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In this edition...
Will Mayne Pharma Group be able to overcome its dependency on Doryx as generic competition looms? Mayne's new CEO Scott Richards has fashioned a four point plan to deal with an anticipated drop in revenues. Universal Biosensors is a stock with a weakened share price, despite its fundamentals appearing sound. Will it become a take-over target? Pharmaxis is moving ahead with the selling of Bronchitol for CF in Europe. Although rival CF drug developer Vertex Pharmaceuticals delivered some positive data on a Phase II drug combo trial, putting $5 billion on its cap, the presentation of the data omitted a key metric. And with Acrux now capped at almost $700 million, we suggest its time to take some profits.
The Editors
Companies Covered: ACL, ACR, MYX, PXS, UBI

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - current)	-3.6%
Cumulative Gain	**233%**
Av. annual gain (11 yrs)	**17.8%**

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Bioshares

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

Mayne Pharma Group – Life After Doryx?

Mayne Pharma Group's (MYX: $0.32) share price peaked at $0.99 in February 2011, after which it fell to $0.33 in July 2011. The company's share price then recovered to $0.51 in November 2011, only fall away again to trade near the $0.30 level for the most part of the year to date.

The weakness in the share price has been due to volatility in sales of Doryx (doxycycline), which is marketed in the US by Warner Chilcott and made by Mayne at its plant in Adelaide. Doryx is prescribed for the treatment of a range of bacterial infections.

For FY2011, Doryx revenues fell by 46% from the previous year. Doryx sales accounted for 42% of revenues in FY2011. Warner Chilcott reduced its inventory of Doryx in that year in anticipation of stocking a new dosage form of Doryx. The appreciating Australian dollar reduced Doryx earnings by approximately $3 million for FY2011, compared to the previous year.

For the half year ending December 31, 2011, Doryx sales increased by 71% from the previous half year as Warner Chilcott normalised ordering. However, the stronger Australian dollar again impacted earnings, culminating in a 6.9% fall in Doryx revenues from the previous corresponding period. Doryx accounted for 46% of Mayne Pharma Group's revenues. Total revenues for the half year were $27.1 million, with a net profit of $3.9 million reported.

By the end of 2011, Doryx sales were accounted for by almost all of the new 150mg dual scored tablet formulation. This followed the FDA's approval of the new formulation in September 2011.

However, the company's chances of maintaining a strong grip on Doryx sales have now been dealt a blow with the decision by a US Court which has accepted Mayne Pharma's patent covering its new formulation of Doryx (the 150mg formulation) but which also ruled that rival generic drug firms, Mylan Pharmaceuticals and Impax Pharmaceuticals proposed generic versions did not infringe Mayne's patent.

This patent (US PTO number 6,958,161; filed April 2002; granted October 2005, expiring April 2022) describes a modified release preparation that has one or more coated core elements, with each core element including an active ingredient and having a modified release coating. The United States District Court judgment implies that the formulations

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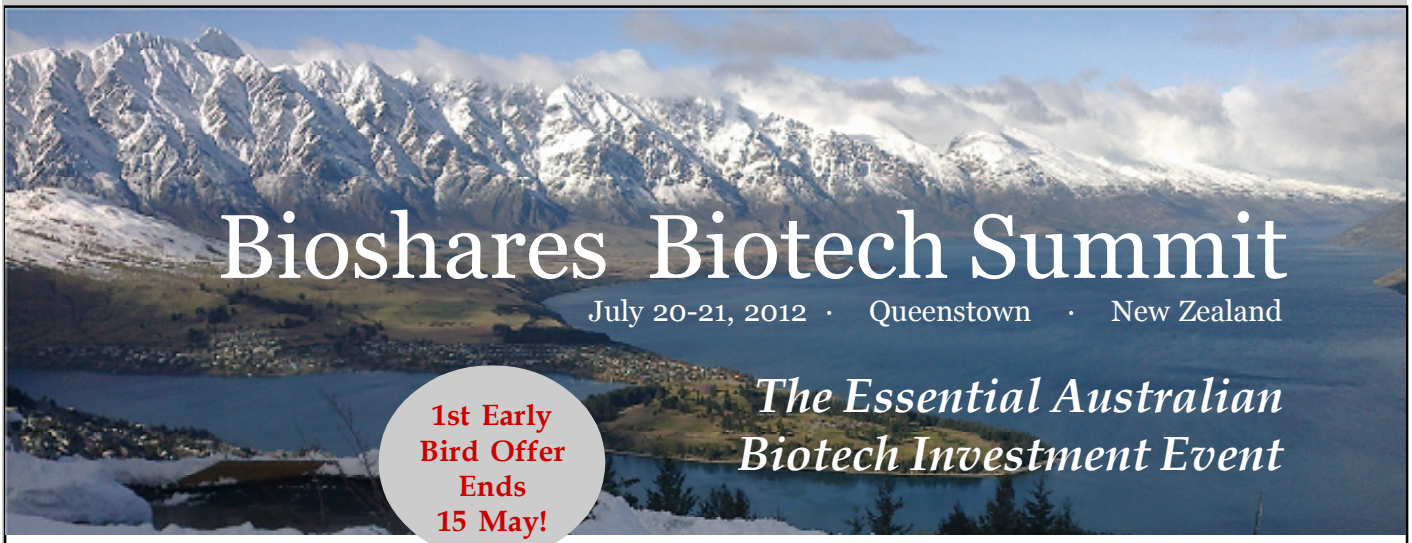

