australian Government reimbursement.

Cont'd over

Australia's Drug Development Progress

	Company	Drug Candidate	Stage of Development
1	Starpharma	Vivagel for treatment of bacterial vaginosis	Phase III started
2	Mesoblast	Heart failure stem cell therapy	Phase III trial due to commence
3	Phosphagenics	Oxycodone patch	Phase III trial due to begin 2012
4	Prima Biomed	Ovarian cancer vaccine	Phase III trial underway
5	QRxPharma	MoxDuoIR pain therapy	NDA submitted in US
6	Pharmaxis	Bronchitol for treatment of cystic fibrosis	Approved in Aust. & recommended for approval in Eu.
7	Clinuvel Pharmaceuticals	Scenesse for treatment of EPP severe sun intolerance	On market in Italy, filed for approval in Europe
8	Psivida	Iluvien for diabetic macular edema	Approval declined in USA, recommended for approval in Europe for chronic DME
9	Acrux	Axiron testosterone lotion	On market in USA
10	Biota Holdings	Relenza flu drug	On market globally
11	Biota Holdings	Laninamivir 2nd gen. flu drug	Fully funded end Phase III for US
12	Peplin	Acquired by Leo Pharmaceuticals	Picato (PEP005) approved by FDA 2012
13	Chemgenex Pharmaceuticals	Acquired by Cephalon	Completed clinical development

– *Cont'd from page 1*

Clinuvel Pharmaceuticals has already gained approval to sell its drug Scenesse in Italy and has recently filed the drug for broader approval in Europe. **pSivida's** partner **Alimera Sciences** was knocked back by the FDA last year for its new drug application for Iluvien for the treatment of diabetic macular edema (DME), but it looks like it will receive approval in Europe for the treatment of chronic DME.

The drug **Peplin** took into Phase III development for the treatment for actinic keratoses (PEP005, now called Picato) was finally approved in January by the FDA. Peplin was acquired by Danish group **Leo Pharmaceuticals** in 2009 for US$287 million. **Chemgenex Pharmaceuticals** was acquired last year for $225 million by Cephalon after taking its cancer drug, Omapro, through to the end of the drug approval stage.

Prima Biomed has launched an 800 patient trial for its ovarian cancer vaccine. **Mesoblast** is due to start its Phase III trial with its stem cell therapy in patients with congestive heart failure. And **Phosphagenics** is preparing to launch a pivotal study with its transdermal oxycodone patch.

Looking at this list, the Australian biotech sector is evolving, seeking to add more value and is looking to deliver bigger returns to investors as it brings new therapys into global markets. For investors, this is a good reason stay invested in this sector.

Starpharma Commences Phase III Trials in with Vivagel in BV

Starpharma (SPL: $1.60) this week announced the start of two Phase III studies with its drug candidate, Vivagel, for the treatment of bacterial vaginosis. The two studies will involve 220 women each and are expected to be completed by the end of this year.

If the results are successful, Starpharma will lodge its new drug application with the FDA, we estimate in the first half of 2013, and will then initiate partnering discussions. CEO Jackie Fairley said the company is already in contact with a number of potential partners that are following the company's progress.

There is good reason to think the outcome of this trial should deliver a positive outcome. These forthcoming trials are very similar in design to its Phase II study. In that Phase II study, the results showed a high level of confidence in their accuracy with a probability value (p-value) of only 0.0002. (For a trial to deliver statistical significance, the p-value needs to be lower that 0.05.) That reduces the clinical risk.

The company also has a Special Protocol Assessment (SPA) agreement in place with the FDA. This means that if the company achieves its present outcomes, it should receive FDA approval. That reduces regulatory risk.

The Phase II trial looked at three different doses of Vivagel, these being a 3% solution, a 0.5% solution, and the 1% solution (which the company is taking into the Phase III trials). At the end of treatment, a clinical cure was achieved in 63%, 55% and 74% of patients with the respective strengths.

These trials are evaluating Vivagel for the treatment of bacterial vaginosis. Starpharma is also running a Phase II trial *prevention* study. Results from that study are expected later this year and if positive, the company will move into Phase III studies.

Starpharma is well funded to complete its Phase III studies, with $49 million in funds at the end of last year. The company is capitalised at $449 million.

Bioshares recommendation: **Take Some Profits**

Bioshares

Pharmaxis Update

Pharmaxis' (PXS: $1.225) cystic fibrosis drug, Bronchitol, has been recommended for listing on Australia's Pharmaceutical Benefits Scheme (PBS). We expect the Australian Benefits Pricing Authority will finalise the reimbursement in the next six weeks. The listing of Bronchitol on the PBS in Australia is more significant than it appears for a number of reasons.

