Meeting Transcript

Annual General Meeting
of
Acrux Limited

2.00pm, Thursday 21 November 2013

- **Welcome**

Good morning ladies and gentlemen. My name is Ross Dobinson, and I'm the Executive Chairman of Acrux Limited. Before we commence proceedings could I ask that you turn off your mobile phones for the duration of the meeting?

It is my pleasure to welcome shareholders to the 2013 Acrux Annual General Meeting. We would like to thank Pitcher Partners for the use of their facilities today.

The time is now 2.00 pm and as there is a quorum of members present, I formally declare the Meeting open.

I would like to introduce the Non-Executive Directors:

- Ross Barrow,
- Bruce Parncutt
- Tim Oldham

and also the Senior Management Team:

- CFO & Company Secretary - Tony Di Pietro
- Chief Operating Officer - Dr Clive Blower
- Commercial Director – Dr Nina Webster

Before we proceed to the formal business of the meeting I would like to provide an overview of progress since we last convened, and then we will hear from both Nina Webster and Clive Blower.

Chairman's Address

ACR at a Glance

Advances in the Last Year

Lilly has made significant progress with growth in market share in the US market and the international rollout of Axiron.

The key drivers for Axiron's growth include:

- Improved managed care formulary access
- New sales force efficiency
- Continuing effective Direct to Consumer ('DTC') marketing
- Product differentiation
- Improved marketing strategies for product awareness and brand loyalty

Axiron

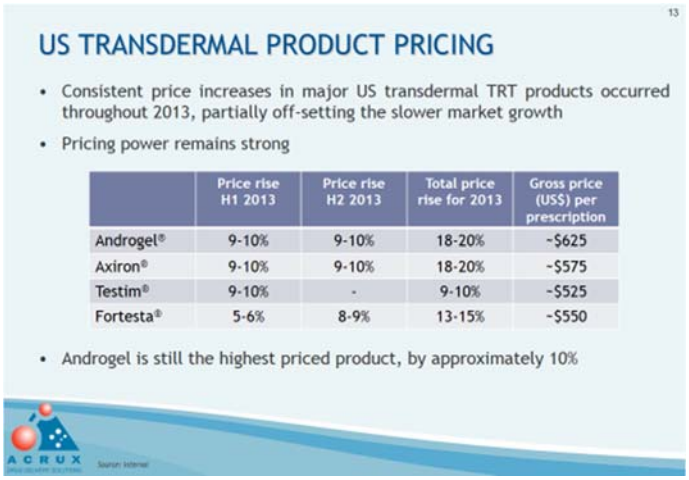
US Testosterone Market

As most of you are already aware, the TRT market growth has slowed over the past 12 months. However, following 2 years of rapid growth, the market continues to grow at double digit figures, with a current annualised growth rate of 11% over the first 3 quarters of the year.

We have received a number of questions about the market growth rate of the injectables compared to the transdermals. Note that the injectable market growth has also slowed considerably compared with previous years, and it is important to note that this is off a much lower sales base.

As you can see, the topical prescription market remains substantially larger, and with the cost of transdermals approximately 60% higher than injectables, the dollar value of the transdermal compared to the injectable market is further separated.

US Transdermal Product Pricing



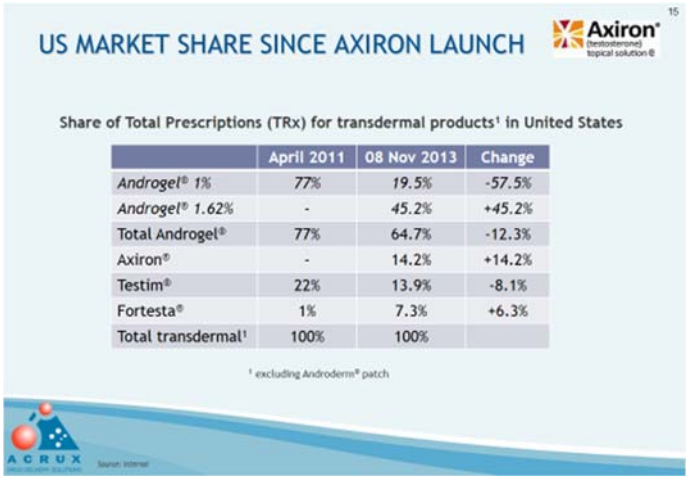
	Price rise H1 2013	Price rise H2 2013	Total price rise for 2013	Gross price (US$) per prescription
Androgel®	9-10%	9-10%	18-20%	~$625
Axiron®	9-10%	9-10%	18-20%	~$575
Testim®	9-10%	-	9-10%	~$525
Fortesta®	5-6%	8-9%	13-15%	~$550

Throughout 2013, we have seen consistent price increases across the major US transdermal TRT products, which have partially off-set the impact of the slower market growth.