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of Doryx as devised by Mylan and Impax stepped around the coating methods and dissolution profile devised by Mayne (originally F. H. Faulding) chemists.

The implication for Mayne and sales partner Warner Chilcott is that sales of Doryx will be subject to competition from generic firms and that consequently sales are likely to decline considerably. However, Mayne believes it may take several weeks before a clear understanding of the prospective competitive landscape can be achieved. Mayne also expects Warner Chilcott to put several strategies into play to dampen or slow the impact of the generic competition to Doryx.

Mayne's Revised Business Strategy

The Mayne board appointed a new CEO, Scott Richards, in December 2011 to replace Dr Roger Aston. Richard did not formally take up his position until February this year. Richards was previously the President of European Operations and Global Hospital Business for Intas Pharmaceuticals, and prior to that was the Executive Vice President of the Global Hospital Generics Business of Actavis. He also spent 18 years with Mayne and F. H. Faulding earlier in his career, which means he has come to the CEO role at Mayne with an extensive insider's knowledge of the company.

Richards has developed a business plan for Mayne Pharma that assumes a weakened position for Doryx in the doxycycline market. The strategy builds on selling existing products into new markets, the positioning of Mayne Pharma as an independent Australian specialty pharmaceutical group, continuation of contract manufacturing and the revitalization of R&D program.

1. Sales Territory Expansion

The first plank of the strategy involves expanding the number of territories (currently 7-8) into which Mayne sells its existing products.

2. Acquire/In-license Specialty Brands and Products

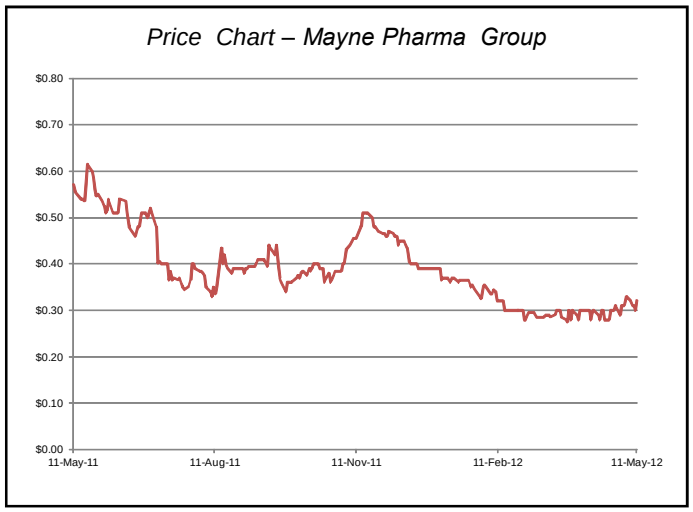
The positioning of Mayne Pharma as an independent Australian specialty pharmaceutical group will see the company acquire or in-license products and brands that fit with the heritage of the Mayne (Faulding) brand. However, the niche or specialty focus will be based on the sales of either branded or generic products into the hospital market, with products targeted towards the US and with sales in the US$200-$500 million p.a. range.

3. Drive Manufacturing Harder

The company's liquids and creams manufacturing capability delivers about 20% of top line revenue but also consumes significant overheads. Richard's new plan would aim to substantially increase exploitation of Mayne's contract manufacturing capability.

4. Revitalise R&D

The final plank to the revised strategy is to invigorate R&D, building on the strengths of Mayne's globally relevant operations in Adelaide.



