

# Acrux (ASX: ACR)

23 August 2012

# FORWARD-LOOKING STATEMENTS

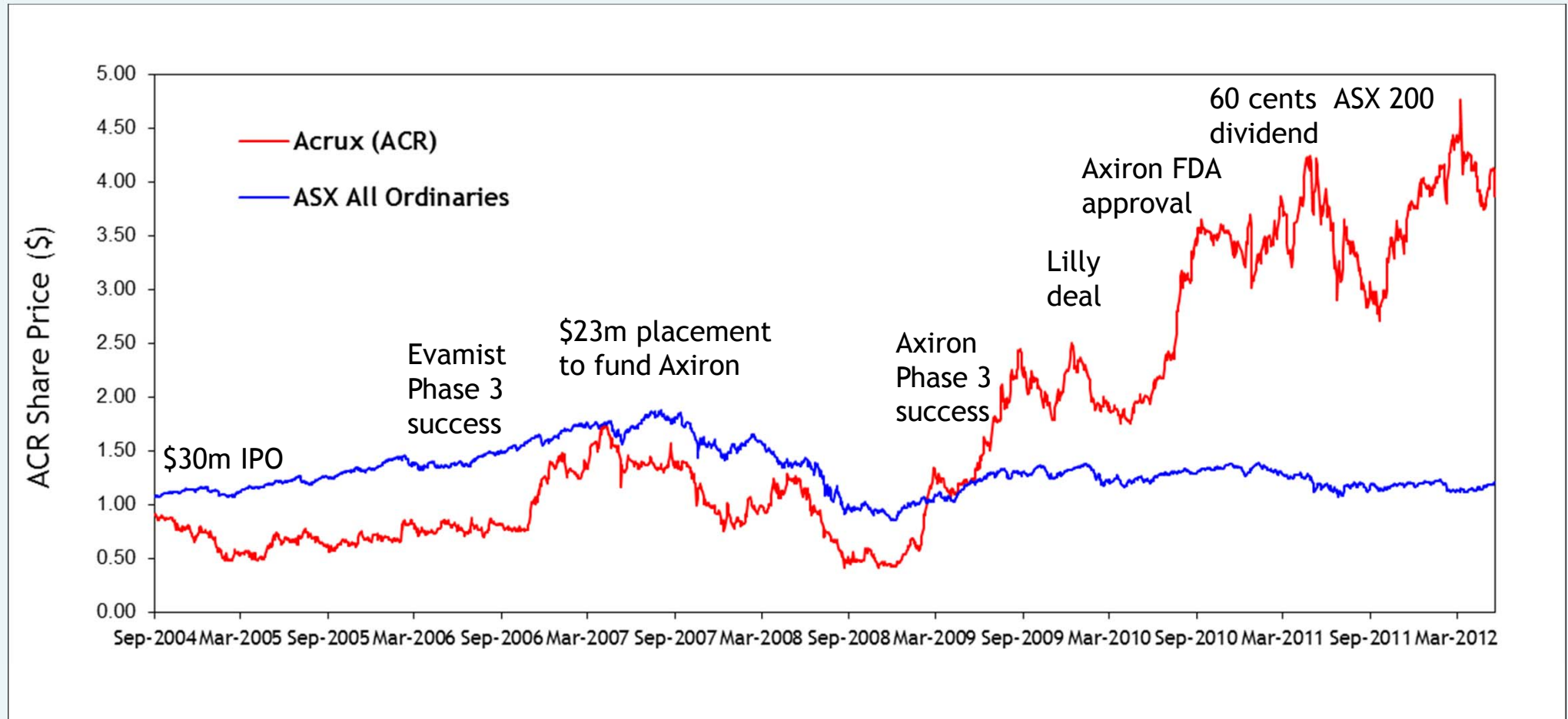
This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Acrux to be materially different from the statements in this presentation.

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.

## ACRUX (ASX: ACR) AT A GLANCE

- Market cap ~\$650m; joined S&P/ASX 200 in September 2011
- Pooled Development Fund; capital gains and dividends exempt from tax
- Unique, patented technology for delivering drugs through the skin; commercialisation through partnerships
- Key product Axiron<sup>®</sup>, partnered with Eli Lilly
  - testosterone therapy for men with hypogonadism (low testosterone)
  - US market worth ~US\$1.5 billion in 2011; current growth ~30% per annum
  - Axiron launched in April 2011; 12.5% market share in July 2012

# ACR SHARE PRICE PERFORMANCE SINCE IPO



## AXIRON PARTNERSHIP WITH ELI LILLY

- Lilly receives exclusive worldwide rights to Axiron
- Acrux revenue:
  - US\$50 million on signing (received 2009/10)
  - US\$3 million on transfer of manufacturing assets (received 2010)
  - US\$87 million on FDA marketing authorisation (received 2010/11)
  - Potential net sales milestone payments of US\$195 million
    - US\$25 million expected 2013/14
    - US\$50 million expected 2014/15
    - US\$120 million expected 2018/19 to 2021/22
  - Royalties on worldwide net sales - tiered structure with average rate increasing as sales increase

