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**In this edition...**
Taxation aspects of Acrux's $100 million Acrux dividend have now been established, with shareholders bank accounts to be credited on April 19. Phylogica has brought in new institutional investors via a $5.2 million placement. In a welcome step forward, Medical Developments Int. is close to commencing a European registration trial of emergency pain relief product Penthrox, funded out of the company's cash reserves. Also moving forward on many more fronts is Phosphagenics, which has announced a Phase I trial funded by an unnamed US company, combining its agent for treating psoriasis with Phosphagenics' TPM technology. While Mayne Pharma's half year earnings took a hit from decreased Doryx sales, the cause was a temporary product transition issue.
**The Editors**
**Companies Covered: ACR, CXS, MVP, MYX, POH, PYC**

| | 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) | 28.5% |
| **Cumulative Gain** | **272%** |
| **Av Annual Gain (9 yrs)** | **18.5%** |

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# Bioshares

**25 March 2011**
**Edition 401**

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

## *Acrux – Axiron Launch Imminent & $100 Million to be Paid to Shareholders*

Acrux (ACR: $3.65) is about to start doing what all businesses aim for, deliver a return to shareholders. On April 19 the company will pay a 60 cents per share dividend to shareholders equating to a total distribution of $100 million. The dividends will be unfranked and the dividend will be exempt from tax because of the company's pooled development status. The stock will trade ex-dividend from 31 March.

All subsequent returns are expected to be fully franked. The company had waited on a ruling from the Australian Taxation Office before it could declare its dividend, due to the complexity around the company's Pooled Development Fund status. Once the dividends are franked, shareholders can elect to either treat the dividend as tax exempt, or treat the dividend as taxed and receive the franking benefits. The advantage of the latter it appears may be in say a superannuation fund where the tax rate is 15% and the fund could receive a tax refund for the remaining 15% tax paid. (Investors should confirm this with their tax advisor.)

The launch of the company's leading product, Axiron, a testosterone gel for men, is due for 'imminent' launch in the US, a few months earlier than anticipated. Other developments to look out for are the approval of the company's Hormone Replacement Therapy product in Europe, called Ellavie, and a decision about extension of the company's patent protection in the US out to 2026.

Acrux is capitalised at $607 million.

*Bioshares* recommendation: **Hold**

Bioshares

# *Phosphagenics – The Slicing and Dicing Continues*

Transdermal delivery technology company Phosphagenics (POH: $0.11) recently completed a capital raising, adding $7.1 million to its cash reserves, which stood at $2.7 million at December 31, 2010.

While cash resources may appear at the low end, given the development projects at hand, the company anticipates revenues of $6 million for calendar year 2011.

Some of this revenue is expected to flow from sales of its Elixia range of cosmetics, which incorporate the company's TPM technology. The product range is expected to be launched in Australia in April, the US in May and India in July.

And while Phosphagenics has five pharmaceutical products underway, four of those are funded or are expected to be by partners, leaving the oxycodone patch program to be fully funded by Phosphagenics. Phosphagenics also expects to announce a partner for its dermatology program for tretinoin delivery. Tretinoin, which is also known as retinoic acid, is used to treat acne.

### New Dermatology Collaboration

In February, Phosphagenics announced a collaboration with an unnamed private US dermatology company to develop a prescription drug to treat psoriasis. The company will fund a Phase I study of the IND cleared program. This trial is expected to commence in the first half of 2011.

The dermatology company has an option to license the Phosphagenics TPM technology after completion of the Phase I trial. Phosphagenics reported that in vitro studies showed the TPM instigated a 5-fold increase in the amount of active drug.

### New Agricultural Opportunity

Phosphagenics recently structured a deal with Mastitis Management Australia (MMA) for the development of a formulation to treat mastitis in dairy cattle.

Mastitis is a term that refers to infections and inflammations on the udders of dairy cattle, affecting up to 5% of dairy herds.

Phosphagenics expects to receive revenue from this application in 2011, from September onwards. The formulation will be delivered by drenching, a standard method for treating farm stock for many conditions. MMA expects to sell the formulation for $30 for a month's worth of treatment, or $1 a dose. The competitive point of difference for the TPM mastitis formulation is that dairy farmers should be in a position to eliminate or reduce the use of antibiotics used to treat mastitis and avoid placing cattle in 'hold' while antibiotic treatment is effected. Potentially, lost milk production is regained.