Benefits of Australian Reimbursement

Firstly, Pharmaxis can generate up to $10 million in revenue from sales in Australia that will be reimbursed by the Australian Government. In Australia there are approximately 2,800 people living with CF. The second important factor is that Australia has very restrictive reimbursement policies for medicines, being a monopoly buyer for drugs in this country. That Bronchitol has been viewed as warranting reimbursement by this regulator positions the drug well for reimbursement with other payors.

Our understanding is that Pharmaxis has secured a good price for reimbursement, by our estimates around $10,000 a year, just under what another CF drug Pulmozyme is reimbursed at. Pulmozyme generates global annual sales of around $550 million for the treatment of CF. Healthy pricing in the country of origin of development of the drug should help support strong pricing in other regions.

In Australia, Bronchitol is approved for the treatment of cystic fibrosis in people aged six and over.

European Approval

In October last year, the European Committee for Medicinal Products for Human Use (CHMP) reversed an earlier decision and recommended that Bronchitol should be approved for the treatment of cystic fibrosis in people aged 18 and over. Next month, the company expects that the processing of its marketing authorisation for Bronchitol should be completed. That should see Bronchitol released onto the market within three weeks after approval is granted.

Pharmaxis will start selling the product into Germany and the UK first, which makes up 40% of the European market. The company will then expand sales into other countries in Europe once reimbursement has been arranged. Italy, Spain and France require a health economics review prior to reimbursement being granted. There are 110 CF centres in these countries.

Cont'd over

– PXS cont'd

Pharmaxis has a contracted sales team in place in Germany. The company believes awareness of the product is at over 80%. In Germany, there are 110 CF clinics and 50 in the UK. In the UK, NICE (the National Institute for Health and Clinical Excellence) will review the pricing and effectiveness of Bronchitol after launch. Whilst it is not essential to have NICE backing, it is certainly advantageous to get on healthcare budgets in that country.

In the third quarter of this year, Pharmaxis is expected to start a pediatric trial with Bronchitol in people with CF, which will potentially allow the company to expand the drug's use to those under 18 years of age.

2012 Q2 NDA Filing with FDA

In the second quarter of this year, the company expects to file Bronchitol for approval for CF treatment in the US. We suspect the process for gaining approval in the US will be more linear and less complicated. In the US, the company potentially may have the product approved within 12 months from now.

In the US there are between 150-180 CF centers which the company believes it can access with a sales force of only 20-25 people.

Bronchiectasis Phase III Fully Recruited

In December last year Pharmaxis completed recruitment for its Phase III trial of Bronchitol in people with the condition bronchiectasis. Bronchiectasis is a broad degenerative condition of the lungs. It is a much more common condition, with 320,000 people seeking treatment in the US and Europe (compared to 70,000 people living with CF).

Pharmaxis will be able to file for a label expansion of Bronchitol after results from this second Phase III trial are available, in the first half of 2013, assuming results are positive.

One of the issues that will need to be addressed is pricing, whether payors will accept the same price as for the treatment of CF. At this stage, the company expects pricing will be the same for both indications.

Summary

Over the next 12 months, investors in Pharmaxis have many key milestones to monitor. As meaningful sales start to take hold in coming months from Bronchitol, it should start to attract interest from a wider group of investors. Investors should also not rule out the possibility of larger pharmaceutical firms running the acquisition ruler over the Pharmaxis business during this time.

Pharmaxis is capitalizsd at $381 million. It had $101 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Atcor Medical to Introduce More User Friendly Instrument

The process to get a new diagnostic procedure taken up by healthcare practitioners across the globe is long and slow. Cellestis was successful with its TB diagnostic test, however, it took three product iterations and the publishing of guidelines from central authorities more than once to finally see the test begin to be accepted in markets around the world.

Likewise, Universal Biosensors has developed an improved glucose monitor for which it is also much cheaper to manufacture the consumables. And its next test will go up against the **Roche** product, Coaguchek, used for titrating warfarin dosage.

However, several Australian companies have developed new tests for applications where the market has yet to be established. These include: **Impedimed** with its LDex device aiding in early detection of lymphedema post cancer surgery; **Cogstate** with its cognition test for use in managing concussion in sport; and **Atcor Medical**, which has pioneered a central blood pressure test, SphygmoCor, which delivers valuable information about the health or stiffness of a person's arteries.

In FY2011, Atcor's sales fell by 4.7% in constant currency to $7.8 million. In the first half of this financial year, sales were $3.8 million, down 7.5% in constant currency terms. For the full year the company is forecasting 10%-20% growth in constant currency terms, with some good pharmaceutical clinical trials deals expected.