SUBACAP Update

The company has been finalizing an extensive review of SUBACAP, a proprietary formulation of the antifungal agent itraconazole in development to treat toe nail fungal infection. The review has expanded the number of potential opportunities for the drug to also include blood born fungal infections, or systemic infections as opposed to superficial infections.

Following discussions with the FDA, the company now understands that it will need to complete a single Phase III trial under a Special Protocol Assessment. A decision on the trial protocol is expected in two-to-three months time. One feature that is likely is that the trial will have a treatment period greater than the 24 weeks period used in trials to date. This is so the trial design can yield conclusive outcome on complete cure rates for the treatment of infected toe nails.

A response to Mayne's filing of a Marketing Authorisation Application (MAA) SUBACAP with the UK's MHRA was met with additional questions, delaying the previously targeted approval date of mid-2012. The company may need to complete further clinical studies to answer the questions of the MHRA.

Richards' objective with the SUBACAP program is to develop a definitive dossier suitable for partnering discussions.

Summary

Mayne Pharma has now returned to being a capital growth play. Despite the anticipated negative impact of the recent US District Court decision to apparently open the gates to generic competition to Maynes patented formulations of doxycycline, the company has substantial assets, resources and capabilities to build revenues over the longer term. The stock will be one to watch very closely under the leadership of its new CEO.

Mayne Pharma is capitalised at $48 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Universal Biosensors Update

Universal Biosensors' (UBI: $0.645 cents) share price keeps falling although why that's happening remains a mystery. The stock has fallen 50% over the last year. The company's lead product is a glucose monitoring system, called the OneTouch Verio, which is being marketed globally by Johnson & Johnson.

UBI has a reasonably comfortable cash balance of $15.7 million. It's net cash outflow for the 12 months to the end of March was only $4.9 million. It's net loss for CY2011 was $14.7 million although that included depreciation and amortisation of assets. In the March quarter, the company generated a positive cash flow of $72,000, and recorded a loss of $2.1 million.

CEO Paul Wright expects its glucose diagnostic business grow well. In the last two quarters the company has been outside of its 'interim costing period', which means order quantities for its glucose strips it makes for Lifescan (Johnson & Johnson) had increased and the company can now charge a margin for its product (as opposed to making the strips on an initial cost-recovery basis).

The glucose test was only launched in the US in January and is now available in all major western markets. Lifescan has a 27% global market share of the glucose testing business and a 33% share in the US. J&J's Diabetes Care division increased revenue by 13.2% in the March quarter.

UBI's diabetes business segment is now profitable, delivering a gross margin of $1.7 million in 2011. This includes additional service work the company is conducting for Lifescan for next generation products.

Lifescan has also started its own manufacturing line in Scotland to make the glucose strips. Whether UBI makes the strips or not, it receives a service fee of around US1 cent per strip that Lifescan sells. If UBI makes the strips, it makes a manufacturing margin on the strips. This service fee from strips sold increased by 116% in the March quarter over the December quarter.

The company is progressing well with its second product, which is a point-of-care diagnostic for titrating correct warfarin levels, call the PT-INR test. Its partner Siemens Healthcare Diagnostics plans to launch the test in 2013. The company is in late stages of development of this product.

UBI is also developing a dry strip immunoassay. If it can succeed with this area, which is a very challenging extension of the technology, then it will significantly broaden the application of the UBI diagnostic platform.

If the company's share price continues to fall, it may become a takeover target. UBI is capitalised at $103 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Pharmaxis Update

Pharmaxis (PXS: $1.18) is ready to start selling its cystic fibrosis drug, Bronchitol, into Europe. The company is already marketing to cystic fibrosis specialists. It is using its own sales staff in the UK, where it currently has 22 people, and in Germany it is using a contract sales force from Quintiles. The Quintiles team will effectively have the appearance of a Pharmaxis sales or 'market access' team and will market only Bronchitol. In the UK, its sales team will also be marketing the lung function test Aridol.

The awareness of the drug is high according to CEO Alan Robertson, with about 80% of clinicians expected to prescribe the drug. Pharmaxis will be making sure there is penetration across as many clinics as possibly and will focus on making sure the drug is utilized correctly and optimally to ensure clinicians have positive initial experiences with the drug, which is very important.

In Australia the company is still awaiting listing on the PBS, for which it has been recommended. The drug is already proving very effective. In one eight year girl with CF treated with Bronchitol, her lung function improved from a very poor 41% to 75% following treatment.

Last month Pharmaxis' chairman Denis Hanley stepped down, after more than 10 years with the company. The transition was reflective of the company's move from a technology development group to a company with a cash flow generating business.