Mastitis Management Australia was formed in March 2010. MMA conducted pilot studies in South Australia which reported a 61% decrease in somatic cells in milk (a clinical definition of mastitis).

The appointment of Australian and New Zealand licencees and distributors is pending.

### Oxycodone Update

Phosphagenics has been developing an oxycodone product for the treatment of chronic pain.

After several years of research the company has elected to use a matrix patch instead of a reservoir design and has been working with 3M on commercial scale manufacturing of the product.

The company is planning a Phase II/III trial, enrolling potentially 150 subjects in the Phase II trial, and continuing with 50 subjects for the Phase III component to evaluate chronic (longer term) exposure.

Phosphagenics expects to commence an Australian component of the Phase II/III trial in 2011 Q3, after 3M signs off on large scale manufacturing. The company anticipates submitting an IND to the US FDA in 2011 Q4.

A Phase I trial demonstrated that therapeutic levels of greater that 8 ng/ml were achieved with repeat dosing.

### Anti-cellulite compound (AOP9604)

Phosphagenics took a license to **Metabolic Pharmaceuticals'** AOD9604 ( a peptide fragment of the human growth hormone) in September, 2010. It has been developing a cosmecuetical topical product to reduce cellulite and sub-cutaneous fat. It expects to announce results of a formulation study in 2011 Q2. Phosphagenics has also developed an assay for the product.

The AOP9604 formulation also contains two other agents, forskolin and caffeine, which are lypolitic (i.e. break up fat cells), and also work synergistically. The inclusion of these two agents should mean that the quantity of AOD9604 used can be reduced significantly, and reduce cost of goods.

### Summary

The goal of a platform technology company such as Phosphagenics should be to get as many products in the market as possible, whether through direct development or through partnerships and collaborations. Not all will succeed, however, if managed properly, the recourse to shareholders for funds should be limited yet significant income streams should still eventuate.

The challenge for Phosphagenics is to execute successfully on internal programs but at the same time maintain careful oversight of partnered programs.

Phosphagenics is capitalised at $91 million.

*Bioshares* recommendation: **Speculative Buy Class A**

**Bioshares**

# *Mayne Pharma Takes Hit to First Half Earnings*

Mayne Pharma Group (MYX: 70 cents) didn't hit its minimum earnings forecast in the first half of the current financial year. It delivered an EBITDA of only $5.1 million, less than the expected $9.1 million for the half.

The reasons for the significant shortfall was an appreciating Australian dollar (a forecast 90 cents against the USD with the average actual settled rate being 94 cents) and a delay by its partner **Warner Chilcott** in getting a new version of the acne treatment drug Doryx approved, which Mayne manufactures in Adelaide.

Revenue that Mayne receives from Warner Chilcott for manufacturing Doryx previously contributed to around 60% of sales. Based on total sales at mid-2010, which were tracking around $70 million, that equated to Doryx manufacturing revenue estimated at $42 million. Total sales in the first half on this financial year were just under $27 million, or annualised at around $54 million. With Doryx manufacturing revenue now contributing to 50% of total sales, that indicates that Doryx revenue for Mayne has dropped from $42 million to $27 million on an annualised basis.

### Life Cycle Management

As a part of a life cycle management strategy to keep generics at bay, Warner Chilcott continues to modify its product, either from new strength formulations, or from improved formulations. Warner Chilcott is currently waiting on the approval of an improved formulation of Doryx from the FDA and in the meantime has been letting inventory levels run down low in anticipation of the new formulation approval. It previously had four months of Doryx 150mg stock. Each time Warner Chilcott has introduced a new version of Doryx it has managed to increase the market size for the product.

In December last year the FDA approved generic versions of Doryx in the 75mg and 100mg doses from Mylan and Impax. These launched in January this year 'at risk' as Warner Chilcott puts it, because there are legal disputes pending between the respective companies. That means those companies may be required to pay Warner Chilcott damages if they patent dispute goes against them. However, these doses of Doryx only contribute to 5% of Doryx sales.

The other 95% of Doryx sales come from the 150mg dose. As of September this year, **Impax** and **Mylan** may start manufacturing the 150mg dose of Doryx. However, there is a patent dispute (litigation) between Warner Chilcott and Impax and Mylan in process. So this 150mg dose may also be released 'at risk'.

In December last year Warner Chilcott settled with one of the generics, **Heritage Pharmaceuticals**, where Heritage can start selling all three doses of Doryx after December 2016. Analysts at UBS are expecting Warner Chilcott to maintain its stronghold over Doryx to 2016. UBS is forecasting sales to increase 12% this year to $193 million, and to almost double in 2016 to $334 million.