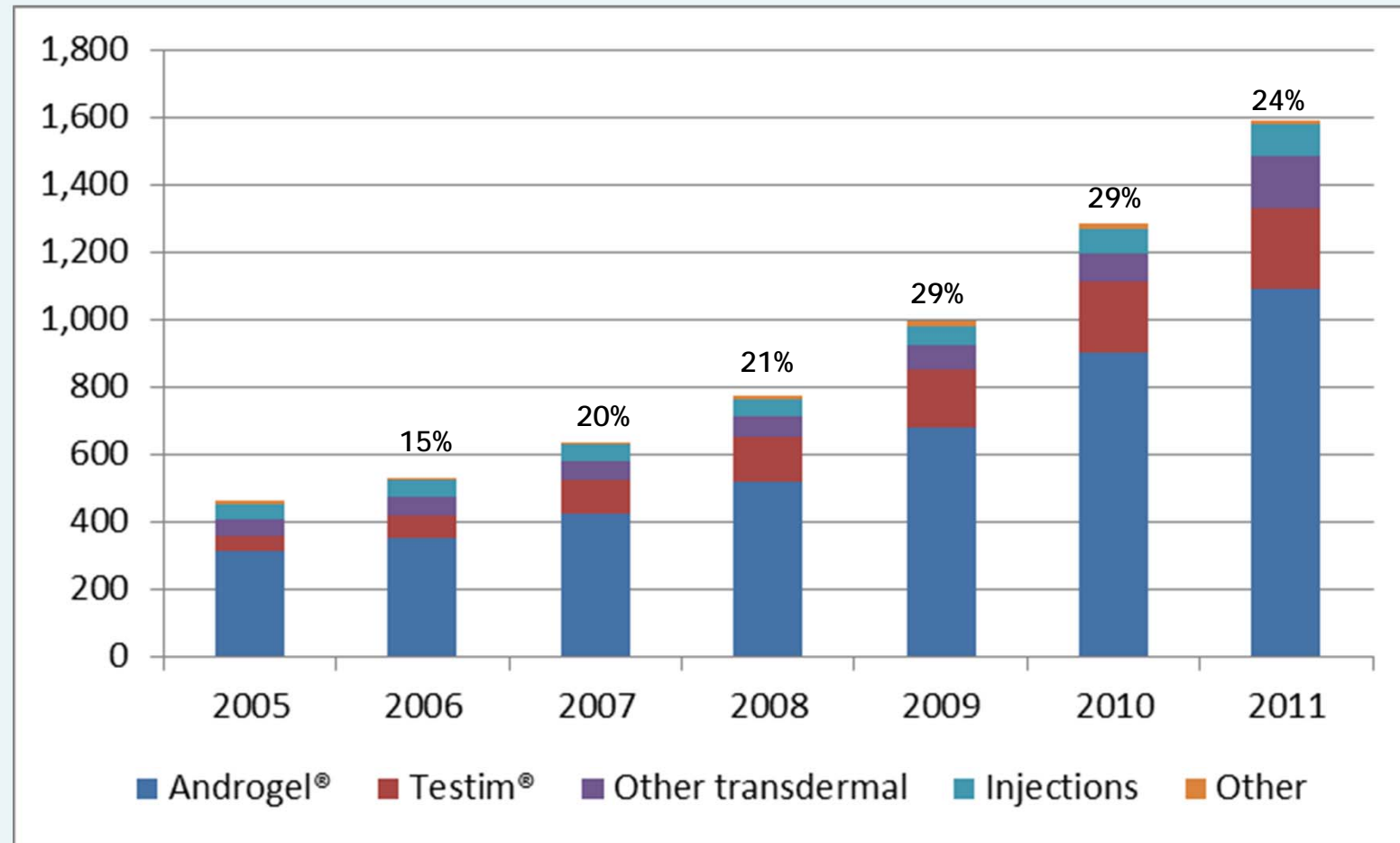
## LILLY IS COMMITTED TO MEN'S HEALTH



- Cialis® rivals Viagra® globally as leading erectile dysfunction treatment
- Significant ongoing investment in Axiron:
  - increasing promotion to specialists, primary care physicians and direct-to-consumer
  - expansion of manufacturing capacity in H2 2012 to meet anticipated rapid growth in demand for US and other markets
  - additional clinical studies to continue improving prospects for Axiron

# US TESTOSTERONE MARKET GROWTH

Male Testosterone Therapy Market, United States 2005 to 2011 (US\$million)



Source: IMS data

- 5 Year CAGR = 24.5%
- H1 2012 year-on-year growth ~ 30%
- Transdermal therapies comprise 93% of sales

