ACRUX (ACR) - ASX ANNOUNCEMENT 27 AUGUST 2013

ACRUX ANNOUNCES 2012/13 RESULTS AND DIVIDEND

Highlights:

- Final dividend of 8 cents per share unfranked, exempt from tax:
  - Record date – 9 September 2013
  - Expected payment date – 23 September 2013
- Financial results for 2012/13:
  - Revenue up 56% to $16.7 million
  - Profit before tax up 104% to $10.0 million
  - Profit after tax $6.9 million (2012: $7.4 million)
  - Earnings per share 4.2 cents (2012: 4.4 cents)
  - Cash at 30 June $22.8 million (30 June 2012: $30 million)
- Axiron® net sales more than doubled:
  - Net sales US$124 million, up from US$55 million in previous year
  - Acrux royalties $14 million, up from $6 million in previous year
  - Axiron launched in Australia and Canada; marketing authorisation received in Brazil
  - Axiron grew to be second largest product in the US testosterone therapy market based on share of total prescriptions
  - US healthcare plan (formulary) coverage expanded
  - Gross-to-net sales differential significantly reduced, as anticipated
  - Net sales US$84 million in the first half of 2013 calendar year; Acrux will receive a milestone payment of US$25 million in March 2014 if net sales in the 2013 calendar year exceed US$100 million
- Gedeon Richter appointed to commercialise estradiol skin spray therapy for female menopause symptoms in ex-US markets; Acrux has received US$1m and can earn further payments of US$2.6 million plus royalties on sales
- Low-cost proof of concept development activities initiated on two new topical products

Melbourne, 27 August 2013: Acrux (ASX: ACR) today declared a final dividend for 2012/13 of 8 cents per share, unfranked. The record date for entitlement to the dividend is 9 September 2013 and the estimated date for dispatch of payment is 23 September 2013. **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.

"We are pleased to declare another tax-free dividend of 8 cents per share, with the prospect of significantly higher dividends from 2013/14 as Axiron royalties grow and we earn the sales milestone payments", commented Acrux Chairman Ross Dobinson. "We are also pleased to have initiated proof of concept development on two new topical product opportunities for large markets", he added.

Axiron

Net sales (invoiced sales less rebates, discounts and returns) more than doubled to US$124 million, compared with $55 million in the 2011/12 financial year and in the first half of 2013 increased significantly to US$84 million, compared with US$40 million in the second half of 2012. Rebates in the initial launch period had been high, but as anticipated these have reduced in 2013 and are now comparable with the market leader.

Royalties on net sales were $14 million, compared with $6 million in the 2011/12 financial year. The average royalty rate is expected to increase in the second half of 2013. As well as royalties, Acrux will receive a milestone payment of US$25 million in March 2014 if net sales in the 2013 calendar year exceed US$100 million. Acrux intends to pay an interim dividend following receipt of that payment.

Whilst the topical market growth rate slowed in the first half of 2013 with the increased use of injectables, driven by adoption in new Men's Low-T clinics, Axiron has seen topical market share growth as a result of increased promotional activities, including a national television advertising campaign, and a fully operational men's health sales force within Lilly. Since the start of 2013, Axiron has achieved the second largest share of the US topical testosterone therapy market based on share of total prescriptions. Lilly has significantly expanded the healthcare plan formulary coverage of Axiron during the last year.

The current ex-US markets for testosterone therapy are underdeveloped (current annual sales approximately US$300 million), however the number of potential patients in these markets is greater than the number in the US. Commercialisation of Axiron outside the US is already well underway. Sales are growing in both

Australia and Canada (which currently is the largest ex-US market for testosterone), and a launch in Brazil is planned. Marketing applications in Europe have been filed, including in Germany, which is the second largest ex-US market.

The testosterone therapy market has a number of long term growth prospects, with testosterone recently linked as a potential treatment to a number of growing disease states. In particular, the growing incidence of Type II Diabetes and obesity has been associated with a higher incidence of low testosterone. Current studies indicate that approximately 50% of obese men (including obese diabetics) and approximately 30% of lean diabetics have low testosterone (Mulligan, T, et al, Prevalence of hypogonadism in males aged at least 45 years: the HIM study, *Int J Clin Pract*, July 2006,**60**, 7, 762-769). The World Health Organisation predicts that there will be 700 million obese adults by 2015. Exploratory clinical studies have also been publicised investigating testosterone effects in both Alzheimer's and Multiple Sclerosis. Further clinical studies on the indications and benefits of testosterone therapy are warranted, and Lilly has already initiated clinical trials with Axiron to study sex drive/energy levels, ejaculatory dysfunction and suboptimal responders to testosterone gels.