Androgel remains the highest priced product, by about 10%

Importantly, the transdermal products have held premium pricing despite pressure from injectables and have not lost any market share as a result.

US Market Share

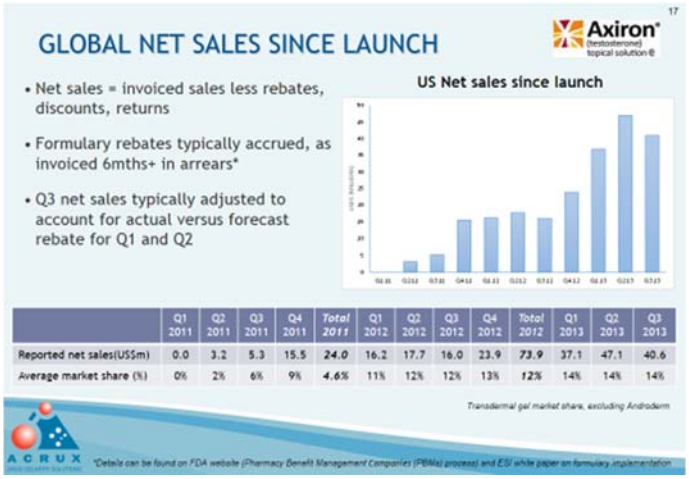


	April 2011	08 Nov 2013	Change
Androgel® 1%	*77%*	*19.5%*	*-57.5%*
Androgel® 1.62%	*-*	*45.2%*	*+45.2%*
Total Androgel®	77%	64.7%	-12.3%
Axiron®	-	14.2%	+14.2%
Testim®	22%	13.9%	-8.1%
Fortesta®	1%	7.3%	+6.3%
Total transdermal[1]	100%	100%	

Over the past 6 months or so, Axiron market share has remained relatively flat, at around 14%, despite the sales force disruption earlier in the year and the price increases. Essentially, the same number of prescription units have been sold, albeit at a higher price.

This is a testament to the impact of the direct-to-consumer marketing campaign conducted by Lilly during this time.

Global Net Sales Since Launch



To help you interpret our quarterly results, I would like to explain briefly how the health system works in the US. The US health system is unique in that it currently operates using private health schemes which are typically provided as part of an employee's total remuneration package. These schemes are managed by Commercial Managed Care entities ('CMC'), including Pharmacy Benefit Managers (PBM). Each PBM has its own formulary, which is a list of pharmaceuticals reimbursed by the insurer to the insured party. Typically, if a product is not on the list, then it is not covered by the employee's insurance.

Pharmaceutical companies wanting to have their product(s) listed on the formulary of a PBM have to negotiate with that PBM. The efficacy and safety of the product(s) are key drivers for inclusion, but where there are several alternative products available (which is generally the case), a percentage of the cost of the product, which is referred to as a rebate, is negotiated. After a patient has filled their script for the product and claimed this expense on their insurance, the PBM retrospectively claims the agreed rebate from the Pharmaceutical Company. Because of the complexity of the system, this claim is generally made approximately six to nine months after the product script has been filled.

The actual rebates payable to the PBMs by the pharmaceutical companies cannot be calculated in real time. The pharmaceutical companies have to

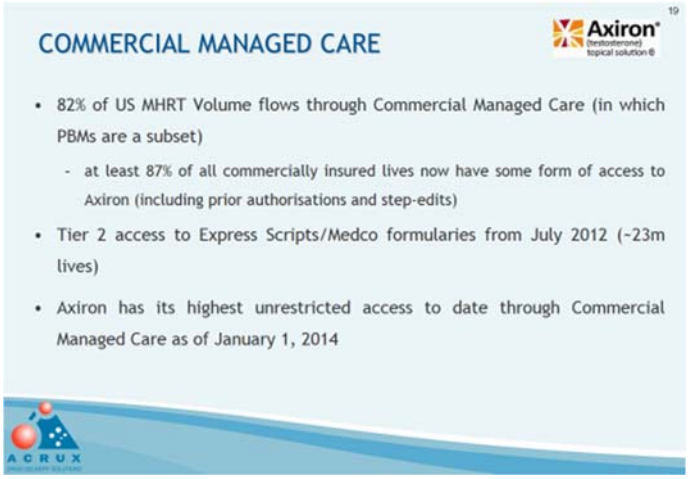
forecast or accrue what rebates they expect to pay to each PBM to calculate each quarter's net sales.

