ACRUX (ACR) - ASX ANNOUNCEMENT 23 AUGUST 2012

ACRUX ANNOUNCES RESULTS AND DIVIDEND FOR 2011/12 AND PROVIDES UPDATE ON AXIRON®

Highlights:

- **Final dividend of 8 cents per share unfranked, exempt from tax:**
  - **Record date – 10 September 2012**
  - **Expected payment date – 24 September 2012**
- **Financial results for 2011/12:**
  - **Profit after tax $7.4 million**
  - **Earnings per share 4.4 cents**
  - **Cash at 30 June $30 million**
  - **Profit before tax $4.9 million**
- **Axiron® update:**
  - **Process to achieve grant of underarm administration patent in US underway**
  - **US transdermal testosterone therapy market growing at approximately 30% per annum, with potential sales of $1.9 billion in 2012**
  - **Significant expansion of Axiron manufacturing capacity**
  - **US healthcare plan coverage for Axiron increasing**
  - **Gross-to-net sales differential expected to reduce from Q4 2012**
  - **Further guidance on milestone payments outlook:**
    - **US$25 million expected in 2013/14**
    - **US$50 million expected in 2014/15**
    - **US$120 million expected from 2018/19 to 2021/22**

Acrux (ASX: ACR) today declared a final dividend for 2011/12 of 8 cents per share, unfranked. The record date for entitlement to the dividend is 10 September 2012 and the estimated date for despatch of payment is 24 September 2012. **Acrux is a Pooled Development Fund, which means that the dividend will be exempt from tax and**

should not be included in Australian shareholders' taxable income. The franking credits that have been accumulated to date by Acrux will be retained for application in future capital management initiatives.

"This initial tax-free dividend of 8 cents per share reflects the Board's confidence in Axiron's future and reaffirms its intention to maximise shareholder returns", commented Acrux Chairman Ross Dobinson.

Axiron Update:

Underarm administration patent pending

In the United States, Axiron is currently protected by granted patents describing the formulation and delivery system, and the applicator device, with these patents expiring in 2017 and 2030 respectively. Acrux is pursuing additional protection until 2026 through a new patent describing the underarm (axilla) application method. The axilla patent has already been granted in Australia, New Zealand, Singapore and South Africa.

In June 2012, the US Patent and Trademark Office (USPTO) raised two objections to the pending claims contained in Acrux's axilla application patent. Acrux has confidence in the claims and is preparing a response to the objections. The market will be notified when the response has been filed with the USPTO.

Axiron and the US testosterone therapy market

The high rate of growth in the US testosterone therapy market noted in Acrux's last update has been maintained. The number of prescriptions of transdermal testosterone therapies in the first half of 2012 was approximately 30% higher than in the first half of 2011. If the current growth rate is maintained in the second half, total sales of transdermal testosterone therapies in the US for 2012 are expected to reach $1.9 billion.

Promotional efforts by the pharmaceutical groups supplying the market-leading testosterone treatments have played a significant role in expanding market awareness and understanding of testosterone deficiency. Competition among those products has intensified during the last 6 months. While the growth rate of Axiron's market share has slowed, Acrux remains confident of continuing to build in the near term on the 12.5% share of transdermal testosterone therapy prescriptions recorded in July 2012. Acrux has confidence in the experience that Axiron provides for patients and anticipates additional clinical studies will continue to improve the prospects for this product. Increasingly, healthcare providers are prescribing Axiron for patients new to testosterone therapy, which now account for the majority of Axiron prescriptions.

Outside the US, Axiron was approved in Canada in early April and in Australia mid-May. Applications for regulatory approval have also been filed in selected European and South American countries.

In order to meet the growth in demand for Axiron in the US and other markets, a staged program to increase manufacturing capacity significantly is underway and is expected to be completed in early 2013.

US healthcare plan coverage and co-pay card rebates

US healthcare insurance plans may wait 12 months after the launch of new products before reviewing their approved drug formularies and adding new products. During this period a co-pay card has been offered for Axiron. When using a card, eligible patients will pay no more than US$25 for a 30-day supply, for up to one year.

Gross sales of Axiron have been consistent with the capture of a significant share of the growing market. However, in the initial launch period net sales have been reduced by the use of the co-pay card which provides financial assistance to the patient.