Product transition is one of the ways branded pharmaceutical companies can keep generics at bay, moving on to improved formulations. However, it will need to get that new formulation out before September just in case its litigation against Mylan and Impax for the 150mg dose is not successful.

Our expectation is that Mayne's revenue from Doryx manufacturing will bounce back this year, although the company admits that this financial year will not meet previous forecasts. Mayne is also seeking price rises for its services given the strengthening Australian dollar and the delay in Doryx orders. It has some good grounds to argue its case.

### European SUBACAP Approval

Mayne has developed an improved version of the antifungal drug, itraconazole, which generates global sales of US$545 million a year. The leading brand is Sporanox from **Johnson & Johnson**. Mayne's version has twice the bioavailability, meaning that a half dose form can deliver the same result, has less side effects, and delivers a more consistent result across patients due to its more consistent absorption profile.

The drug candidate was filed for European approval in December last year. The company should receive a decision by the end of this year and then reach the market in 2012, once a marketing partner is assigned. The annual sales of itraconazole in Europe are around $120 million.

Further blue sky for Mayne is if it can widen the usage of itraconazole and take market share away from other antifungals. Itraconazole has a wider effectiveness against fungal infection, however, it has a poorer toxicity profile because its poor absorption has hindered its use. If Mayne is successful in improving that toxicity profile through better absorption, then it may well increase the market.

Although the global market for itraconazole last year was US$545 million, the global market for the top 10 antifungal drugs was just under US$5 billion.

The company will also seek to start selling the drug into Asia and South America with European approval. The market for itraconazole is currently expanding in China.

The company's European submission is based on two 50mg doses of SUBACAP, versus the standard two 100mg doses of itraconazole (Sporanox). In the pharmacokinetic trials, the company found that comparable effect at half dose was achieved, how there was substantially less variability between patients in terms of level of drug absorbed compared to Sporanox. At low absorption of itraconazole, there is no efficacy, and at high absorption rates the drug becomes toxic (see table on page 13 on the company's 2010 Annual Report).

### US SUBACAP Regulatory Submission

In November last year Mayne completed successful Phase II results in the US with SUBACAP. Those trials also found that SUBACAP was not inferior to Sporanox at half the dose. The company will meet with the FDA in the second quarter of this year to discuss those results and the requirements to get the drug approved in the US. The market in the US is worth less than $100

*– Cont'd over*

# *Medical Developments International – Initiating Clinical Program to Gain Access to European Markets*

Medical Developments International (MDI) (MVP: $0.42) is a Melbourne-based supplier of respiratory products such as spacer chambers, peak flow meters and masks, oxygen delivery units and carbon dioxide absorbers. However, the company is better known as the supplier of a fast acting pain relief product, Penthrox (methoxyflurane), known as the 'green whistle'.

Penthrox is sold to ambulance services, the military and other organizations where emergency pain relief is required. The company is also looking to build sales to dentists, podiatrists and cosmetic surgeons.

Penthrox is administered by inhalation of a 3 ml dose, providing up to 25 minutes of pain relief. No more than 6 ml is recommended for administration per day.

Penthrox is not used outside of short-term pain relief because higher doses (in the range of 40-60 ml) were found to cause kidney damage.

Although Penthrox has safety limitations, it is not an opioid based medication. Opioids are a class of drug that give rise to dependency issues. A drug similar to Penthrox in delivering fast pain relief is fentanyl, which is however an opioid class drug.

Penthrox sells for approximately $23 in Australia. The product was listed on the PBS in 2010 under the Doctors Bag Item List, which covers the inclusion of one unit per doctor's bag.

### Half Year Results

For the half year ended December 31, 2011, MDI recorded sales of $5.1 million, an increase of 23% from the previous corresponding year. The company recorded a net profit after tax of $0.8 million, 143% higher from the same period a year ago.

MDI's gross profit margin for the half year was 63.4%, down slightly from 64.6% from previous corresponding year.

The company's pharmaceuticals (predominantly Penthrox) business turned over $3 million in the most recent half year, or 60% of sales. Respiratory products account for 36% of sales. Approximately 80% of sales of Penthrox are to ambulance services.

[Sales for FY2010 were $8.3 million, down 5% from $8.7 million in FY2009. NPAT for FY2010 was $0.88 million, up slightly from $0.8 million in FY2009.]