The level of net sales of the product also has to incorporate the costs of vouchers or co-pay cards that are instrumental in establishing market share when new products are first launched. The actual costs associated with the co-pay cards are difficult to establish accurately on a monthly basis during the initial launch period due to the distribution arrangements for these cards.

As a result, accounting entries to correct accruals for rebates on sales are made as claims patterns emerge and are typically made later in the calendar year in which those sales are made. These accounting entries provide adjustments to accruals in both recent and preceding quarters. With Axiron having now been on the market for more than 2 years, we anticipate future net sales of Axiron will more accurately reflect actual sales rather than being based on forecast accruals. Allowing for accounting adjustments for accrued rebates, Axiron has shown a consistent growth trajectory this year, and the next milestone of US$25 million is due in the first quarter of 2014, with a subsequent distribution to shareholders.

We also anticipate continuing growth in market share for Axiron, both within and outside the US.

Commercial Managed Care



Commercial Managed Care, which includes PBM Formulary Plan coverage, determines approximately 82% of the male hormone replacement therapy market volume in the US. Tier 2 access to national formulary coverage is

critical to the growth and maintenance of market share. Formulary coverage is a highly competitive field, with contracts usually negotiated annually. Axiron has secured the second largest share of market in a highly competitive growth sector and we expect the position to consolidate in calendar 2014 as the benefits of new marketing strategies, formulary access, a dedicated sales force and effective direct to consumer marketing result in higher consumer loyalty. Broadly based formulary coverage has been developed by Lilly since Axiron was introduced to the US market in 2011. Axiron's current ranking as the second highest prescribed product in the gel sector should improve future prospects for national formulary rankings among providers who are targeting a narrower spread of reimbursed products as part of a drive to improve overall operational efficiency.

Lilly's effective use of direct to consumer ('DTC') marketing has been instrumental in building and maintaining market share. During the period in which the Axiron sales force was being restructured, Axiron's market share was maintained by the DTC campaign run by Lilly. Given the effectiveness of DTC advertising in building Axiron's market to date, we anticipate Lilly will continue to use this as a key plank in their overall market development platform.

Potential beyond the US market

Ex-US markets for testosterone therapy are underdeveloped

- Current annual sales are approximately US$300 million
- Annual US sales were approximately US$300 million ten years ago

- The number of potential patients in the rest of world is greater than in the US, although pricing and reimbursement scheduling are less beneficial
- Axiron has already been launched in Canada and Australia and approved in Brazil and Germany
- Canada, Australia, Germany and Brazil comprise more than half the current ex-US market
- Canada is currently the largest ex-US market for testosterone
- Germany, which is the first European approval, is currently the second largest ex-US market

Lilly as a Committed Partner

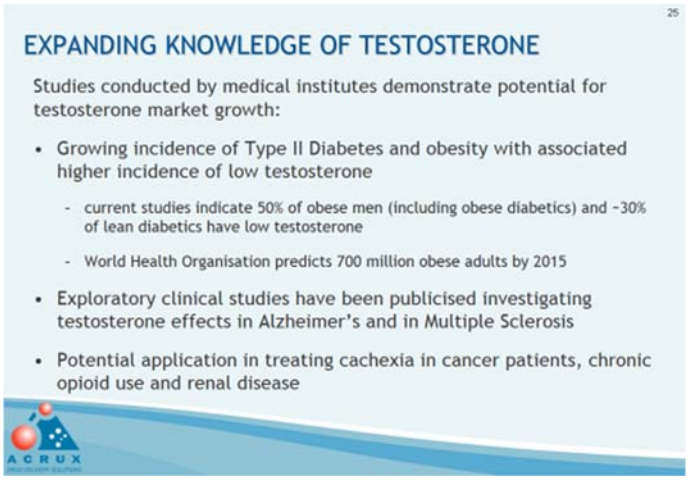
- Lilly has already paid Acrux approximately $171m, and as stated previously, we expect to receive the next milestone payment of $25m under the License Agreement in the first quarter of 2014
- Lilly restructured their sales force in early 2013. This restructure resulted in a hiatus in the second and third quarters, however with a fully operational men's health focused sales force, it is expected to provide renewed impetus and focus on increasing market share in 2014.
- Lilly has made significant investments in both supply chain improvements and expansion of manufacturing capacity, reflecting a confidence in the long term prospects for Axiron
- Intensive direct to consumer marketing is ongoing, and this has been critical in building the overall market and maintaining market share during restructuring activity
- Lilly is constantly refining its methodology for marketing to specialists and Primary Care Physicians to improve market share