Commercialisation Australia Grant

This year there have been a number of significant events that should help accelerate adoption of the company's test. There is a degree of technical difficulty in using the SphygmoCor test. It requires the physician pressing a probe across a vein in the wrist, blocking off blood flow. In February this year the company was awarded a Commercialisation Australia grant worth $1.1 million. The grant has gone towards improving the features of SphygmoCor but also the ease of use of the test. The new product should be able to be introduced this year and may change the rate at which the test is adopted by physicians.

CPT Category III Code

Early this month, a procedure to measure central blood pressure was granted a CPT III code that will allow physicians to be reimbursed for the SphygmoCor procedure from 1 January 2013 in the USA. Reimbursement levels will need to be negotiated with individual funds, and it could see reimbursement of around $50 per test.

In January this year, three US medical associations publicly supported and advocated the use of central blood pressure, particularly in the African American population.

The National Medical Association, The Association of Black Cardiologists and the Association of Minority Nephrologists stated that central blood pressure should be added to the tests used by

Cont'd on page 6

Vale Dr Andrew Rainsford Baker PhD (23 March 1961 – 18 March 2012)

Andrew joined GBS Venture Partners in 2002 as the backbone of GBS's efforts in creating a pre-seed fund along with his great colleague and friend, Leigh Farrell. They formed a formidable team, allowing GBS to raise the Genesis Fund in late 2002. Andrew then set about building a world class portfolio of companies for the Genesis Fund, whereby he worked with Australian scientists, entrepreneurs and university technology offices, crafting sustainable biotech companies from scratch. Amongst many other tasks, he completed licence agreements, oversaw R& D plans, raised capital, hired management teams and recruited boards. The companies include Spinifex, Hatchtech, ProActa, Xenome, KaloBios, Pathway and Verva.

Andrew had his own distinctive style and the unique ability to turn people around to his way of thinking without ever causing disharmony. Along the way, he also gave enormous amounts of free advice to researchers and entrepreneurs on how to go about commercialising their technologies, even though the Genesis Fund may not have invested with them. That is simply the way Andrew was.

Andrew had an incredible breadth of knowledge across many fields of science. After a distinguished scientific research career working with Prof John Shine, Andrew turned to the biotech industry where he forged a career in Silicon Valley with California Biotechnology and later Genentech. He moved back to Australia to work for a long time with Leigh at Johnson & Johnson under the helm of Denis Wade. This deep combination of research and corporate experience gave Andrew the perfect background for venture capital, where he combined a passion for improving patient outcomes with deep scientific insight and sound business judgement.

Andrew successfully identified great medical technologies and helped build companies to deliver their products to patients. His legacy includes essential roles in bringing multiple new medical therapies to human clinical trials and developing products which have the potential to treat major global diseases such as cancer, neuropathic pain, acute pain, dermatology, diabetes, and depression.

Andrew was a leading light in the building of the Australian biotechnology industry, helping bring together the best science, management, finance and clinical development to develop new medicines and therapeutic devices.

Outside of his working hours, Andrew had a truly rich life. A devoted husband and father, he was a committed member of his local church. Also, he was a fabulous sportsman, especially as a golfer and tennis player.

Andrew dealt with his illness with incredible bravery and good grace. He was still working at GBS and with the companies of which he was a director just a week before he died. He was an understated man, with a wicked sense of humour, which we all enjoyed immensely. Our deepest sympathies are with his family.

Andrew was a cherished friend and colleague who will be greatly missed by all who were touched by him.

– GBS Venture Partners

I first met Andrew in 1997 when he was interviewing for the position of Deputy Director of the Johnson & Johnson Research laboratories in Sydney. We worked together as colleagues for four years and quickly became close friends. Our families often went on vacation together and we shared many hilarious dinners at our respective houses over the years.

Andrew was a brilliant sportsman, excelling in many sports including cricket, golf and tennis. When we were at J&J, we used to play tennis at lunchtime; he always beat me. One day I thought I had a chance at beating him; Andrew mistakenly brought two left footed tennis shoes and opted to wear the shoes anyway. He still beat me! The moral of the story is that you can still have two left feet and win!

In 2002, Andrew and I moved our families to Melbourne to take up the positions of Associate Director at GBS Venture Partners. At GBS we raised and managed the Genesis Preseed Fund. Around the office Andrew and I became known as B1 and B2 from Bananas in Pyjamas; maybe because one's ying complemented the other's yang. Andrew continued his successful career at GBS and ultimately became a partner in the firm. Andrew was a highly respected person in international venture capital and biotechnology circles. His calming knowledgeable persona was a salve to many a difficult discussion around board room tables.

