2010 AGM CHAIRMAN'S ADDRESS AND CEO'S PRESENTATION

Chairman's Address

Before addressing the formal matters before the AGM I would like to provide you with a brief summary of the history of Acrux. Recent successes may have overshadowed the facts underlying the Company's development, and as it's often noted, success has a hundred fathers and failure is a bastard child.

Acrux was the result of an introduction by Peter Burrowes, who has subsequently been the guardian at every Acrux AGM since. Peter introduced me to Barrie Finnin approximately 12 years ago, setting in motion a chain of events that was kept on track initially by the tireless intervention of Prof. Colin Chapman at the Victorian College of Pharmacy during our negotiations to make sure that the technology didn't end up being a part of FH Faulding & Co. Ltd.

After this interaction in 1998 the Company's development strategy was formulated, identifying the target indications for the technology including estradiol and testosterone. We brought on our first employees, including Nina Webster and Felicia Colagrande, who are still with the Company today. Since then we have seen a number of employees and stakeholders come and go, but we still have many of our initial shareholders with us today. The fact that so many shareholders shared the vision and were generous enough to trust us with the custodial role has been a source of immense satisfaction to myself and the other remaining founders of the Company.

Barrie worked on the IP for almost twenty years before the Company was established, taking his involvement with the technology to a thirty year span. He has played an integral role in the Company's development, and unlike some founders I have dealt with in the past, Barrie has retained a significant shareholding and his absolute alignment with the interests of other shareholders.

Ken Windle has also played a key role in the development of Australian biotechnology and Biota's Relenza would not have existed without Ken's involvement. Ken was a relatively early member of Acrux's Board following his introduction of a significant investment in Acrux through Blue Dot Capital. Like Barrie, Ken has retained his shareholding through a long and tortuous development period and his knowledge base has been integral to the Board's strategic decisions.

While Axiron has attracted more attention than our other initiatives, it is worth bearing in mind that other developments like Evamist have paved the way for Axiron by proving the commercial viability of the Company's intellectual property. While Axiron was a long standing candidate for development, Acrux has faced the problem of limited

resources for most of its commercial life, and we have only been in a position to undertake the development internally following our success with the licensing and outsourcing of the development of Evamist to a US based licensee. Our success with the development of Axiron may help overcome the historical lack of confidence in the competence of Australian companies to undertake comparable projects in Australia and to capture full value here. This should be one of the major benefits of the Company's recent achievements.

I have always maintained that the role of Boards is twofold - to provide the strategies to realise value for shareholders and to ensure that resourcing is appropriate to enable implementation of the strategies adopted. Acrux's Board composition has varied over time but two Directors have been with the Company from inception and a third member joined early in the Company's formative period. The commercialisation of male testosterone has been a key plank of the Company's strategy for over a decade, and the Board has modified the management team over time to enable this application of the Company's intellectual property and other key development strategies to be implemented.

From 1998 I financed the Company for the first eighteen months of its existence when the title to the IP was unclear and the risk profile was very high. I subsequently committed to further investments in the Company, both prior to and including the IPO in 2004 when the Company was still in a high risk category. To provide the capital base required for the Axiron development program the Board undertook a rights issue which I committed to above my pro rata allocation to ensure there was sufficient confidence among other shareholders in the Board's commitment to the raising and the application of those funds. My confidence in Acrux at the stage of the rights issue was a simpler decision than had previously been the case.

.The actions of the Board, the founding shareholders, individuals like Prof. Chapman and many other stakeholders since have enabled the Company's management team to implement the Company's strategy with the Board's assistance. In the negotiations with Lilly, the Board's experience base was integral to optimising the commercial outcome and laying the foundations for strong, sustainable cash flows and a robust dividend policy.

The Board has always had a policy of including the management team as material shareholders to align their interests with those of other shareholders. The Company has also maintained a remuneration scale that is highly competitive, which has enabled us to attract and keep the highly competent team which has helped us to deliver the Axiron approval.

The Axiron and Evamist approvals and the licensing deal with Eli Lilly & Co. have delivered on part of the strategy that was first outlined to investors during the

Company's inaugural presentation to investors in the offices of Deutschebank in mid 1999. We believe the next phase of the Company's commercial maturation will be more rapid and more rewarding for investors, and I would like to extend the appreciation of the Board for the confidence, support and patience displayed by stakeholders that has enabled the Acrux team to reach this critical point in our development path.

The Board is pleased to have achieved success with the approval of Axiron, but we are more excited about the prospects of a successful product launch in 2011 and strong market growth in a rapidly growing market niche.

