ACRUX PROVIDES HALF YEAR UPDATE

2013 Highlights:

- **Axiron® sales milestone achieved – US$25 million receivable early March 2014**
- **Half-year financials:**
  - **Revenue $43.7 million (2012: $5.1 million)**
  - **Profit before tax $38.4 million (2012: $2.0 million)**
  - **Operating cash inflow $7.7 million (2012: inflow $2.3 million)**
  - **Cash reserves $17.5 million (30 June 2013: $22.8 million)**
- **Declared unfranked special dividend of 12 cents per share (exempt from tax):**
  - **Record date – 3 March 2014**
  - **Payment date – 20 March 2014**
- **Axiron launched in Australia, Canada and Brazil**
- **Axiron EU approval in Germany, launch anticipated end February 2014**
  - **Canada, Australia, Germany and Brazil comprise more than half the ex-US market value**
- **US transdermal testosterone replacement therapy (TRT) $ sales growth has continued:**
  - **Total TRT for 2013 ~9% higher than 2012**
  - **Total transdermal TRT December 2013 ~6% higher than December 2012**
- **US healthcare plan coverage for Axiron increasing:**
  - **As of January 2014, Axiron is the only transdermal TRT registered as a preferred product on both ESI and CVS Caremark National Formularies (ESI and CVS are the two largest Pharmacy Benefit Managers in the US)**

2014 Outlook:

- **Growth in royalties on Axiron net sales in 2014 will be driven by multiple factors:**
  - **New Direct to Consumer marketing message initiated 1 January 2014**
  - **Increased presence with the leading formularies**
  - **New Savings Card system initiated 1 January 2014**
  - **Brand loyalty developed among both consumers and physicians**
  - **Price increases implemented in 2013**
  - **Ex-US product launches**
- **Based on current knowledge, it is a reasonable expectation that the second Axiron sales milestone payment of US$50 million will be earned on 2014 calendar year net sales**
- **New intellectual property being filed for non-melanoma skin cancer and antifungal products**

Acrux (ASX: ACR) today reported its financial results for the half-year to December 2013 and declared an unfranked special dividend of 12 cents per share.

Today's report follows the recent confirmation that Acrux had achieved the 2013 sales threshold for Axiron required to trigger the right to receive a US$25 million milestone payment from Eli Lilly. Consistent with previous advice, Acrux will distribute cash in excess of medium term working capital requirements, and consistent with this policy have declared a special dividend of 12 cents per share.

Despite a slowdown in total prescriptions during the latter half of 2013, in dollar terms the United States testosterone therapy market grew moderately in 2013. Total market value of testosterone replacement therapy (TRT) was approximately 9% higher than in 2012. Transdermal TRT $ sales in January 2014 were approximately 6% higher than in January 2013.

Axiron achieved global net sales of US$178.7 million for the 2013 calendar year. The product improved its positioning with leading formularies from January 2013 and increased market share to become the second largest prescribed transdermal TRT product in the US. As of 1 January 2014 Axiron is the only transdermal TRT to be registered as a preferred product on both ESI and CVS Caremark National Formularies.

The trajectory of quarterly sales remains positive. Acrux expects significant growth in the royalties on Axiron net sales in 2014 which will be driven by a number of factors. A new Direct to Consumer marketing message was initiated from 1 January 2014 and the product has improved positioning with the leading formularies from the same date. Brand loyalty is increasing with consumers and physicians. A new Savings Card program that was initiated from 1 January 2014 is expected to improve market reach to consumers.

On 31 January 2014, the U.S. Food and Drug Administration (FDA) issued a Drug Safety Communication (DSC), which stated that the FDA is investigating the risk of stroke, heart attack (myocardial infarction) and death in men taking FDA-approved testosterone products. The FDA has not concluded that FDA-approved testosterone treatments increase the risk of stroke, heart attack, or death. This process is expected to take many months to complete. The FDA stated that patients should not stop taking prescribed testosterone products without first discussing any questions or concerns with their healthcare professionals. No significant change in prescription numbers has been noted after the FDA DSC was issued.

In addition to the US market, Axiron is now available for use in Canada, Australia and Brazil. Approval in Germany was received in September 2013, and the product launch is anticipated for end of February 2014. Additional regulatory approvals and launches are expected subsequently.