- Clinical trials are being conducted by Lilly, including:

    - A trial for enhanced sex drive and energy levels
    - An ejaculatory dysfunction trial, and
    - A trial for suboptimal responders to testosterone gels other than Axiron

  These trials represent significant commitments by Lilly to expanding the therapeutic indications for Axiron.

Expanding knowledge of testosterone



- The clinical trials and marketing being undertaken by Lilly and other pharmaceutical companies will be instrumental in helping create awareness of hypogonadism and disease states that have high incidences of hypogonadism
- There is scope for testosterone use in other indications such as cachexia, which is the muscle wasting and weight loss that occurs in the later stages of cancer.

Axiron's growth will also be driven by:

- product differentiation
- ease of application, and
- safety profile

The major threat to Axiron is likely to come from the introduction of generic 2% strength gels, which are anticipated to be introduced from 2017.

Product differentiation for Axiron will continue to be based around the area of application required, the site of application, i.e. the axilla, and the ease of application. We believe that our intellectual property portfolio will provide significant differentiation relative to the competitive products that are currently available and generic versions that will be released to the market in future. Patient compliance will be driven by these differentiating factors. A high level of compliance and consumer acceptance of the product will be integral to maintaining support from both prescribers and insurers.

I will now ask Nina to provide the overview of Acrux's intellectual property position and the competitive landscape in the United States…

Nina's talk

Thank you Ross.

Patent Protection in the United States

In the United States Axiron, is protected by 8 patents, the last of which expires in 2030. The patents cover 3 different important aspects of the product – the formulation and delivery method, administration of testosterone to the underarm and the physical applicator. As always, we continue to assess and grow our intellectual property portfolio.

Axiron's sales have now reached a level that has attracted two generic companies, Perrigo and Watson (now known as Actavis), to attempt to challenge our patents. This type of action is very common in the US (Watson and Perrigo have also separately challenged the Androgel, Testim and/or Fortesta patents). Lilly and Acrux have filed two lawsuits in the US alleging infringement by Perrigo and Watson of the Axiron patents. Both companies

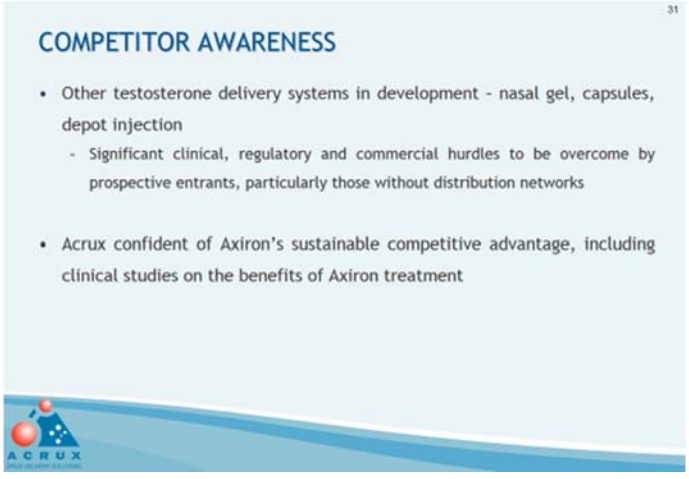
have independently submitted an ANDA to the FDA for a copy of Axiron, including a "Paragraph IV" certification that it did not infringe the Axiron patents. In order to be able to market the product, both Perrigo and Watson are likely to have to prove to the judge that the Axiron patents are invalid or unenforceable. The process is long and it is unlikely that we will see an outcome for several years. Importantly, the lawsuits will not have a material impact on Acrux's operating expenditure.

Competitive landscape in the US

As expected in such an attractive market, other companies are trying to find a way to enter.

A number of companies have also challenged Androgel, Testim and/or Fortesta patents in advance of the respective 2020/2026, 2023 and 2018 expiries. Multiple litigations are in progress as well as a US Supreme Court review of a past deal between Solvay, Watson and Par. We think that Abbvie, Auxilium and Endo will aggressively defend their patents. However, because this market is so differentiated, if any copies of these products were launched, none would be substitutable for Axiron.