We expect Axiron to be the global market leader in its sector, and Richard will address the growth prospects in detail in his presentation. The Board has been assessing the appropriate strategy for Acrux post the Axiron launch since the development of the product was initiated. During the intervening period we have assessed and discarded both a number of alternative development proposals and several drug candidates. The Board's key consideration is optimisation of shareholder value. This is not necessarily guaranteed by embarking on programs with high technical risk, high capital requirements or long development timetables. Another consideration has been the availability of genuinely compelling and novel projects in our area of expertise, namely the transdermal delivery of drugs for the treatment of chronic disease. The Board has been conscious of the need to avoid creating continuity for continuity's sake - all things have a useful life and we have constantly been assessing what Acrux's useful life is and the form that the Company should have at each stage of its commercial maturation.

We have previously advised shareholders of our intention to extract value from all commercially viable applications of the Company's technology. Richard will address progress with Luramist, contraception and non-steroidal anti-inflammatories or NSAIDs in his presentation. None of these applications warrants continuity of the present Company structure in its own right. The most compelling proposal assessed by the Board since the development of Axiron was initiated lies in complementary products for Axiron, and management is undertaking a detailed analysis of these projects before the decision is taken to pursue or abandon this initiative. The Board expects to reach this decision point prior to the end of the first quarter of 2011.

We are currently reviewing our licensing arrangements and assessing the optimal organisational structure. We will maintain as comprehensive communications as possible with shareholders regarding these developments,, subject to confidentiality provisions.

While this represents a major development in the Company's maturation I am pleased to advise that the prognosis for the Company is overwhelmingly positive. Subject to exchange rates and progress with Tax Office Rulings, we anticipate being able to pay a dividend of approximately sixty cents per share in the first quarter of 2011. This represents something of a landmark in the biotech sector In Australia, and subject to a reasonably successful launch of Axiron we anticipate that the Company should be in a position to continue to pay dividends in future. This is consistent with the Board's

decision to pursue the late stage development of Axiron in-house to enable the Company to structure a licensing deal with Lilly which provided the Company with a royalty stream that enabled meaningful dividends. The Board is confident that its expectations are not overly optimistic.

The Board is keen to ensure that any expenditure that reduces the dividends paid are warranted in the context of building shareholder value with a relatively low risk profile. Shareholders familiar with the risk profile of pharmaceutical development (and that is most of you) are conscious of the risk return profile of most companies in the sector in Australia. The Board has extensive experience with the risk considerations that are peculiar to our sector and this has been a key parameter in determining our strategic approach to the Company's longevity and critical mass. Expressed simply, we are intent on ensuring that shareholder value is optimised and that working capital is confined to key activities in either creating new value or preserving the existing assets of the Company.

To preempt the obvious questions regarding liquidity events, I will note that neither the Directors nor Senior Management are in a position to speculate on hypothetical scenarios. We have clearly had a reasonable level of appreciation in our share price, reflecting the Company's success in pursuing the commercialisation of Axiron. Today's announcement of a dividend and our anticipated dividend policy in future should provide the optimal return for shareholders while preserving capital value, We will not be commenting or speculating on the Company's future outside of the guidance provided today. This is the analysts' domain and they are most welcome to it.

I would now like to ask Richard to provide a more detailed commentary on our operational activity, and will ask that any questions from the floor to be deferred until Richard has completed his presentation, as this will allow all shareholders to be able to consider our position from a fully informed perspective.

CEO's Presentation

Introduction

Ladies and gentlemen, it is my pleasure to review the operational aspects of the Acrux business and in particular the strong progress that we have made over the last 12 months, as well as set out for you our objectives for the balance of the current financial year.

Some of you may have noticed that Acrux received a little bit of press coverage last week.

This broad level of interest in your company and in Axiron and our partnership with Lilly illustrates the remarkable achievement of Acrux in delivering on its major promise of winning FDA approval for our testosterone product.

Forward Looking Statements

This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Acrux to be materially different from the statements in this presentation.

Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and effects of regulatory actions, the strength of competition and the effectiveness of patent protection

Achievements of the last 12 months

At the AGM last year I made the statement that *"09/10 will be an exciting and pivotal year for Acrux."* We knew that this was a bold, but also a perfectly accurate statement. In fact, we went on to detail two specific commitments to our shareholders.

Firstly, that we expected to conclude a significant licensing deal for Axiron in the first half of 2010 and secondly that we would deliver a maiden profit in the 09/10 financial year.

I am pleased to stand before you today, along with my fellow Board members and colleagues, and report that we have delivered fully on both of these promises.

In late January, Acrux filed a New Drug Application (NDA) for Axiron with the US Food and Drug Administration and then in April, the agency accepted the application for full review. The review process proceeded smoothly and the interactions with the FDA were always productive. I would never wish to describe the FDA process as straightforward or simple, but the Acrux team prosecuted the application with great attention to detail and we worked closely and effectively with our partner Eli Lilly. We were naturally delighted when the FDA granted the marketing approval for Axiron on November 24th. In all, the review and approval was completed in just less than 10 months.

In March we concluded Australia's largest ever biotechnology licensing deal. We entered into a global and exclusive agreement with Eli Lilly, after running what could best be described as a robust and competitive tendering process. Ultimately, we were able to agree a set of strong commercial terms with an outstanding partner. The financial terms ensure that we retain a substantial proportion of the overall value of Axiron and this will provide tangible benefits to our shareholders.