Vertex Phase II Trial Results - Kalydeco and VX-809

This week Vertex Pharmaceuticals released some Phase II data on a combination of two of its drug compounds for the treatment of cystic fibrosis. The Phase II trial is investigating the combination of Kalydeco, which was approved by the FDA in January this year, and drug candidate VX-809.

The patient population the trial was addressing were patients with a particular mutation of the CFTR gene, called the F508del mutation. Cystic fibrosis is caused by a mutation in the gene that codes for the CFTR protein. The Phase II trial being run by Vertex is investigating the combination of these therapies in people with one or two copies of the F508del mutation.

The data released this week was from patients with two copies of the F508del mutation. This accounts for about 50% of people with cystic fibrosis.

The interim results showed that in this arm, 46% of patients achieved better than a 5% improvement in lung function (FEV1), and 30% achieved a better than 10% improvement in lung function.

By coincidence, these results are very similar to those published for Pharmaxis' Bronchitol for a Phase II study in 2008. In that two week trial in 39 patients, 43% achieved more than a 5% improvement in lung function and 33% achieved a better than 10% improvement. (The mean improvement in lung function (FEV1) was 7%).

Cont'd over

Bioshares Model Portfolio (11 May 2012)

Company	Price (current)	Price added to portfolio	Date added
Osprey Medical	$0.40	$0.40	April 2012
QRxPharma	$1.77	$1.66	October 2011
Mayne Pharma Group	$0.320	$0.435	September 2011
Somnomed	$0.91	$0.94	January 2011
Phylogica	$0.049	$0.053	September 2010
Biota Holdings	$0.85	$1.09	May 2010
Tissue Therapies	$0.54	$0.21	January 2010
Atcor Medical	$0.07	$0.10	October 2008
Bionomics	$0.34	$0.42	December 2007
Cogstate	$0.275	$0.13	November 2007
Sirtex Medical	$6.10	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.76	$6.60	September 2007
Pharmaxis	$1.18	$3.15	August 2007
Universal Biosensors	$0.65	$1.23	June 2007
Alchemia	$0.470	$0.67	May 2004

Portfolio Changes – 11 May 2012

IN:
No changes

OUT:
Acrux has been removed following our recommendation to 'Take Profits'.

– PXS cont'd

Of interest was the way these results were presented. There was no overall improvement value in FEV1 supplied, which is a common measure of efficacy of treatment of this disease.

The improvement noted above also included pooled data from three different drug doses, which is not a way in which regulators assess drug efficacy. No information was provided on the health of the patients entering the trial. And on the primary measure of reduction in sweat chloride levels, the result was not statistically significant.

Vertex's market capitalisation jumped by US$5 billion on the news. However that reaction may be overzealous. Vertex will still need to complete the Phase II study, and conduct two Phase III studies, suggesting the drug combination will take at least three more years to get to market.

Kalydeco is approved for people with CF who have at least one copy of the G551D mutation of the CFTR gene. This represents around 4% of the those people with CF.

Pharmaxis is capitalised at $358 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Acrux Update

The Acrux (ACR: $4.14) share price has had a very solid run. It is now capitalized at $689 million. There is a transition occurring in the company's register, with AMP becoming a substantial shareholder at 6.2%, Paradice Investment Management also substantial at 6.3%, and its previously largest shareholder Allan Gray Australian (formerly Orbis) reducing its stake now to 6.0%. We recommend it's a good time to take profits with this stock.

Bioshares recommendation: **Take Profits**

Bioshares

Alchemia Update

Alchemia's (ACL: $0.47) fondaparinux sales (sold by Dr Reddy's Laboratories in the USA) are believed to have been US$20 million for the most recent quarter, according to Bloomberg. This translates to an estimated profit share for Alchemia of $28 million a year.

Of interest was that Dr Reddy's, while not providing specific sales numbers for fondaparinux, stated that it expected expanded market share in the US in coming quarters. Dr Reddy's also stated that it now has sufficient product to service both the retail and hospitals sectors. There had previously been some question over its manufacturing capacity for fondaparinux.

Alchemia is capitalised at $132 million with $17.2 million in cash. Revenues for Alchemia from fondaparinux are due to start this month. However Alchemia needs to pay back development costs of around $9 million first. This means the first significant payment should be received in August, with $7 million expected per quarter on current numbers.

There has been no update on the progress of spinning out Alchemia's oncology business. However market conditions have deteriorated in the US, with Rib-X Pharmaceuticals postponing its IPO in the US, even after cutting its listing price by 50%. The company stated market conditions as a reason for the postponement.

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

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