Competitor Awareness



Other delivery systems for testosterone are in development, in particular a nasal gel, a long-acting injection and capsules. All still need to overcome clinical and/or regulatory hurdles and most are with companies that have no distribution capability. Two of the lead products, Androxal (an oral product) and CompleoTRT (an intra-nasal product) have both hit further regulatory hurdles in the past month, and need to further address safety and efficacy concerns which will delay any product approvals. It is also unlikely that a commercial partner will be secured for either of these products until clarity from the FDA is achieved.

Either way, we believe that Axiron has sustainable competitive advantage against all of these potential competitors.

Thank you, and back over to you Ross…

Thank you Nina.

Other Products

During the year we licensed Evamist, which was our first product, outside the US. We expect an additional milestone to be payable soon under the terms of this agreement.

Pipeline Products

Acrux has been searching for complementary products and delivery technologies since inception. A screening mechanism to identify new products and technologies has been in place, together with an active assessment of potentially complementary companies. This assessment work has been undertaken on a confidential basis. The assessment process has been undertaken efficiently and the cost absorbed in our annual burn rate as the assessments have been undertaken on a 'fast to fail' basis. We have not proceeded with any new technologies until now and we have not made past assessments public, as the likelihood of their progressing has been relatively low. Our methodology has been based on the following project attributes:

- Within our experience and knowledge base
- Able to be assessed on a 'fast to fail' basis – if the project's viability could only be assessed after significant expenditure and/or over a lengthy period it hasn't been pursued
- Offer significant upside
- An acceptable level of commercial and technical risk
- Strong intellectual property base
- Recognised market opportunity (not a nascent one)

- Preferably developed by a team with a track record and industry recognition
- Appropriately priced
- Clear regulatory path to market

Although this list is relatively brief there are very few projects that meet most of the requirements we have set. The projects that Clive will now present on have met all these requirements, which is the reason we are presenting an outline to shareholders. I will still add the caveat that commercialising science is difficult and the projects meet the criteria of being 'fast to fail'. We will be able to advise shareholders early next year regarding progress with proofs of concept for both projects.

I will now hand over to Clive to provide a more detailed overview of our pipeline products.

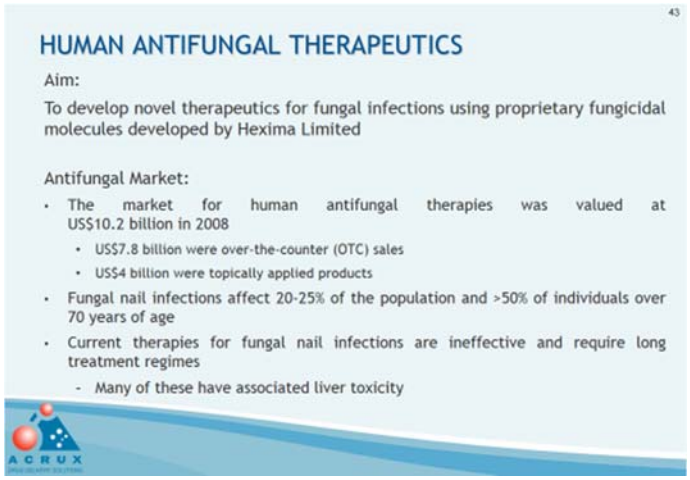
Clive's slides

Thank you Ross.

Cancer Therapeutics

Human Antifungal Therapeutics

The second pipeline product we are currently investigating is in the field of anti-fungal therapies



Overall we are very encouraged with the progress to date for both of these therapeutic programmes.

Thanks you, and back to you Ross.

Thanks Clive. We are very pleased to have initiated these new programs, which have the potential to build significant shareholder value.

I will close the operational report by summarising the financial outlook for revenue and expenditure.

Resolutions

This concludes the operational report and we will now proceed to the formal business of the meeting. Each shareholder who registered today would have received a yellow voting card. On a show of hands to vote on a resolution to be put to the meeting I will ask you to raise your voting card to assist in the counting of votes.

Shareholders should be aware that the Company has received proxies representing over 85 million shares, for each of the resolutions. Details of these proxies will be provided prior to each resolution being put to the meeting by way of an overhead slide.

If you wish to speak to a motion or ask a question, please raise your hand. When you have been acknowledged, please identify yourself before speaking, and I would ask that you raise only one topic at a time. If a poll is required on any resolution, it will be held at the appropriate time.