On completion of the license deal, US$50m was received from Lilly. We were able to utilise most of our accumulated tax losses and this revenue underpinned our maiden profit of $46.6m at June 30th 2010.

Acrux's achievements have also been recognised amongst its peers and in October of last year, Acrux was awarded the prestigious Ausbiotech-Roche Excellence Award for outstanding contribution to the biotechnology industry and in October of this year Acrux was Awarded two Governor of Victoria Export Awards.

AXIRON

Axiron has been the primary focus and key value driver within our business for the last 4 years. The Board's decision NOT to license the product at the end of Phase 2 in mid-2007, we believe, has now been fully vindicated. The additional value that we have been able to generate as a result of this strategy has been somewhere in the vicinity of 10-fold.

In 2007 we recognised that the unique, underarm-applied testosterone product had the potential to be a company-maker.

I am pleased to say that our shareholders shared in that view and with an additional $23 million investment we were able to proceed with a pivotal phase 3 development program, as well as establish the commercial manufacturing line for Axiron at Orion in Finland.

The clinical trial results that we announced in September 2009 demonstrated very clearly that Axiron was effective in 84% of patients with low testosterone and importantly, it is was well tolerated and safe. Feedback from patients and physicians alike was very positive.

In addition to meeting the primary endpoint of the study, 75% of patients were effectively maintained on the starting dose of 60mg, with the remaining 25% requiring some level of dose adjustment.

It is worth noting at this point that in its approval of Axiron last week, the FDA approved all four doses, i.e.30mg, 60mg, 90mg and 120mg.

Let's hear directly from Dr Ron Swerdloff, a senior physician and clinical investigator in the US, who has witnessed first hand the benefits of treating patients with Axiron.

The Testosterone Therapy Market

I wish now to discuss some key features of the testosterone replacement market and highlight just why this is such an attractive commercial opportunity for Acrux and Lilly.

AXIRON will be targeting an annual market worth more than US$1.2 billion per annum, with a CAGR of 18%, measured from 2005-2009.

We have every reason to believe that this strong growth trend will continue. Underpinning this growth is an ageing population in most of the major markets, a greater awareness of men's health conditions such as prostate health, erectile dysfunction, depression, etc. and the startling estimate that only 5-10% of men with low testosterone are currently receiving treatment.

Unit pricing in the testosterone replacement market is strong and the reimbursement landscape in the US is favourable for these products. I should remind you that Axiron itself is not a cure however it represents an effective chronic therapy, with patients highly motivated to remain on their daily treatment for the rest of their lives.

Finally, although the US currently represents 83% of the global testosterone replacement market, we expect the full potential of Axiron to be realised in the next decade as markets outside the US, in particular the larger emerging market countries such as Brazil and China, start to come on line.

Axiron partnership with Lilly

Acrux is very fortunate to have such a strong and globally powerful marketing partner in Eli Lilly. They are a top-10 international company, headquartered in Indianapolis, with reported revenue in 2009 of US$22 billion.

They are represented in 143 countries and most importantly they have established a leadership position in the marketing and distribution of men's health products. Their experience and insights in this therapeutic segment has its foundation in their success with the erectile dysfunction therapy - Cialis, which with current sales of US$1.6 billion per annum has now surpassed the global sales of Viagra.

I would like to share with you a few further insights into our partnership.

Lilly participated actively in the competitive licensing process that we ran earlier this year. As an organisation, Lilly recognises both the need and the value of pharmaceutical innovation in so much as the innovation itself makes a real difference to patients' lives.

Our two companies have worked very effectively and easily together on the Axiron project, and in so doing we have been able to capitalise on the best capabilities of two very different, but nonetheless complimentary organisations.

Axiron and the commercial impact on Acrux

It is worth me spending a little time detailing the commercial impact of the Lilly partnership. Firstly I will run through the breakdown of the various milestone payments that total US$335 million.

In late March Acrux received a US$50 million non-contingent payment following the completion of the license deal.

With the FDA approval last week, we will now receive a further US$87 million on, or before December 9th 2010.

We have already received US$1 million following the transfer to Lilly of certain Axiron manufacturing assets and we will receive an additional US$2 million for further assets in the first quarter of 2011.

Acrux is entitled to receive additional once-off payments, up to an aggregate amount of US$195million, comprising a number of separate payments, and payable to Acrux over a number of years. These payments are contingent on the successful commercialisation of Axiron. We believe that these so-called commercialisation milestones have been set at realistic levels.

We will not receive a separate payment from Lilly upon the US launch of Axiron, however we do begin to earn royalties on every unit of Axiron that is sold. The royalties are tiered, and on a weighted basis, they are very much in line with industry norms for late stage licensing deals.

