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In this edition...
An approval of a new medicine by Australia's TGA can give an insight into how other regulatory authorities that cover far larger markets may choose to act. That is the case for Pharmaxis, which this week saw Bronchitol (for cystic fibrosis) approved by the TGA, with a European decision expected in April.
Biota's co-developed long-acting flu drug Inavir is half way through its first season of sales in Japan. So far it looks to be outselling Tamiflu and Relenza.
Somnomed has received a major boost from Medicare in the US, which is now accepting oral appliances as first line treatments for mild-to-moderate sleep apnea. And we note that Phylogica's collaboration with Roche will be one to monitor this year
The Editors
Companies Covered: BTA, PYC, PXS, SOM

	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)	32.9%
Cumulative Gain	**285%**
Av Annual Gain (9 yrs)	**18.5%**

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Bioshares

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Edition 395

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

Success for Pharmaxis! Bronchitol Gains Australian Approval for the Treatment of Cystic Fibrosis

The impressive progress of the Australian biotech sector continues with this week Pharmaxis (PXS: $2.65) gaining regulatory approval from the TGA in Australia to sell its novel cystic fibrosis (CF) treatment drug, Bronchitol. This is an outstanding achievement by the Pharmaxis team.

It is a very long road to bring a new therapeutic to market. The research behind Bronchitol commenced in 1993 and Pharmaxis was formed 13 years ago, in 1998. The flip side to the long and expensive development pathways is that companies that are successful can enjoy clear monopolies from their drug franchises until competitors emerge, in markets that are in the order of hundreds of millions of dollars in sales with gross margins or around 80-90%.

Market Potential

There are 70,000 people living with cystic fibrosis in Europe and the US, and 2,400 people in Australia with the genetic disorder. If the drug were to be sold for $10,000 a year, it would equate to an addressable market in Australia of $24 million a year and in Europe and the US of $700,00 million.

The likely take-up of the drug we estimate would be expected to be between 30% at the low end, of people with CF, to 60% at the high end. That puts likely sales of the drug by our estimates of between $220 million a year to $430 million a year in Europe, the US and Australia, based on a selling price of $10,000 per year of treatment per patient. And that's excluding the market for the treatment of bronchiectasis. The only other drug available that targets the mucous build-up associated with CF is Pulmozyme, which last year generated sales of $460 million.

As we stated last week, Bronchitol has shown it can improve lung function by 8.1% and 8.2% at 12 months in two Phase III continuation studies, with an expected improvement in quality survival of at least four to six years.

European Approval in April?

Pharmaxis should hear back from European regulators about its new drug application submission in April. Although the Australian approval will not directly influence the European regulator, that the only advance in 15 years in CF treatment that affects the underlying symptoms of the disease has now been approved in one jurisdiction, should help support the argument for wider approval of this drug.

Pharmaxis expects to file Bronchitol for approval in the US by mid year for the treatment of CF. Pharmaxis also intends to expand the application of Bronchitol beyond CF to bronchiectasis, which is a market about eight times larger than CF. The first trial in over

– Cont'd over

Phylogica: Progression of Roche Deal will be a Key Milestone

In the 12 months to December last year, Phylogica (PYC: 7.9 cents) signed three research deals with major pharmaceutical companies – **Roche**, **AstraZeneca** and **Pfizer**. In 2011, the goal for the company is to sign a further three deals with some of the other leading global pharmaceutical companies. But on top of that, there's the potential to progress/expand its existing research collaborations.

Three more deals this year could see the company moving into the black either in this calendar year or financial year 2012, depending on the timing of milestone payments. This is part of the company's revamped business plan, where it can move into profitability in the short-to-medium term from revenue generating research collaborations rather than lengthy in-house drug development programs. There is also upside from milestone payments and royalties should any drugs reach the market. Total milestone payment deals to date have been in the order of $100 million.

Progression of Roche deal will be a Major Validation

In the short term, the key milestones for investors to look out for will be progression of the Roche collaboration. In December 2009 Phylogica signed a research collaboration to look at using Phylogica's peptides to drag drags into cells. In October last year Phylogica and Roche completed the first stage of this partnership, with Roche now assessing the work and considering the next steps. Roche paid an option fee to initiate the collaboration.

Phylogica would like to see Roche exercise its option to progress this collaboration, which would involve a decent milestone payment and probably the largest Phylogica has received to date from any of its partners. If this occurs, it will arguably be the most important external validation of the potential of the Phylogica technology to date.

Phylogica's new CFO and VP of Corporate Development, Nick Woolf, said in discussions with *Bioshares* that the dialogue with all three partners remains excellent. The company is hitting its milestones and so he believes the partners are pleased with so far with the collaborations.

If these relationships continue to progress well, then not only may the company complete three new research collaborations this year, but it may see existing collaborations progressed or expanded into other research collaboration areas.

The collaboration with MedImmune (AstraZeneca) remains in the research phase says Woolf and the Pfizer deal was only signed in December last year. All research collaborations are between six to 12 months in length.

