# Acrux (ASX: ACR)

**2012 Annual General Meeting** 

22 November 2012



#### FORWARD-LOOKING STATEMENTS

This presentation 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 presentation.

Actual results could differ materially depending on factors such as the availability of resources, the results of clinical studies, the timing and effects of regulatory actions, the strength of competition and the effectiveness of patent protection.



#### STRATEGY

Maximise shareholder value by:

- Helping Lilly ensure Axiron optimises global long-term potential
- Optimising the commercial value of estradiol spray and animal health
- Exploiting commercial potential of Luramist
- Commercialising a new product with current delivery IP
- Evaluating other opportunities complementary to Axiron
- Maintaining core competencies in a low cost infrastructure
- Avoiding funding highly speculative R&D





# Axiron



#### ADVANCES IN LAST YEAR

- Gross sales growth in line with Acrux's expectations
  - 30% growth in transdermal testosterone US prescriptions 2012 versus 2011 market expected to be ~US\$1.9 billion in 2012
  - Current 13% share of transdermal testosterone prescriptions in US
- Access to National and Regional Managed Care formularies
  - Pharmacy Benefit Managers:
    - Express Scripts/Medco upgraded to Tier 2 from 1 July 2012 for ~35m lives
    - CVS Caremark upgraded from not reimbursed to preferred formulary status from 1 January 2013 for ~22m lives. Androgel & Testim will be not reimbursed.
  - Regional Commercial Managed Care:
    - Capital BCBS, Carefirst, Harvard Pilgrim & BCBS Vermont
- Marketing approvals in Canada and Australia
- Underarm administration patent granted in four countries, applicator patent granted to 2030 in United States





### LILLY'S INVESTMENTS IN AXIRON

- Payments to Acrux (to date ~ \$150m)
- Supply chain improvements
- Manufacturing capacity expansion
- Substantial and ongoing direct-to-consumer advertising
- Promotion to specialist physicians and PCPs
- Further clinical study of the indications and benefits of treatment
- Ex-US marketing applications and product launch preparations



#### **ERECTILE DYSFUNCTION MARKET**

- Cialis<sup>®</sup> entered erectile dysfunction market in 2003, 5 years after a very well established and dominant Viagra<sup>®</sup>
- Cialis now rivals Viagra<sup>®</sup> globally as leading erectile dysfunction treatment net sales in 2011:
  - Cialis \$1.9 billion (including \$1.2 billion ex-US)
  - Viagra \$2.0 billion (including \$1.0 billion ex-US)
- Product differentiation and understanding needs of patients and physicians in men's health
- Substantial and effective direct to consumer marketing



## ADVANCES EXPECTED IN NEXT YEAR

- Continuing US market growth
  - Transdermal prescriptions Q3 2012 were 4% higher than Q2 2012 (30% higher than Q3 2011)
- Market share growth
  - Become second largest product
  - Driven by increasing national direct to consumer marketing
- Significant increase in net sales
  - Growth in formulary coverage
  - Reduced gross to net deductions
- Axilla (underarm) administration patent
  - Response to US Patent and Trademark Office in December 2012
- Initiating global commercialisation
  - Launches in Australia and Canada
  - Marketing application decisions in Europe



#### AXIRON - BEYOND THE CURRENT US MARKET

- Ex-US markets for testosterone therapy underdeveloped
  - Current annual sales approximately US\$300 million
  - Annual US sales were ~US\$300 million ten years ago
  - Number of potential patients is greater than in the US
  - Axiron will be the first global brand
- Growing incidence of Type II Diabetes, obesity, metabolic disease with associated high incidence of low testosterone



# Other products



#### ADVANCES IN LAST YEAR

- Recuvyra marketing approval in United States and launched in Europe
- Estradiol spray marketing approval notice in Switzerland
- Formulation development in progress for new transdermal products



#### ADVANCES EXPECTED IN NEXT YEAR

- Recuvyra first royalties
- Estradiol spray distributor outside the US
- Resolution of estradiol spray license in US
- Licensing opportunities with new products



# Financials



### **REPORTED FINANCIALS**

	FY 2009/10 \$m	FY 2010/11 \$m	FY 2011/12 \$m
Revenue	56 <sup>1</sup>	<b>93</b> <sup>2</sup>	11
Profit before tax	49	82	4.9
Tax (charge)/benefit	(2)	(25)	2.5
Profit after tax	47	57	7.4
Earnings per share	29 cents	35 cents	4 cents
Dividend (tax-free)	-	60 cents	8 cents
Cash at 30 June	59	33	<b>30</b> <sup>3</sup>
Franking account at 30 June			10

<sup>1</sup> Included US\$50m from Lilly on signing Axiron agreement
<sup>2</sup> Included US\$87m from Lilly on FDA approval of Axiron
<sup>3</sup> Prior to dividend payment of \$13.3m



## FINANCIAL OUTLOOK - REVENUE



Royalty = (US market size x US market share - Rebates + Ex-US sales) x average royalty %							
Outlook:	$\uparrow$	$\uparrow$	$\downarrow$	$\uparrow$	$\uparrow$		

- Axiron royalties:
  - Percentages of worldwide net sales
  - Tiered structure with average rate increasing as sales increase
  - Multiple factors combining to drive future growth from US\$6m in 2011/12
- Axiron milestone payments:
  - US\$25 million expected 2013/14 (net sales  $\geq$  US\$100m in calendar year)
  - US\$50 million expected 2014/15
  - US\$120 million expected 2018/19 to 2021/22
- Other revenue, including animal health and estradiol spray



## FINANCIAL OUTLOOK - EXPENDITURE



- 2011/12 expenditure reduced to \$5.3m, excluding:
  - Monash royalty (3.5% of product revenues, expiring 2017)
  - Amortisation of capitalised R&D costs
- Expenditure excluding these items reduced to ~\$5m in 2012/13
- Minimising costs, but retaining core competencies to support Lilly and exploit new product opportunities