As a fisherman, Andrew was a good golfer! I tried to get him interested in kayak fishing on Port Phillip Bay, but when I turned up on his doorstep at 5am to get going, he would greet me in his pyjamas and give me a cup of tea, adding that the fish would still be there when we eventually got on the water. That was Andrew to a tee, very laid back, but insightful. Although, I know that if Andrew had to get up for a 5am game of golf, he would have been "booted and suited" on time!

Jocularity aside, it was heart wrenching to say my last good bye to Andrew on 18 March. Andrew was my best mate and I already miss him terribly. My family and I will continue to provide strength and support to Andrew's wife Nancy, son Sam and daughter Clare. Rest in peace Andrew.

– Leigh Farrell

Cont'd over

I first met Andrew way back in the late 80's, introduced by Brian McNamee, when Andrew was working at CalBio in Mountain View, CA. At our first meeting, we decided to play tennis at Stanford University, and that afternoon get-together led to 25 years of friendship and work association, as well as never enough games of tennis and golf. A keen member of the Woodlands Golf Club, Andrew enjoyed many an encounter with his golf tragic biotech mates. To see his swing was like watching ballet. It was silk and a copy of his personality. It was the envy of all who had the pleasure to play with him. When GBS wanted to create a pre-seed fund, Andrew was the perfect person to lead it. We will all miss him so much. Our hearts go out to Nancy and their two children.

– Geoff Brooke

Memorial Service:
A Memorial Service for Dr. ANDREW RAINSFORD BAKER will be held at St. Leonards Uniting Church, 2 Wolseley Ave, Brighton, Vic. on Monday (March 26, 2012) at 1.30 p.m.

Donations:
In lieu of flowers, donations to the Australasian Sarcoma Study Group would be greatly appreciated. Please note Andrew Baker as the bequest: **http://www.australiansarcomagroup.org/support-sarcoma-research.html**

Company	Price (current)	Price added to portfolio	Date added
QRxPharma	$1.75	$1.66	October 2011
Mayne Pharma Group	$0.285	$0.435	September 2011
Acrux	$4.02	$3.37	June 2011
Bioniche	$0.60	$1.35	March 2011
Somnomed	$0.90	$0.94	January 2011
Phylogica	$0.045	$0.053	September 2010
Biota Holdings	$0.87	$1.09	May 2010
Tissue Therapies	$0.39	$0.21	January 2010
Atcor Medical	$0.07	$0.10	October 2008
Impedimed	$0.54	$0.70	August 2008
Bionomics	$0.45	$0.42	December 2007
Cogstate	$0.26	$0.13	November 2007
Sirtex Medical	$5.16	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.85	$6.60	September 2007
Pharmaxis	$1.25	$3.15	August 2007
Universal Biosensors	$0.73	$1.23	June 2007
Alchemia	$0.470	$0.67	May 2004

Portfolio Changes – 23 March 2012

IN:
No changes

OUT:
No changes

– Atcor Medical cont'd from page 3

doctors in diagnosing and treating African Americans for hypertension.

Hypertension is 50% greater in African Americans than in Caucasians, and this subset of the population experiences early onset of hypertension, inadequate blood pressure control and increased damage to kidneys and other organs.

"Central blood pressure is seen as a major advance in the identification of cardiovascular risk. It also provides physicians with more comprehensive information to improve hypertension treatment and management decisions. These leading organizations believe that the measurement of central blood pressure will advance the national effort to decrease health disparities associated with hypertension", according to the joint statement released by these organizations.

Summary

Atcor Medical is capitalized at only $9 million. One issue for the company is that it only had $1.1 million in cash at the end of last year. Its cash outflow in the first half was $361,000.

Atcor Medical is out of favour with investors. However it is the leading provider of central blood testing instruments, with its approach supported by over 600 peer-reviewed publications. There are several recent events that suggest adoption of its test is due to accelerate in the next 12-24 months.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

pSivida – Iluvien Gains Positive Review from UK Regulator

pSivida's partner Alimera Sciences has received a positive review from the Medicines and Healthcare Products Regulatory Agency of the UK that the company's depot injection, Iluvien, is approvable for the treatment of chronic diabetic macular edema.

Following a rejection from the FDA, Alimera narrowed down its application to only patients with chronic form of the condition. Alimera is following the decentralised regulatory pathway in Europe. The regulatory process now moves to a national phase where each member state will grant the necessary marketing license.

For any licensing deal, pSivida will receive 33% of any upfront payments and a 20% of profit share from sales. Sales in Europe for Iluvien potentially could reach $150 million a year.

Bioshares recommendation: **Under Review**

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, Circadian Technologies, Biota Holdings, Impedimed, QRxPharma, LBT Innovations, Mesoblast, Atcor Medical, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Genetic Technologies, Calzada

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