The precise details of the royalties remain confidential, although by our own estimate of the sales potential of Axiron, the revenue from these royalties could potentially exceed the US$335 milestone payments.

Finally, it is worth noting that the royalties from Lilly will continue to pay out on all global sales, for as long as Lilly is selling Axiron i.e. the royalties do not cease at any pre-defined time point or a particular event.

Next steps for Axiron

The green light from the FDA now means that Lilly, as well as our manufacturing partner in Finland, Orion Corporation, are able to place maximum effort behind the preparations for the market introduction of Axiron.

The set up of the manufacturing at Orion in Turku, Finland, has proceeded according to plan, with the mixing, filling and packaging line now fully operational. Orion underwent an Axiron pre-approval inspection by the FDA in October of this year and both the readiness and the compliance of their manufacturing facility received a strong endorsement from the FDA.

Let's now take a brief look at the actual manufacturing line at Orion in action, as it goes about filling and capping the Axiron bottles.

For market introduction, Lilly will retain the registered trademark - Axiron, however they have chosen to introduce the product with a stronger visual identity incorporating a striking new logo, along with a bold red and orange colour scheme.

The Lilly marketing team is presently refining their launch plans and we expect that Axiron will be introduced in the US in the first half of 2011. For clarity I should confirm that no marketing costs will be borne by Acrux.

Currently, the market-leading gel product, Androgel sells approximately US$700m per annum. We are not at liberty to share Lilly's sales forecasts publicly, as these are confidential; however it is reasonable to assume that that Lilly will be seeking a leadership position in the male testosterone therapy market. Of course, we cannot predict with any degree of accuracy when peak sales of Axiron will be reached and it remains to be seen what the extent of any competitor response will be. What we can be confident of however, is that Lilly's full commitment; experience and resources will be brought to bear on the Axiron opportunity.

Let me add a few words about Axiron in Australia. I can confirm that Lilly Australia will be making a marketing application to the TGA and that this will be included in the first round of registration applications outside of the USA. We are not able to provide exact timing at this point.

As a consequence of last weeks FDA approval, Lilly has already commenced with the preparation of marketing applications in other territories. Again, all costs related to these additional marketing applications is borne by Lilly.

In parallel with the commercial activities that I have described, we are excited that Lilly's medical and regulatory teams are already progressing their thinking around potential further medical applications for Axiron. You will understand if I am not able to expand on this and of course there can be no certainty about the outcomes, but it does speak volumes about Lilly's genuine commitment to maximise the value of our Axiron product.

But better still; let's hear a few words directly from Mr Dave Ricks, President of Eli Lilly USA.

Animal health

I will remain with the Lilly theme for a moment; however I will move my remarks to our partnership with Elanco, Lilly's animal health subsidiary,

Acrux has an exclusive global licence for the application of the Acrux drug delivery technology in animal health pharmaceutical products.

Marketing applications for the first Lilly developed product are currently being reviewed by the veterinary division of the FDA as well as the European Medicines Evaluation Agency (EMEA). We expect a decision from the FDA during the first quarter of 2011 and from the EMEA closer to mid-year. The application with the FDA has taken longer to progress than expected; however from our most recent discussions with Elanco, we remain confident that the application is on track.

If these marketing applications are approved, Acrux will earn milestone payments, as well as royalties on worldwide sales.

The FDA approval of the first product would give public disclosure to the exact nature of this product and it will trigger a payment to Acrux of $1m. We would anticipate that Elanco would launch this product in the US by mid-2011.

An FDA approval would also provide a strong catalyst for Lilly to accelerate the development and registration of a number of other products utilising the Acrux technology. Elanco has already conducted a significant amount of groundwork on other products and consequently it is possible that additional Phase 3 studies could commence in 2011.

It is important to note that Acrux does not bear any of the development, registration, manufacturing or marketing costs associated with the products developed under the Elanco partnership.

Under the terms of the agreement, Acrux is entitled to receive up to $8.25m in product approval milestones. Again, the royalty rates remain confidential, but they are consistent with rates that are normally attributable to early-stage license deals. Using reasonable estimates for the annual sales of a successful veterinary health pharmaceutical product, this partnership has the potential to deliver meaningful annual revenue to Acrux, without our company having to incur direct overhead charges or costs relating to the sales.

Women's health

I would like to now provide an update on our female health products.

The first product developed by Acrux was the estradiol spray for women to treat menopause symptoms (branded Evamist™ in the USA). This product was approved by the FDA in 2007 and launched into the US market in April 2008. Evamist is distributed in the United States by our licensee KV Pharmaceutical (KV).

In 2009, KV underwent a significant restructuring of its business following a number of product recalls and the suspension of its manufacturing activities by the FDA. This suspension did not impact Evamist directly, although given the nature of KV's challenges, it is reasonable to assume that the potential of the Evamist product has not been maximised.

We have monitored KV's financial position closely as they continue to make efforts to meet the FDA's requirements and regain compliance with Good Manufacturing Practice.

