

MARKET UPDATE

Highlights:

- Axiron® (testosterone) topical solution approved by FDA for marketing in United States
- Acrux joins select group of Australian companies to exclusively develop and achieve FDA approval of a therapeutic drug product
- Acrux will receive a second milestone payment of US\$87 million from Lilly, which increases Acrux's cash to approximately \$145 million
- Following launch of Axiron in 2011, Acrux will receive royalties on global sales and is eligible for further commercial milestone payments of up to US\$195 million
- Testosterone therapy market in the United States is US\$1 billion per annum, growing at 20% annually
- Lilly responsible for obtaining marketing approval for Axiron in territories outside the USA
- Acrux intends to pay a dividend to shareholders early in 2011
- Two further marketing applications under late stage review:
 - o First animal health product under review by FDA
 - o Estradiol spray under review by MPA in Sweden

Melbourne, 24 November 2010: In a joint media release today, Acrux (ASX: ACR) and Eli Lilly and Company announced that the US Food and Drug Administration (FDA) has approved Acrux's New Drug Application (NDA) for Axiron® (testosterone) topical solution for replacement therapy in men with a deficiency or absence of testosterone.

Axiron is the first testosterone replacement product approved for administration via the armpit (underarm). Acrux Chairman Ross Dobinson noted that Acrux joins a select group of Australian companies to wholly develop and achieve FDA approval of a therapeutic product. He also noted that Axiron is the second product from Acrux's platform delivery technology to be approved.

“The FDA approval is a major milestone for Axiron and Acrux,” said Acrux CEO Richard Treagus. “We have a very strong partner in Lilly and we are excited about making Axiron available to patients in the US next year.”

Acrux anticipates that Lilly will launch Axiron into the US testosterone therapy market in 2011. Global annual sales of testosterone therapies are approximately US\$1.2 billion, of which sales in the United States comprise US\$1 billion, with the market currently growing at 20% per annum¹.

Under the terms of the exclusive global licence agreement signed in March 2010, Acrux will receive a milestone payment of US\$87 million from Lilly within the next 15 days. This payment is expected to increase Acrux’s cash reserves to approximately \$145 million.

Following the market launch of Axiron, Acrux will receive royalties on worldwide sales, and is eligible for further commercial milestone payments of up to US\$195 million. Acrux expects the royalties to provide a substantial part of the total value of Axiron.

Acrux expects that the commercial performance of Axiron will benefit from Lilly’s leadership position and experience in men’s health. Sales of Lilly’s erectile dysfunction therapy Cialis[®] grew to US\$1.6 billion in 2009, rivaling Pfizer’s Viagra[®] as the largest selling product in that category.

Lilly distributes products in 143 countries, including high growth markets in Asia and South America, which Acrux believes could be attractive future markets for Axiron. Lilly is responsible for obtaining regulatory approvals to market Axiron in territories outside the United States and Acrux expects marketing applications to be submitted in due course.

Acrux intends to pay a dividend to shareholders in the first half of 2011. The amount and timing of the dividend will be announced following a review of tax and legal requirements, as well as giving consideration to the ongoing funding requirements of the business. Acrux is a Pooled Development Fund, which means that shareholders are exempt from tax on both capital gains and dividends.

“This achievement is the culmination of a decade of skill and commitment from all Acrux’s stakeholders, including staff, board, shareholders and state and federal governments”, commented Acrux Chairman Ross Dobinson. “We now look forward to the launch of Axiron and to the first dividend payment to our loyal shareholders”, he added.

¹ IMS Health, year to December 2009

Acrux has marketing applications for two further products currently under late-stage review by regulatory agencies. Firstly, the FDA is reviewing Lilly's marketing application for the first animal health product that has been developed under an exclusive licence agreement between Acrux and Lilly. Secondly, the Medical Products Agency in Sweden is reviewing Acrux's marketing application for the estradiol spray, Ellavie. The outcome of each of these reviews is expected in the first quarter of 2011.

A strategic review of Acrux's current and potential product development pipeline is in progress, the outcome of which will be announced in due course.

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About Acrux - www.acrux.com.au

- Acrux is an Australian drug delivery company, developing and commercialising a range of patient-preferred, 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 two products approved for marketing in the USA, one product in registration in the USA, one product in registration in Europe and further products at earlier stages of development.
- Acrux received two 2010 Governor of Victoria Export Awards, including the Victorian Export Award for Innovation Excellence.