### Clinical Trial for Europan Registration

MVP has announced plans to conduct a pivotal clinical trial of Penthrox in Europe to enable access to European markets. The trial will be a randomized, double-blinded, multi-centre, placebo controlled study to evaluate the safety and efficacy of Penthrox for the treatment of acute pain in patients presenting to an Emergency Department with minor trauma.

The company will invest approximately $2.5 million on the European clinical study. The study, although not completely finalized, is expected to be conducted at up to four sites in both UK and France. The goal is to start recruiting in April and be completed by the end of the year. A regulatory submission would follow in 2012.

### Other Clinical Trials

In recent years MDI has sponsored trials of Penthrox, including a 60 patient randomized trial in patients undergoing computed tomography enteroclysis, a procedure which requires the insertion of a nasal tube. Patients who were administered Penthrox were more comfortable than with the scented saline placebo (p=0.002).

A randomized trial at the **Peter MaCallum Institute of Cancer Research** in 110 patients undergoing bone marrow biopsy was completed in 2009. The trial showed that Penthrox delivered a significant improvement in comfort compared to placebo. However, these results have yet to be formally published.

### Comment

MVP has built a solid business in Australia from sales of Penthrox and respiratory medicine products. The challenge, which it is now addressing, is to take Penthrox into major pharmaceutical markets.

The company's decision to invest in a clinical trial is to be welcomed, although it must be noted that it has taken some time to put the company on a more solid footing from which to generate cash for such a project. The recruitment of a new CEO, John Sharman (formerly with **Vita Life Sciences**, **Cyclopharm** and **CVC Venture Managers**), in April 2010 could be seen as a turning point in lifting the company's sales figures, which are running a t$10 million on an annualized basis. MVI has also focused on improving stock management and raw materials purchasing.

Medical Developments International is capitalised at $22 million and retained cash of $3 million at December 31, 2010.

*Bioshares* recommendation: **Buy**

**Bioshares**

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*– Mayne Pharma cont'd*

million a year.

### Financials

Mayne Pharma is capitalised at $106 million. It had cash after debts of $8.5 million at the end of last year. It has paid out $6.5 million of its maximum $41.6 million earn out over six years to **Hospira** from its acquisition of the Mayne business in 2009.

*Bioshares* recommendation: **Buy**

**Bioshares**

# *Phylogica Beefs Up Cash Balance*

Phylogica (PYC: 7.1 cents) announced it has secured $5.2 million by way of a placement to US sophisticated and institutional investors. The shares will be issued at 5.9 cents and will include a free option (exercisable at 9 cents) for each two shares acquired under the placement.

At the end of last year Phylogica had $1.8 million in cash and should have received just under $1 million from deals in January. The company expects to move into profitability in FY2012, the implication being that this raising may not have been required.

The move to install Nick Woolf, a very experienced European biotech finance executive, as CFO and head of investor relations, is working well for the company. Woolf is a good communicator who is able to articulate the company's assets and prospects to local and overseas investors. The founder and CEO of the company, Paul Watt, has moved to the UK to be closer to partners and Woolf is now based in Perth.

Woolf said the funds raised would also help strengthen the company's balance sheet which would place it in a stronger position when negotiating further pharmaceutical discovery deals this year.

## Insititutional Investor Interest

Another important aspect of this raising is that several new local and international institutional shareholders have taken part, including **Ascent Biomedical** in the US, which is mainly a venture capital group but also runs a listed companies fund. Woolf had known the Ascent Biomedical group through his previous roles in the UK. This raising consisted of 20% retail investors and 80% institutional funds, which Woolf said helps mature the company's register.

The additional funds will allow the company to further invest in its R&D facility, including additional robotics, to handle the expected increase in workflow from its collaborations. Currently the company can conduct seven screens at once and the new robotics will allow the company to handle 20 screens at a time. More work will be conducted on upgrading the company's libraries, adding new genomes, delivering different formats and different types of screens, as well as investing in lead optimisation capabilities. This will equate to a modest increase in R&D, and the company will also invest further in business development.

## Further Deal Flow Expected

Phylogica has signed three pharmaceutical discovery deals since December 2009. These have been with Roche, MedImmune (Astrazeneca) and Pfizer. The Roche program has been successfully completed, meeting all the milestones, and Phylogica is in discussions to expand that into a second program. The company says all running programs are on track and is hopeful to progress all three of these collaborations. The company is also seeking to sign deals with three new pharmaceutical companies this year.