Evamist sales remain below expectations, with prescription numbers at approximately 16-18,000 per month. Royalties from Evamist sales do not yet provide Acrux with significant revenues.

Acrux currently has marketing applications for our estradiol spray filed with the Swedish regulatory authority (MPA), and our partners have applications filed with the Swiss, South African and South Korean regulatory authorities.

A review decision for the Swedish application is anticipated in the first quarter of 2011.

During the year, we announced the termination of a distribution agreement with HRA-Pharma. We will seek to appoint a new distributor for the major European markets after we receive approval of the Swedish marketing application.

In April 2010, we announced that Acrux had successfully regained the US rights to Luramist™, our testosterone spray for women to treat hypoactive sexual desire disorder, from our former licensee Vivus Inc.

We now have global rights to this product and we remain confident that we have the best-in-class delivery mechanism for female testosterone therapy. Although the commercial opportunity in this market remains very attractive, the cost of development in relation to the safety trials represents a substantial financial commitment.

Our core patents on this product are valid through to 2017 and with regrettable delays incurred while licensed to Vivus, this now means that we will need to find a quicker and more cost effective way of getting our product to market.

We will continue to explore how we can satisfy the FDA's safety requirements, and at the same time seek partnerships that may allow us to develop the product in a less costly manner. In addition to this, the Acrux team is looking at the feasibility of increasing the duration of patent protection for this product, and if this is turns out to be possible it is likely to strengthen the business case.

In summary, we will be actively exploring all strategic alternatives for our portfolio of female health products, including the contraceptive sprays, with the clear objective of capturing and returning maximum value to our shareholders.

Financials

I will now detail our company's financial position for you.

For the 09/10 financial year Acrux delivered a maiden profit of $46.6m, which was in line with our commitment to the market. We are not providing a profit forecast at this stage for June 30th 2011, but we will do so in Q1 2011. Revenue for financial year 2010/11 will of course include the US$87 million payment from Lilly.

I am pleased to report that Acrux's cash balance at 31 Dec 2010 will be approximately $145m compared to our cash position of $9.6m for the same time last year.

The current cash burn is approximately $7m per annum. We are in the process of examining the optimum organizational structure and our resource requirements in order to best serve our needs in 2011 and beyond. The Board does not anticipate incurring expenditure that does not have a direct and commensurate value-add for our shareholders.

On the performance of the share price, I can say that despite many other broader economic factors at play, we have remained very disciplined on the issues that have mattered to our business and it is therefore pleasing to see that the Acrux share has appreciated 186% since June 2009 and that the company is now capitalised at well over $500 million.

As a footnote, I once again remind all shareholders that we continue to maintain our status as a Pooled Development Fund and that capital gains and dividends are exempt from tax. We do not expect that this status will be relinquished or altered in the near future.

Outlook

I will now turn to the specific objectives that we have set ourselves for the current financial year, ending June 2011.

1. Firstly, with cash reserves that are surplus to the needs of the business, and subject to tax clearance and exchange rates, the Board intends to pay a special dividend of approximately 60 cps in the first quarter of 2011.

2. Secondly we expect that Lilly will launch Axiron into the US market in the first half of 2011 and proceed to file marketing applications for Axiron in a number of countries outside of the US.

3. Thirdly, with regards to our global veterinary health partnership, Elanco is anticipating a decision from the FDA in Q1 2011 in relation to their first animal health product and if approved this could be available in the US by mid-2011.

4. And fourthly, we are expecting a decision from the Swedish MPA in relation to our Ellavie product during Q1 2011 and shortly following this we will look to secure a suitable distributor for the major European markets.

Finally, I wish to make some observations regarding further growth opportunities for the business.

We have always had a very strong focus on shareholder returns and I am pleased to say that as we move into 2011, the Acrux business is well placed to optimise returns from a number of our products as they are commercialised.

Inevitably however, absolute returns from product development programs do become more marginal as the useful patent life of the platform technology diminishes. The Acrux team is constantly exploring ways to increase the duration of patent protection, although this is not a simple process. Similarly, we continue to look for ways of advancing our remaining product opportunities as quickly and as cost effectively as possible.

I should emphasise that we are fully committed to extracting maximum value from all commercially relevant applications of our platform technology, however it is reasonable to assume that the value-add, on a scale of what we have managed to achieve with Axiron, is more likely at this stage of our company's development, to come from externally sourced opportunities.

With this in mind, the Acrux Board is evaluating all growth opportunities that may be complimentary or synergistic to our existing business. We have a strong financial position, a committed Board and management team and some very significant partnerships in place. The Board intends to maintain a disciplined approach to evaluating any such opportunities and will ensure that shareholders funds are deployed in a productive way with the commensurate level of returns.

With one product, i.e. Evamist currently available in the US, and quite possibly two more products to be made available by mid-2011, Acrux is in an enviably strong position and by any measure; it is now one of Australia's leading biotechnology companies.

In concluding, I would like to thank the Acrux team for their loyalty, their persistence and a healthy level of dogged determination. Most importantly, I commend them for living our team mantra of, "executing to perfect".

My sincere thanks in particular to Ross, our Chairman, who has never tired or wavered in his own belief of what this company could achieve, and to Ken and Barrie for their unqualified support of management's efforts.

Finally, to you our loyal shareholders, many who have stayed the course for a number of years, we are grateful for the trust you have placed in us. In particular, I wish to acknowledge the shareholders that kept the faith as we pursued our marketing application with the FDA. As we all know there have been many examples of companies that have stumbled at this final and critical hurdle… but as a Board and a management team, we always had a closely held belief, that with Axiron, we had a real opportunity to be just a little bit different from the rest.

Thank you for your attention.

Acrux Annual General Meeting
30 November 2010

CEO & MANAGING DIRECTOR PRESENTATION

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November 24, 2010

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PRESS RELEASE

Nov. 23, 2010, 10:16 p.m. EST

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Axiron is the first approved testosterone replacement therapy applied to th underarm

PR Newswire
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INDIANAPOLIS, Ind. and MELBOURNE, Australia, No
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announced that the U.S. Food and Drug Administrat
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certain conditions associated with a deficiency or ab
and efficacy of Axiron in males younger than 18 yea
established.

To view the multimedia assets associated with this release, please click: http://multi
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Axiron is the first testosterone topical solution approved for application via an armpi
forms of testosterone replacement therapy include: oral tablets, buccal tablets, subc

n CIII

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By Simeon Bennett · Nov 25, 2010 8:13 AM ET

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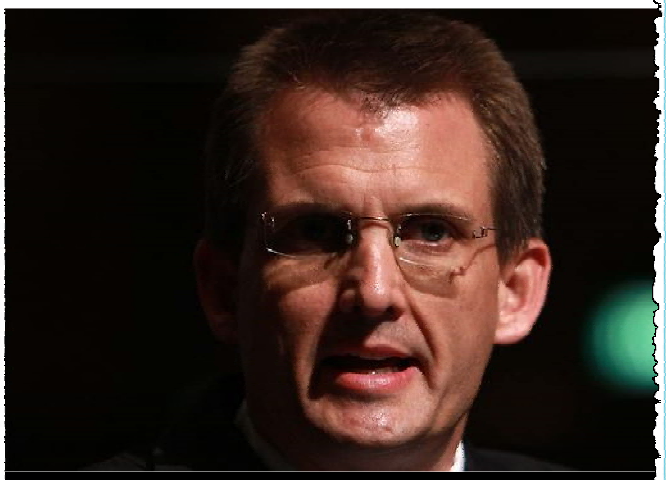


Richard Treagus delivers his news regarding US approval of a testosterone drug at the Acrux media con
Crown Palladium. Source: Herald Sun

IMPOTENCY drug developer Acrux's shares have rocketed after gaining sell its testosterone product Axiron.

In this edition...

Acrux has achieved arguably one of the most successful commercial outcomes in Australian biotech this week when its drug, Axiron, was approved by the FDA. This triggers a US$87 million milestone payment to Acrux with the drug expected to reach the market in early 2011.

Next cab off the rank could be Alchemia, and we report from its AGM this week.

Biota Holdings has signalled a much more aggressive approach forward at its AGM this week. We also continue the AGM coverage with a report on Hexima.

And Bionomics looks like it will fight its proposed sale by tender all the way, appointing a corporate advisor from the US. Well, the final quarter of 2010 was always expected to be an exciting one!

The Editors

Companies Covered: ACR, ACL, BNO, BTA, HXL

	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%

Bioshares

26 November 2010
Edition 387

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

Simply Magnificent Acrux!

Acrux's (ACR: $3.31) Axiron testosterone product, which is licensed to **Eli Lilly**, was approved by the FDA this week. This approval represents an outstanding achievement for the Australian biotech sector. Axiron is a formulation of testosterone as a topical solution, which uses a device similar to a roll-on deodorant applicator to deliver the drug under the armpit. Axiron is the first drug approved for delivery of a molecule in this manner.

The approval triggers a US$87 million milestone payment from Eli Lilly, increasing Acrux's

FORWARD-LOOKING STATEMENTS

This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Acrux to be materially different from the statements in this presentation.

Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and effects of regulatory actions, the strength of competition and the effectiveness of patent protection.