Acrux expects the gap between gross and net sales to reduce from the fourth quarter of 2012 as Acrux believes that the use of co-pay cards will decrease.

Lilly has made good progress in achieving access to healthcare insurance plan formularies and recently a plan added Axiron to its national formulary effective 1 July 2012.

Milestone payments outlook

Under the agreement between Acrux and Lilly, Acrux receives royalties on net sales, and in addition is entitled to receive up to US$195 million in milestone payments which are related to the net sales performance of Axiron.

The first milestone of US$25 million is payable when the worldwide net sales of Axiron in a calendar year equal, or exceed US$100 million. Due to the higher than anticipated gross-to-net sales deductions in 2012, Acrux now expects the first milestone of $100 million net sales to be exceeded in the 2013 calendar year (previously expected in 2012), so that the milestone payment of US$25 million will be earned in Acrux's 2013/14 financial year (previously 2012/13). Acrux expects to earn a milestone payment of $50m in the 2014/15 financial year and milestone payments totalling US$120 million over the 4 financial years commencing 2018/19.

Summary of financial results:

	30 June 2012 $m	30 June 2011 $m
Product agreement revenue	9.0	89.6
Interest and grant income	1.7	3.9
Total revenue	10.7	93.5
Total expenditure	(5.8)	(12.5)
Profit before capitalised development costs	4.9	81.0
Capitalised Axiron	-	1.4
Capitalised Ellavie	-	0.1
Profit before tax	4.9	82.5
Income tax benefit/(expense)	2.5	(25.4)
Profit after tax	7.4	57.1
Earnings per share	4 cents	35 cents
Net cash (outflow)/inflow before financing	(2.5)	64.4
New share capital	-	8.0
Dividends paid	(0.6)	(99.0)
Cash	30.0	33.2

Revenue

Total revenue for the financial year was $10.7 million (2011: $93.5 million). Revenue related to product agreements was $9.0 million (2011: $89.6 million), including Axiron royalties of US$6 million. The prior year included US$87 million in milestone revenue from Eli Lilly. Interest income reduced to $1.6 million (2011: $3.7 million), as cash reserves were reduced by the payment of $99 million in a special dividend to shareholders in April 2011.

Expenses

Reported operating expenditure was $5.8 million (2011: $11.0 million). Royalty payments reduced to $0.3 million (2011: $3.0 million), as the prior year included royalty due on the US$87 million milestone revenue from Eli Lilly. A foreign currency gain of $0.2 million was recorded for 2012 financial year, compared to a foreign currency loss of $1.8 million for the prior year, the result of appreciation of the Australian dollar versus the US dollar prior to settlement of the milestone revenue.

The reported operating expenditure for the prior year of $11.0 million was reduced by the capitalisation of product development expenses. No development expenses were capitalised for the financial year to 30 June 2012. Total expenditure, including the amounts capitalised, for external research and development expenses reduced to $0.9 million (2011: $1.7 million) and for employee benefits expense reduced to $2.6 million (2011: $3.6 million). The reduction in total employee benefits expense was the result of a reduction in the number of staff.

Income tax benefit of $2.5 million was recorded for the financial year compared to an income tax expense of $25.4 million for the prior year. Tax expense of $1.6 million was offset by tax benefit of $4.1 million due to tax losses from excess imputation credits on dividends received by the parent entity as well as amendments to prior year tax returns to include additional deductions due under the research and development tax concession.

Cash flow

Net cash outflow for the reported period was $3.1 million (2011: $26.7 million). Cash reserves at the end of the period were $30.0 million (30 June 2011: $33.2 million).

Receipts from product agreements were $6.4 million (2011: $86.0 million). The prior year included the receipt of the Axiron milestone revenue from Eli Lilly. Interest receipts added $1.4 million (2011: $3.9 million), on reduced cash reserves following payment of the special dividend. Payments to suppliers and employees reduced to $5.6 million (2011: $9.6 million). Income tax of $4.6 million was paid during the year (2011: $15.3 million).

The purchase of plant and equipment produced a small outflow for investing activities of $0.1 million (2011: $0.7 million). The prior year outflow of $0.7 million included payments for capitalised development expenses, offset by the sale of plant and equipment to Eli Lilly.

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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 products marketed by licensees in the USA, approved in Europe, Canada and Australia and in registration or development.