Success breeds success and likewise for Phylogica, the more deals it can sign and progress, the easier it is becoming to get the attention of large partners. Another reason the company is gaining more attention from pharma is that the view of peptides as pharmaceuticals is changing according to the company, with more interest in this drug class. The company says it is very comfortable with the guidance it has provided the market in relation to future potential deal flow.

## New Joint Venture Formed

Earlier this month Phylogica announced it had formed a joint venture company, called **Phenomica**. The company will contribute Phylogica's peptide libraries (called Phylomers) to a team at **Cambridge University** that will use the libraries for target validation. That team has shown that Phylogica's peptide library can be used to efficiently identify and validate new targets, hence the formation of the collaboration in a commercial venture.

The Phylomers will be used to elucidate the parts of cell and extracellular pathways that are being activated in disease states, to validate disease relevant biological targets. The Phylomers will not be used as drugs, just tools in the drug development process, potentially delivering an alternative technology to RNAi in target validation. One of the problems with RNAi is that they are difficult to deliver into cells. However, this is one problem Phylogica has solved in its collaboration with Roche in delivering other compounds into cells using its phylomers.

One of the reasons the company was formed was due to demand for this service from pharmaceutical companies according to Phylogica. Phenomica will have only non-exclusive rights to use the Phylomer libraries for target validation. The new venture is now attracting interest from UK investors.

Phylogica will be capitalised at $27 million after the raising.

*Bioshares* recommendation: **Speculative Buy Class A**

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**Bioshares**

**Bioshares Model Portfolio (25 March 2011)**

| Company | Price (current) | Price added to portfolio | Date added |
|---|---|---|---|
| Bioniche | $1.35 | $1.35 | March 2011 |
| Somnomed | $1.10 | $0.94 | January 2011 |
| Phylogica | $0.071 | $0.053 | September 2010 |
| Sunshine Heart | $0.034 | $0.036 | June 2010 |
| Biota Holdings | $1.01 | $1.09 | May 2010 |
| Tissue Therapies | $0.67 | $0.21 | January 2010 |
| QRxPharma | $1.41 | $0.25 | December 2008 |
| Hexima | $0.37 | $0.60 | October 2008 |
| Atcor Medical | $0.09 | $0.10 | October 2008 |
| Impedimed | $0.74 | $0.70 | August 2008 |
| Patrys | $0.10 | $0.50 | December 2007 |
| Bionomics | $0.43 | $0.42 | December 2007 |
| Cogstate | $0.18 | $0.13 | November 2007 |
| Sirtex Medical | $5.45 | $3.90 | October 2007 |
| Clinuvel Pharmaceuticals | $1.85 | $6.60 | September 2007 |
| Starpharma Holdings | $1.14 | $0.37 | August 2007 |
| Pharmaxis | $2.52 | $3.15 | August 2007 |
| Universal Biosensors | $1.27 | $1.23 | June 2007 |
| Acrux | $3.65 | $0.83 | November 2004 |
| Alchemia | $0.66 | $0.67 | May 2004 |

### *Portfolio Changes – 25 March 2011*

**IN:**
No changes

**OUT:**
No changes

## *Chemgenex in Trading Halt*

Chemgenex Pharmaceuticals (CXS: $0.44) has gone into a trading halt with a 'significant corporate transaction' to be announced. Chemgenex is due to complete the clinical data collection for the two pivotal studies of its cancer drug candidate, Omapro, for the treatment of chronic myeloid leukemia. The collection of this data should position the company to refile Omapro with European and US regulators.

The company expected its $15 million convertible note (at a conversion price of 50 cents a share) from **Cephalon** to be converted this quarter, giving Cephalon a 10% stake in Chemgenex. Cephalon also has an option to acquire a further 19.9% in Chemgenex at 70 cents a share either by the end of this month or a week after the clinical data from the two trials had been collected.

The collection of the data is looking at patients from the perspective of those who had failed two TKI (tyrosine kinase inhibitor drug) treatments rather than the previous drug submission that looked at one trial in patients with a particular genetic mutation (T315I), some of whom had also failed two TKI treatments.

Our expectation is that Cephalon will move to a 29.9% shareholder stake in Chemgenex, thereby triggering a takeover offer for the company, which if all goes to plan, should be at 70 cents a share.

*Bioshares* recommendation: **Under review pending announcement**

## 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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|---|---|---|
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| | $950 | 6-10 email addresses |

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