ACHIEVEMENTS IN LAST 12 MONTHS

- January 2010 - New Drug Application for Axiron submitted to FDA on time
- March 2010 - global deal for Axiron with Eli Lilly – largest Australian biotech licensing deal
- March 2010 – joined S&P/ASX 300 index
- June 2010 – delivered maiden profit of $46.6 million, as promised
- October 2010 – won two Governor of Victoria Export Awards
- November 2010 – Axiron approved by FDA for marketing

AXIRON®

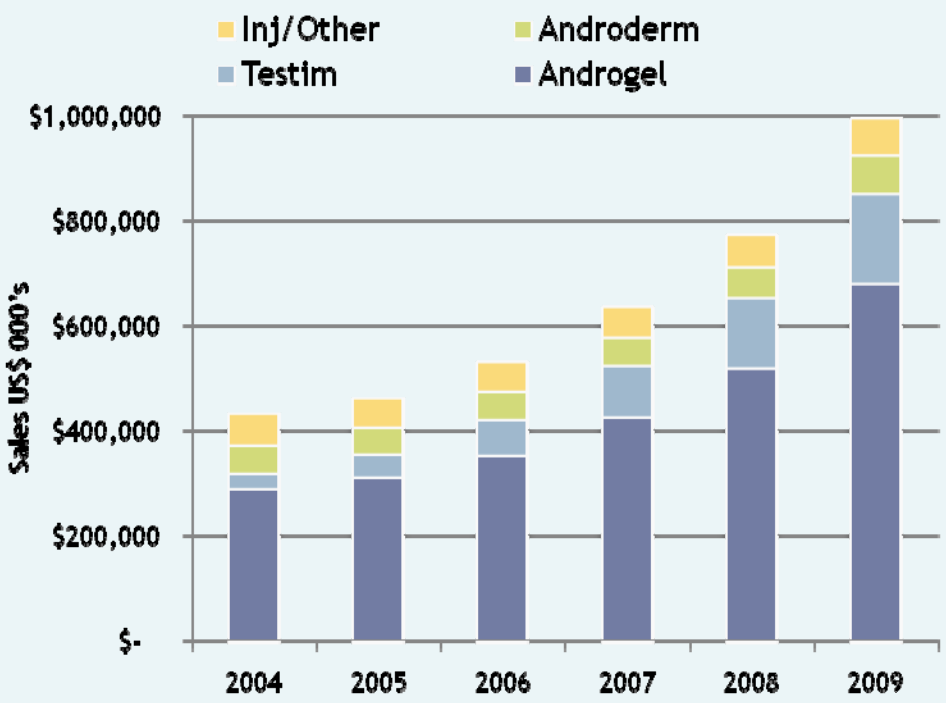
Axiron® (testosterone) topical solution

- Testosterone replacement therapy to treat testosterone deficiency in men
- $23 million capital raised in 2007 to fund Phase 3 development
- Successful Phase 3 trial results in September 2009
- New Drug Application submitted to FDA in January 2010
- Global deal for Axiron with Eli Lilly in March 2010 – largest Australian biotech licensing deal
- FDA approval for marketing in November 2010

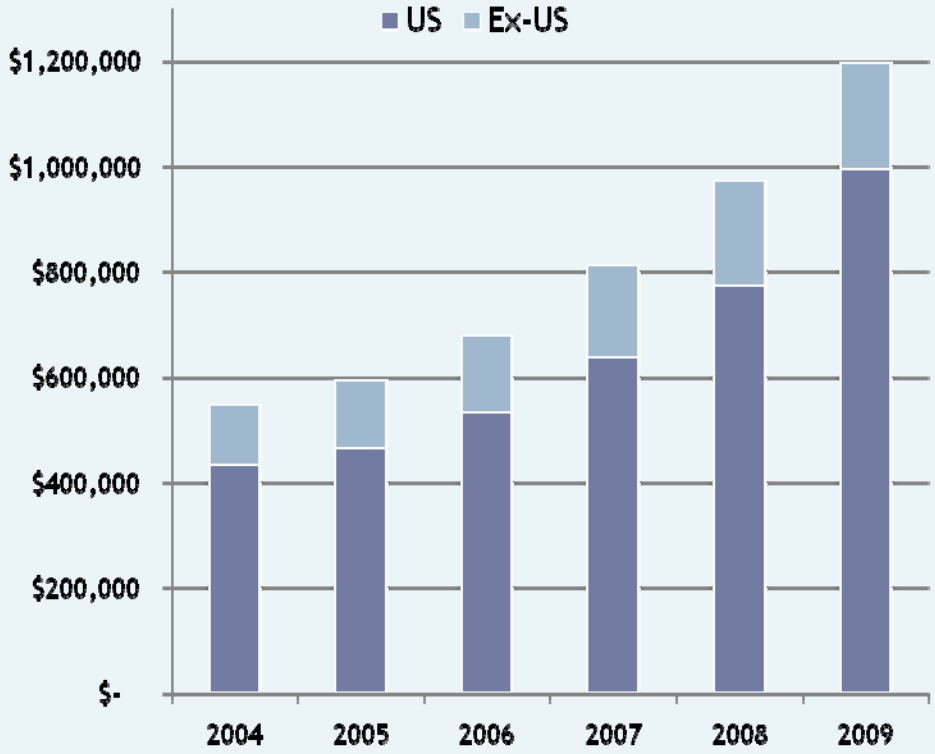
ACRUX DRUG DELIVERY SOLUTIONS

TESTOSTERONE THERAPY MARKET

US market



Global market



- US Market: $1.0B
- US CAGR Growth '04 to '09: 18%
- Androgel still growing significantly in the US