As the company progresses its collaborations and signs on new partners, it should become easier, and in fact has now become easier, to get the attention of other biotech and pharmaceutical companies.

Nick Woolf, who is an experienced biotech analyst and industry executive has recently moved from the UK to Perth to be closer to Australian operations and investors. The company has a team of 18 researchers working out of Perth. The company's CEO, Paul Watt, last year moved to Oxford, UK, to be closer to existing and future partners.

Phylogica has an estimated $2.3 million in cash and is capitalised at $22 million.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

– Pharmaxis continued

300 people was successfully completed, finding the drug improved the quality of life. A second Phase III trial is underway. It's expected around 470 people will be enrolled. Enrolment is around 50% of the way through and due to be fully enrolled by mid year. This trial will also measure exacerbation rates in addition to mucous production and quality of life.

Pharmaxis is added now to the list of successful Australian drug developers. It is led by **Biota**, which developed Relenza and which is marketed by **GlaxoSmithKline**, followed by **Sirtex Medical** with its cancer therapy Sir-Spheres (although this is technology a device using ceramic spheres coated with a radioactive material), **Clinuvel Pharmaceuticals** which has its photoprotective drug on the market now in Italy, and **Acrux**, which developed an improved delivery format of testosterone delivered as a gel product, called Axiron.

Summary

Pharmaxis' aim has always been to build a fully integrated pharmaceutical company, whereby pharmaceutical concepts can be internally developed and independently brought to market without the assistance of larger marketing partners. That goal is now being realised. For investors, a decision from European regulators in the next two months will be the next major milestone to watch out for.

Pharmaxis is capitalised at $605 million and retained a cash balance of $67 million at December 31, 2010.

Bioshares recommendation: **Speculative Buy Class A**

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Bioshares

US Medicare Policy Boost for Somnomed

Somnomed (SOM: $1.00) markets an oral (dental) appliance, the SomnoDent MAS, which is used in the treatment and management of sleep apnea.

This week the Center for Medicare and Medicaid (CMS) in the US released new coverage determinations for Oral Appliance Therapy (OAT) for obstructive sleep apnea.

The new coverage now excludes non-customised oral appliance therapy products. Somnomed's Somnodent MAS is a product that is customised by qualified dentists. The decision positively biases the market opportunity for Somnomed.

First Line Treatment in Mild to Moderate Sleep Apnea

A second determination was that Medicare will now cover (reimburse) OAT therapy for mild-to-moderate sleep apnea patients (~20% of the sleep apnea market), with OAT no longer considered a second line therapy for CPAP patients who either fail or become non-compliant with CPAP machines and masks. It is now a first line treatment in its own right, under the new determination.

US Medicare provides health insurance benefits for around 15% of the US population. However, many private health insurers take their lead from Medicare, which means that the same coverage decision is likely to be gradually extended to an even larger percentage of the insured US population.

Somnomed had expected these decisions to occur as far back as April 2010, with the initial push to install the rulings commencing about two and half years ago, according to CEO Ralf Barschow.

The implication for Somnomed is that can develop a much firmer grip on the US OAT for sleep apnea market and take market share from the non-customised OAT suppliers and also directly compete with the CPAP providers in the mild-to-moderate category of patients.

The USA accounts for 70% of Somnomed's sales. This significant market focus is the main reason CEO Ralf Barschow has announced plans to relocate there in March 2011, basing himself in Dallas, Texas.

One of the features of the Somndent MAS is that offers a potentially profitable income stream to dentists who specialise in oral appliances. The Somnodent device achieves an average selling price of $470 according to Somnomed's CEO. However, the fitting of the device can genarate for dentists a price of between $1,000 to $2,000.

December Quarter Cash Flow Statement

In the half year ending December 31, Somnomed recorded receipts of $5.7 million and posted a net operating cash flows of $-0.5 million. Half yearly receipts increased 20% from the previous corresponding period. Quarterly receipts increased 35% from $2.5 million in the September quarter to $3.4 million in the December quarter. Gross margins improved from 63% in the September quarter to 65% in the December quarter.

Somnomed - Financial Summary

	FY2007	FY2008	FY2009	FY2010	H1 FY 2011	
Sales $(M)	$2.3	$3.7	$7.7	$10.7	$5.9	*R*
change		*61%*	*112%*	*38%*	*20%*	*pcp*
Units Sold	3,503	7,033	12,544	19,543	11,462	
change		*101%*	*78%*	*56%*	*25%*	*pcp*
Gross Margin	$1.00	$1.96	$4.06	$6.08	$3.45	*e*
GM as % Sales	*44%*	*53%*	*52%*	*57%*	*64%*	*e*
Pre-tax P/L	-$3.27	-$2.33	-$1.80	$0.11		
Profit/Loss	-$3.27	-$2.33	-$1.82	$0.79	$0.50	*e*
Cash ($M)	$3.2	$5.4	$4.0	$4.3	$3.7	
Ave Unit Rev.	$649	$520	$617	$548	$518	
Shares (M)					40	
CMP					$1.00	
Capitalisation					$40.3	
PE					51.3	*e*

e - Bioshares estimate R - Receipts (cash flow statement)

Correction: In the version of this table published in Bioshares 385, the average unit revenue figures were incorrect, with the numerator and denomonitor being incorrectly transposed.