In the United States Axiron is now protected by 8 patents until 2030, 2027, 2026 and 2017, and 2 pending patent applications. The patents cover 3 different important aspects of the product – the formulation and delivery method, administration to the underarm and the physical applicator. Acrux and Lilly are seeking to enforce their patent rights relating to Axiron. In a case filed in the United States District Court, Southern District of Indiana in May 2013, Acrux and Lilly, allege that Perrigo Company's and Perrigo Israel Pharmaceutical Ltd.'s proposed generic product infringes Acrux's patents and seek declaratory and injunctive relief. Lilly is fully funding this legal action. Androgel®, Testim® and Fortesta® patents have also been challenged by substitutable (ANDA) and non-substitutable (NDA) products, and multiple litigations are being conducted.

Lilly has demonstrated a substantial financial investment in Axiron which is designed to maximise the product's long term prospects. As well as the AUD$166m it has paid to Acrux to date, a significant investment has been made in the supply chain, US promotion, and preparation for product launches outside the US. Lilly has recently released new TV advertisements that will enhance its national direct to consumer advertising. Importantly, these investments are funded by Lilly and are not deducted from sales.

Estradiol spray

A number of developments are in progress for the first product that Acrux developed – the estradiol spray for menopause symptoms.

Gedeon Richter, Acrux's licensee for ex-US distribution, is preparing for European regulatory submission and commercialisation. Upon signing the agreement in June 2013, Acrux received a US$1 million fee, and will receive up to US$2.6m following further European regulatory milestones, followed by royalties on sales expected to commence in 2015. Marketing applications are also under review in South Africa and South Korea.

KV Pharmaceutical, Acrux's US licensee, is currently in Chapter 11 bankruptcy protection. Acrux expects the bankruptcy process to be resolved in the 2013/14 financial year, the outcome of which will determine Acrux's future actions. US net sales are currently approximately US$10 million per annum.

Elanco Products

Acrux also has a partnership with Lilly on animal health products using the Acrux technology. The first product (Recuvyra), for post-operative pain relief in dogs, has launched in the US and Europe, and the first royalties have been received. Lilly is working on a number of other products for animals for which Acrux will receive royalties on worldwide sales as well as product approval milestones.

New products

Acrux has recently initiated low cost proof of concept development of two new topical products in substantial market sectors, including one cancer treatment being developed using the Acrux technology in partnership with one of the leading cancer research institutes. Proof of concept data is anticipated during the 2013/14 financial year. In addition further formulation development of a topical pain therapy is underway.

Summary of financial results:

	30 June 2013 $m	30 June 2012 $m
Product agreement revenue	15.5	9.0
Interest and grant income	1.2	1.7
Total revenue	16.7	10.7
Royalties payable	(0.5)	(0.3)
Capitalised development amortisation	(1.3)	(0.2)
Other expenditure	(4.8)	(5.3)
Total expenditure	(6.6)	(5.8)
Profit before tax	10.0	4.9
Income tax (expense)/benefit	3.1	2.5
Profit after tax	6.9	7.4
Earnings per share	4 cents	4 cents
Dividends per share	8 cents	8 cents
Net cash inflow/(outflow) before payment of dividends	6.3	(2.5)
Dividends paid	(13.4)	(0.6)
Cash at 30 June	22.8	30.0

Revenue

Total revenue for the financial year was $16.7 million (2012: $10.7 million). Revenue related to product agreements was $15.5 million (2012: $8.8 million). Axiron royalties and development services contributed $14.4 million (2012: $7.2 million) and a signing fee of $1.1 million was recorded following the execution of a manufacturing and marketing agreement with Gedeon Richter to commercialise Acrux's estradiol spray in markets outside the United States. Interest income added $0.9 million (2012: $1.6 million).

Expenses

Total Operating expenditure was $6.6 million (2012: $5.8 million). Employee benefits expenses and Directors' fees reduced to $2.5 million (2012: $2.8 million). Royalty payments to Monash Investment Trust increased to $0.5 million (2012: $0.3 million), in-line with increased product income. Depreciation and amortisation expense increased to $1.4 million from $0.3 million in the prior year, as a result of the International Financial Reporting Committee's (IFRC) clarification of the allowable methods of amortising capitalised research and development expenditure.

Income tax expense for the financial year was $3.1 million, compared with an income tax benefit of $2.5 million in the prior year. The prior year tax benefit was the result of $4.1 million of tax losses recorded from excess imputation credits on dividends received by the parent entity and additional tax deductions received from amended prior year research and development tax concession claims, offset by tax expense of $1.6 million.

Cash flow

Net cash provided by operating activities increased to $6.3 million (2012: net cash used $2.4 million), driven by receipts from product agreements increasing to $12.6 million (2012: $6.4 million) due to the growth of Axiron royalties. Income taxes of $2.6 million were paid during the year (2012: $4.6 million).

Net cash outflow after dividend payments was $7.0 million (2012: $3.1 million). The payment of the final dividend for the 2011/12 financial year produced an outflow for financing activities of $13.4 million compared with a modest outflow in the prior year of $0.6 million representing the clearing of unclaimed payments from the 2011 special dividend.

Cash reserves at 30 June 2013 were $22.8 million (30 June 2012: $30.0 million).

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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 liquid technology to administer drugs through the skin.

Acrux has products marketed by licensees in the US, Europe, Canada and Australia and in registration or development in a number of additional territories.