- Global Market: $1.2B
- Global CAGR Growth '04 to '09: 17%
- US Market: 83% of global market

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DRUG DELIVERY SOLUTIONS

LILLY IS THE IDEAL COMMERCIAL PARTNER

1. Top 10 global pharma company - 2009 revenue US$22 billion
2. Leadership position in men's health - erectile dysfunction therapy Cialis® sales grew to US$1.6 billion in 2009
3. Distribution in 143 countries - including high growth emerging markets
4. Builds on established partnership between Acrux and Elanco - animal health division of Lilly

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DRUG DELIVERY SOLUTIONS

AXIRON PARTNERSHIP WITH ELI LILLY

- Lilly receives exclusive worldwide rights to commercialise Axiron
- Acrux eligible for US$335 million in milestone payments:
  - US$50 million up-front (received 2009/10)
  - US$3 million on transfer of manufacturing assets ($1m received 2009/10)
  - US$87 million on issuance of a marketing authorisation by FDA
  - US$195 million dependent on subsequent commercial milestones
- Acrux eligible for royalties on worldwide sales – royalties provide a substantial part of the deal value to Acrux

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NEXT STEPS FOR AXIRON

- US market launch
- Marketing applications in other territories
- Working with patent offices to expedite pending patents, including patents that potentially extend protection of AXIRON to 2026

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ANIMAL HEALTH

- Exclusive global licence for animal health products utilising Acrux's delivery technology
- First marketing application submitted to FDA by Elanco Dec 2008
- Further products in clinical development
- Acrux eligible for royalties plus up to $8.25m in product approval milestones

Elanco

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WOMEN'S HEALTH PRODUCTS

- Estradiol spray USA (Evamist™) for menopause
  - Marketed by licensee KV Pharmaceutical
  - KV facing major corporate challenges
- Estradiol spray ex-USA (Ellavie™)
  - In registration for Sweden, Switzerland, South Africa and South Korea
- Testosterone spray (Luramist™) for HSDD
  - US rights regained from Vivus after lengthy dispute
  - Potential to be preferred product in an estimated billion dollar market

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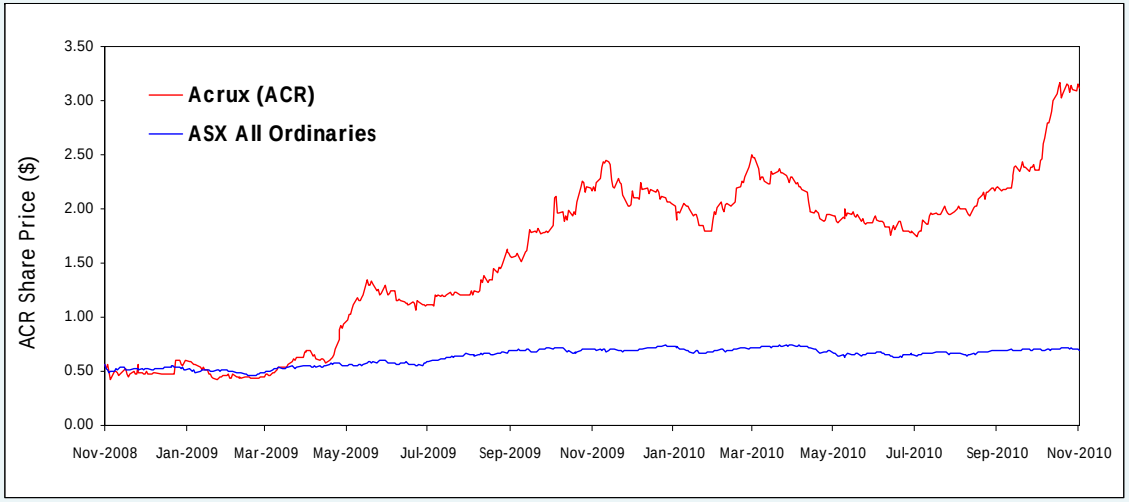
FINANCIALS

- $46.6m maiden profit after tax in 2009/10
- $145 million cash following US$87 million payment
- 186% share price growth since 30 June 2009
- Pooled Development Fund - capital gains and dividends exempt from tax



ACR share price (red) versus ASX All Ordinaries index (blue) over 2 years

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OUTLOOK

- First dividend in early 2011
- US launch of Axiron by Lilly
- Pending patents that potentially extend protection of Axiron to 2026
- Axiron marketing applications in other countries
- FDA review of first animal health product with Elanco
- Swedish regulatory review of Ellavie
- Strategic review of product development pipeline and growth opportunities

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Lilly

Answers That Matter.