The Notice of Meeting was mailed to all registered members on the 18th of October. I will take the Notice of the Meeting, including Explanatory Notes, and the Financial Report, the Directors' Report and Auditor's Report as read.

- **Item 1 - To receive and consider the Financial Report, and the Reports of the Directors and Auditor for the year ended 30 June 2013**

The first item of business is to receive and consider the Financial Report and the Reports of the Directors and Auditor for the year ended 30 June 2013.
This item of business does not require a resolution to be put to the meeting and so I will not be calling for mover or seconder.

I will now open this item for discussion. Would anyone like to address any questions to the Company or to representatives of Pitcher Partners, the Company's Auditor, who are present at this meeting?

- **Item 2 – Adoption of the Company's Remuneration Report**

The *Corporations Act* requires the Directors' Report to include certain information relating to director and executive remuneration in a "Remuneration Report".

The *Corporations Act* further requires that each Australian listed public company put to a vote at its annual general meeting a resolution that the Remuneration Report be adopted. The vote is advisory only and does not bind the Directors of the Company.

The Remuneration Report can be found at pages 24 to 28 of the Company's 2013 Annual Report.

Accordingly I move:

That the Company's remuneration report for the year ended 30 June 2013 be adopted.

Are there any questions or comments in relation to the Remuneration Report?

If there are no (further) questions, you will now see on the screen the proxy votes in relation to this resolution.

I note that a vote must not be cast on this resolution by or on behalf of a member of the Company's key management personnel, details of whose remuneration are included in the Remuneration Report of the Company, and their closely related parties, unless the vote is cast as a proxy in accordance with the directions contained in the proxy and the vote is not cast on behalf of a member of the key management personnel or their closely related parties.

As a member of the key management personnel of the Company, I am not permitted to cast any votes in respect of this resolution that arise from any undirected proxy. I will, however, vote any directed proxy in accordance with the direction contained in the proxy.

I now put the resolution.

All those in favour?

All those against?

I declare the resolution passed.

- **Item 3 – Re-election of Timothy Oldham as a Director**

The next resolution relates to the proposed re-election of Timothy Oldham to the Board. Mr. Oldham was appointed as a Non-Executive Director of the Company in October of 2013. The resolution is confirming his appointment by the Board.

Accordingly I move:

That Timothy Oldham, who in accordance with clause 56 of the Company's constitution offers himself for re-election as a Director, be re-elected as a Director of the Company.

Are there any questions or comments in relation to the resolution?

If there are no (further) questions, you will now see on the screen the proxy votes in relation to this resolution. I also wish to inform the meeting that I intend to vote any undirected proxies in favour of this resolution.

I now put the resolution.

All those in favour?

All those against?

I declare the resolution passed and congratulate Tim on his rejoining the Board.

The next two resolutions relate to me, so for these items of business I will relinquish the chair in favour of Ross Barrow, who Chairs Acrux's Remuneration Committee.

Ross Barrow takes the Chair.

- **Item 4 – Re-election of Ross Dobinson as a Director**

  The next resolution relates to the proposed re-election of Ross Dobinson to the Board. Ross was appointed as a Director of the Company on its incorporation in March 1998. The resolution is confirming his appointment by the Board.

  Accordingly I move:

  That Ross Dobinson, who in accordance with clause 56 of the Company's constitution offers himself for re-election as a Director, be re-elected as a Director of the Company.

  Are there any questions or comments in relation to the resolution?

  If there are no (further) questions, you will now see on the screen the proxy votes in relation to this resolution. I also wish to inform the meeting that I intend to vote any undirected proxies in favour of this resolution.

  I now put the resolution.

  All those in favour?

  All those against?

I declare the resolution passed and congratulate Ross on his re-election to the Board.

- **Item 5 – Grant of options to Ross Dobinson**

The next resolution relates to the proposed grant of options to Ross Dobinson.

Accordingly I move:

That Ross Dobinson be granted options to subscribe for 600,000 ordinary shares, with an exercise price of $4.30 per share and upon exercise of those options, the issue of shares underlying the options.

Are there any questions or comments in relation to the resolution?

If there are no (further) questions, you will now see on the screen the proxy votes in relation to this resolution. I also wish to inform the meeting that I intend to vote any undirected proxies in favour of this resolution.

I now put the resolution.

All those in favour?

All those against?

I declare the resolution passed and pass the Chair back to Ross Dobinson.

- **Close of formal business;**

As that concludes the formal business, I declare the meeting closed.
We will be happy to now take questions from the floor, followed by further discussion over coffee.