Accrued rebates to formularies for sales of Axiron are now made on a contract by contract basis, allowing for more accurate anticipation of rebate needs. This reduces the potential for accounting adjustments such as those that impacted the September 2013 quarterly result. Based on current knowledge and currently expected Axiron net sales growth (for the reasons stated above), in addition to expected growth in royalties, Acrux believes it is a reasonable expectation the Axiron net sales for calendar year 2014 will trigger a US$50 million milestone payment that would be payable in early 2015.

During 2013 Acrux announced two new product candidates: a non-melanoma skin cancer (NMSC) therapy and an antifungal therapy. Both projects have demonstrated encouraging data to date and new patent applications are currently being prepared. The next stage of product development has been initiated and the results will be communicated to investors after intellectual property covering the projects has been advanced.

Acrux Executive Chairman Ross Dobinson commented "We are very pleased to declare a higher than anticipated special dividend. We look forward to sharing development updates on our new product opportunities."

Summary of financial results:

	31 December 2013 $m	31 December 2012 $m
Axiron revenue	42.5	4.4
Other revenue	1.0	0.1
Interest income	0.2	0.6
Total revenue	**43.7**	**5.1**
Total expenditure	**(5.3)**	**(3.1)**
Profit before tax	**38.4**	**2.0**
Income tax expense	(13.8)	(0.2)
Profit after tax	**24.6**	**1.8**
Earnings per share	**15 cents**	**1 cent**
Cash generated by operations	**7.7**	**2.3**
Dividend paid	(13.3)	(13.3)
Net cash outflow	**(5.6)**	**(11.1)**
Net cash at 31 December 2013	**17.5**	**n/a**
Net cash at 30 June 2013	**22.8**	**n/a**

Revenue

Total revenue for the half-year increased to $43.7 million (2012: $5.1 million) including revenue from product agreements of $43.3 million (2012: $4.5 million). Revenue from Axiron increased to $42.5 million (2012: $4.4 million) which includes the recognition of $28.2 million (US$25 million) as milestone revenue, as net sales exceeded US$100 million in the 2013 calendar year, plus an increase in royalty revenue to $14.3 million (2012: $4.4 million). Interest on cash deposits reduced to $0.2 million (2012: $0.6 million).

Expenses

Total operating expenditure for the half-year was $5.3 million (2012: $3.1 million). Royalty payments due to Monash Investment Trust increased to $1.5 million (2012: $0.1 million) in-line with increased product income. A non-cash expense of $0.6 million (2012: Nil) was recorded for employee share options granted during the reporting period, as required by accounting standard AASB 2.

Income Tax

Income tax expense for the half-year was $13.8 million (2012: $0.2 million) representing approximately 36% of profit before income tax. The parent entity (Acrux Limited) received an unfranked dividend of $13.5 million from a subsidiary (Acrux DDS Pty Limited) during the reporting period. This dividend is taxable income for Acrux Limited but it is not an allowable tax deduction for Acrux DDS Pty Limited. If not for this transaction, income tax expense would represent approximately 30% of profit before income tax. It should be noted that income tax expense recognised by Acrux Limited for the unfranked dividend received does not translate to a liability to pay income tax, as the parent entity utilised carried forward tax losses.

Cash flow

Net cash outflow for the half-year reduced to $5.6 million (2012: $11.1 million). Inflows of cash from operating activities increased to $7.7 million (2012: $2.3 million) with receipts from product agreements and government adding $13.3 million (2012: $5.4 million) to cash, while the payment of income taxes increased to $2.9 million (2012: $1.4 million).

Cash outflow from financing investing activities was the same as recorded for the half-year to 31 December 2012, $13.3 million, representing the payment of final dividends to shareholders.

Cash reserves at the end of the period were $17.5 million (30 June 2013: $22.8 million).

Forward-looking statements

This ASX announcement 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 announcement

Contact

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About Acrux (ASX: ACR)

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.
- The Acrux technology, used in marketed products including Axiron®, Evamist® and Recuvyra™, is based on a fast-drying, small volume, accurately dosed solution, containing penetration enhancers, that when applied topically, deposits drug through the skin for long acting delivery.
- Acrux has three products marketed by licensees in the USA, three products approved in Europe, and further products at earlier stages of development.