The company stated in its quarterly commentary that it had no plans to raise additional capital.

Forecasts

Somnomed has provided the market with sales forecasts on previous occasions. Although they have yet to exceed a forecast, the differences between actual and forecast figures are within acceptable bounds, given that strong growth rates have been used.

In September 2007, Somnomed forecast unit sales of 14,000 for FY2009 and 22,000 for FY2010. Actual unit sales were 12,245 and 19543 respectively. The forecast percentage change from FY2009 to FY2010 was 57%, compared to an actual growth rate of 59%.

Somnomed's current sales forecast is for 28,000 units in FY2011 and 36,000 units in FY2012. The company must achieve 20% growth in both the March and Junes quarters of 2011 to achieve its forecast sales figure. Given that there is some integrity to Somnomed's forecasts, we suggest that the company is on track to achieve unit sales in the regions forecast.

Summary

The recent CMS announcement bodes well for the future of Somnomed. The anticipated re-location of CEO Ralf Barschow to the US is a sign of the company's determination to optimise results in its largest market. Barschow will assume the titles of Global CEO of Somnomed and President, Somnomed Inc.

Somnomed is capitalised at $40.3 million and held cash of $3.75 million at December 31, 2010.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares Model Portfolio (11 February 2011)

Company	Price (current)	Price added to portfolio	Date added
Somnomed	$1.00	$0.94	January 2011
Phylogica	$0.079	$0.053	September 2010
Sunshine Heart	$0.043	$0.036	June 2010
Biota Holdings	$1.44	$1.09	May 2010
Tissue Therapies	$0.62	$0.21	January 2010
QRxPharma	$1.24	$0.25	December 2008
Hexima	$0.30	$0.60	October 2008
Atcor Medical	$0.10	$0.10	October 2008
Impedimed	$0.80	$0.70	August 2008
Patrys	$0.09	$0.50	December 2007
Bionomics	$0.39	$0.42	December 2007
Cogstate	$0.23	$0.13	November 2007
Sirtex Medical	$5.46	$3.90	October 2007
Clinuvel Pharmaceuticals	$2.25	$6.60	September 2007
Starpharma Holdings	$1.05	$0.37	August 2007
Pharmaxis	$2.65	$3.15	August 2007
Universal Biosensors	$1.36	$1.23	June 2007
Acrux	$3.53	$0.83	November 2004
Alchemia	$0.71	$0.67	May 2004

Portfolio Changes – 11 February 2011

IN:
No changes

OUT:
No changes

Biota – Inavir Off to a Good Start in Japan

Biota Holdings' (BTA: $1.44) new flu drug, Inavir, partnered with **Daiichi Sankyo**, has got off to a reasonably good start in Japan. In the final two months of last year the drug generated sales of $34 million. This drug goes up against Relenza and Tamiflu and it appears it may have outsold these drugs on entry into the market. It beat global sales of Relenza, which generated sales of only $17.9 million for the last three months of the year in 2010.

Inavir has clear delivery advantages, needing to be taken only once, compared to twice daily for five days for both Tamiflu and Relenza.

Biota will receive a royalty of $1.16 million from those sales of Inavir, which equates to a royalty rate of 3.5%. This is in line with our previous royalty rate estimates of 3.5%-4.0%. For Relenza sales Biota will receive a royalty of 1.2 million. CEO Peter Cook said it is not surprising that a big downturn in sales of Relenza occurred following the end of the influenza pandemic crisis.

The flu season in Japan peaks in February so this quarter's results will be interesting to monitor. Whether the good start last quarter was due to some inventory stocking or clearly represents demand is unknown. Current quarter sales should give a better indication of how well Inavir is taking market share away from its rival products, Tamiflu and Relenza.

In commercializing this drug outside of Japan, Biota shares equal rights to the drug with Daiichi Sankyo. Biota is still waiting to see if it is successful in gaining some US Agency funding (through a tender process) that will help Biota independently commercialise the drug outside of Japan. It will be required to complete both Phase II and Phase III studies. The drug will take at least three years to bring to market outside of Japan and will need to be tested in around 2,000 people. Until a decision about the funding option is received, licensing discussions with commercial partners are on hold.

The company's rhinovirus program is currently in Phase II trials. The company is seeking to enroll 400 patients. Enrolment is half way through and it will probably be completed now in the next northern hemisphere winter.

Biota is capitalised at $260 million and held cash of $105 million at June 30, 2010

Bioshares recommendation: **Speculative Buy Class A**

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, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Mesoblast, Atcor Medical, BioMD, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip