

MARKET UPDATE – A NEW ERA FOR ACRUX

Highlights:

- **Acrux signs exclusive global licensing deal with pharmaceutical giant Eli Lilly for the commercialisation of AXIRON**
- **Acrux eligible to receive up to US\$335 million milestone payments plus royalties**
- **Eli Lilly is the ideal commercial partner for AXIRON:**
 - **established leadership position in men's health with its erectile dysfunction therapy Cialis®**
 - **sales, marketing and distribution capability covering 143 countries**
 - **builds on the existing partnership between Acrux and Elanco (animal health division of Eli Lilly)**
- **Acrux forecasts maiden profit after tax for 2009/10 between \$44 million and \$48 million**
- **Acrux Board intends dividend payments to commence in 2011, subject to FDA approval of AXIRON**
- **Acrux to join S&P/ASX 300 after market close on Friday 19 March 2010**



Introduction

The announcement this morning of Acrux's exclusive global deal with pharmaceutical giant Eli Lilly for the worldwide commercialisation of AXIRON™ places Acrux firmly on the path of becoming the first Australian biotech company to introduce a number of therapeutic products into global pharmaceutical markets.

Under the terms of the AXIRON deal, Acrux is eligible to receive up to US\$335 million in milestone payments, plus royalties on worldwide sales. This commercial arrangement comprehensively transforms Acrux's financial position and, subject to US Food and Drug Administration (FDA) approval of AXIRON, it will allow the Acrux board to pay dividends to shareholders.

Acrux has been promoted to join the S&P/ASX 300 index after market close on 19 March 2010. Along with today's announcement, we expect this will attract a greater level of interest in Acrux from institutional investors.

In a joint media release with Lilly, Acrux's CEO Richard Treagus commented: "We are delighted to build on our established relationship with Lilly and collaborate on the potential worldwide commercialization of AXIRON. Through Lilly's considerable global resources and leadership position in the field of men's health, Acrux now has the opportunity to achieve the full commercial potential of AXIRON."

Acrux's chairman Ross Dobinson paid tribute to the confidence that shareholders had shown in Acrux's ability to commercialise its innovative product range.

"The AXIRON licensing agreement with Eli Lilly, believed to be the largest licensing deal ever struck by an Australian biotech company, validates the commitment and support shown by Acrux's stakeholders, including our State and Federal Governments, over many years," Mr Dobinson commented. "Acrux was founded as a spin-off from Monash University a decade ago, and can now anticipate profitability, dividends and a suite of products in global pharmaceutical markets" he added.

In this market update, Acrux provides further commentary on the AXIRON deal, information on its first profit and dividend intentions, together with an outline of the key activities and expected news flow during the remainder of 2010.

The AXIRON partnership with Eli Lilly

Following the announcement of the Phase 3 results in September last year, Acrux received strong interest in the AXIRON product from a range of potential partners. On a number of measures, Lilly presented a compelling offer and Acrux believes that Lilly is the ideal commercial partner for AXIRON.

Firstly, worldwide sales of its erectile dysfunction treatment Cialis[®] grew to US\$1.6 billion in 2009, now rivalling Pfizer's Viagra[®] as the largest selling product in this category. Acrux views this as an impressive achievement, giving confidence that Lilly has the expertise and capabilities in men's health that will enable Acrux to achieve the full commercial potential of AXIRON.

Secondly, Lilly has considerable commercial strength worldwide, with products distributed in 143 countries. This was an important consideration for Acrux, as it believes that many of the ex-USA markets such as Asia and South America offer great potential for growth over the next 10 years and beyond.

Thirdly, Lilly has a heritage and track record of seeking improved clinical outcomes based on the best science of the day. Acrux views the increasing scientific understanding of the role that testosterone plays in the health of men as an exciting development. There is a body of data proposing that testosterone levels may be a factor in men suffering from a cluster of conditions, such as obesity, metabolic syndrome and type 2 diabetes (*Jones, T.H. (Barnsley/Sheffield) (eds): Advances in the Management of Testosterone Deficiency. Front Horm Res. Basel, Karger, 2009, vol 37, pp 74-90*).

Finally, Acrux already has a productive partnership in place with Lilly's animal health division, Elanco. A marketing application for the first veterinary product utilising Acrux's technology was submitted to the FDA in late 2008 and Acrux anticipates the outcome of the FDA's review process in the near future. Acrux's experience with Elanco gives confidence that Acrux and Lilly will continue to forge a close and effective working relationship during the FDA review process and commercial preparations.

¹ Cialis[®] is a trademark of Eli Lilly & Company

Financial impact on Acrux – first profit and dividends

The deal provides substantial financial returns to Acrux, vindicating the A\$23 million investment made by shareholders in 2007 to fund the Phase 3 development of AXIRON.

Under the terms of the agreement, Lilly will receive exclusive worldwide rights to commercialise AXIRON. In exchange for these rights, Acrux will receive an up-front payment of US\$50 million, plus US\$3 million on the transfer of manufacturing assets. Acrux is further eligible for US\$87 million subject to the issuance of a marketing authorization by the FDA, and up to US\$195 million in potential commercialisation milestones, as well as royalty payments on future global sales if AXIRON is successfully commercialized. The cash flows from royalties comprise a substantial part of the value of the deal to Acrux. The royalty rates are confidential, but in Acrux's view are broadly consistent with comparable late-stage licensing deals.

Acrux expects no deduction of foreign withholding tax from any of the deal payments. Acrux also anticipates that any tax liability on the initial payment of US\$50 million will not be significant, due to the utilisation of past tax losses. From the initial payment of US\$50 million, third-party royalties of approximately A\$1.9 million are expected to be payable.

Importantly, Acrux is forecasting a maiden profit after tax for the year ended 30 June 2010 of between A\$44 million and A\$48 million. This first profit will recover the majority of the Acrux group's accumulated losses since inception. Acrux's ongoing expenditure has already reduced following the completion of the AXIRON Phase 3 clinical trial and it will continue to reduce during the course of 2010/11. Acrux will manage its expenditure and cash reserves prudently as it works closely with Lilly towards the potential approval and launch of AXIRON.

In 2011, contingent on FDA approval of AXIRON and the receipt of the associated payment from Lilly, the board intends to commence payment of dividends to shareholders. Acrux is a Pooled Development Fund, which means that not only are capital gains on the disposal of Acrux shares exempt from capital gains tax, but dividends also benefit from concessionary treatment. Dividends are exempt from tax, so taxpayers with a marginal tax rate in excess of the company rate do not pay additional tax on a dividend. If a dividend is franked, Australian resident shareholders who hold the shares for 45 days or more can elect to treat the dividend as taxable, in order to claim the tax offset and potentially receive a refund of tax where the tax offset exceeds a shareholder's highest marginal tax rate. Dividends paid to non-residents are not subject to withholding tax.¹

¹ This information is of a general nature only and may vary from person to person, dependent on their circumstances. Any shareholder or prospective shareholder should obtain their own tax advice, rather than relying on this summary.

Near-term activity and news flow

During the remainder of 2010, the major focus of the Acrux team will be to work closely with Lilly and the FDA on the regulatory review process and on ensuring that the AXIRON commercial manufacturing line at Orion Corporation is fully operational. Acrux will likewise be working diligently with patent offices to expedite the granting of pending patents, including those patents that potentially extend the protection of AXIRON out to 2026.

In parallel, Acrux will evaluate a range of internal and external growth opportunities, while continuing to monitor and ensure the performance of two of its licensees, Vivus and KV Pharmaceutical.

Acrux anticipates a steady flow of important news over the next 12 months, notably:

- The outcome of the FDA review of the marketing application for Elanco's first animal health product utilising the Acrux technology;
- A progress update from Vivus regarding the Arbitration Panel deadline of 1 April 2010 for the start of a Luramist™ Phase 3 trial;
- Key regulatory milestones for the Estradiol spray, Ellavie™, including the potential approval in Sweden and filing of marketing applications by our partners in other territories;
- The outcome of the FDA review of the AXIRON marketing application.

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About Acrux - www.acrux.com.au

- Acrux is an Australian drug delivery company, developing and commercialising a range of patented pharmaceutical products for global markets, using its innovative technology to administer drugs through the skin.
- Fast-drying, invisible sprays or liquids provide a delivery platform with low or no skin irritation, superior cosmetic acceptability and simple, accurate and flexible dosing. The technology platform is covered by broad and well-differentiated, issued patents.
- Acrux has one product, Evamist™ (brand name Ellavie™ outside the USA) to treat menopause symptoms, marketed by its licensee in the USA and has the following products in registration or in clinical development:
 - AXIRON™ to treat testosterone deficiency in men
 - Testosterone MDTS® to treat decreased libido in women
 - Nestorone® MDTS® contraceptive sprays for women
 - An undisclosed companion animal health product
 - Nicotine MDTS® for smoking cessation
- Acrux has licensed to Eli Lilly global rights for AXIRON, as well as for veterinary healthcare products. Acrux has licensed US rights for Evamist to KV Pharmaceutical and for Testosterone MDTS to VIVUS, as well as appointing distributors for Ellavie in 9 European countries and in Southern Africa, South Korea and Australia.