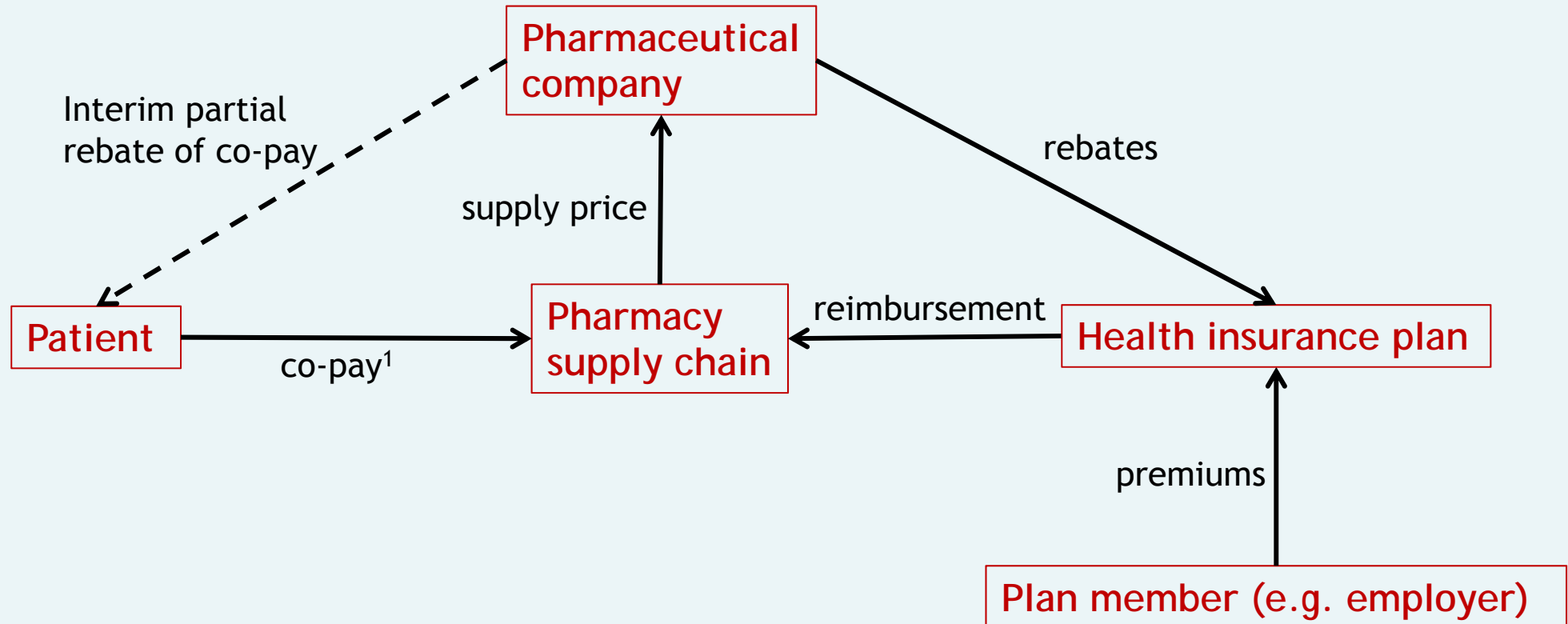
# US MARKET SHARE SINCE LAUNCH

Share of Total Prescriptions (TRx) for transdermal products in United States

	April 2011	July 2012	Change
<i>Androgel</i> <sup>®</sup> 1%	72%	30%	-42%
<i>Androgel</i> <sup>®</sup> 1.62%	-	33%	+33%
Total <i>Androgel</i> <sup>®</sup>	72%	63%	-9%
<i>Testim</i> <sup>®</sup>	20%	16%	-4%
<i>Axiron</i> <sup>®</sup>	-	13%	+13%
<i>Androderm</i> <sup>®</sup>	7%	5%	-2%
<i>Fortesta</i> <sup>®</sup>	1%	3%	+2%
Total transdermal	100%	100%	



# US REIMBURSEMENT CASHFLOWS



<sup>1</sup> Plans may wait 12 months before adding new products to approved drug formularies; amount of co-pay is determined by plan drug formulary access (tier 2 < tier 3 < no formulary access)

# GROSS TO NET SALES

- Net sales = invoiced sales less rebates, discounts, returns
- Axiron co-pay card has assisted patients prior to securing access to health plan formularies, so that out-of-pocket expense for Axiron patients is similar to other testosterone therapies that already have access to formularies
- Gross to net deductions in launch period have been high due to the use of co-pay cards - expected to reduce from Q4 2012 as card use decreases
- Axiron health plan formulary access increased significantly from 1 July 2012

## US Net sales since launch

	Q1 2011	Q2 2011	Q3 2011	Q4 2011	Total 2011	Q1 2012	Q2 2012
Reported net sales (US\$m)	0.0	3.2	5.3	15.5	24.0	16.2	17.7
Average market share (%)	0%	2%	6%	9%	4.6%	11%	12%
Total market (US\$b)					1.5		
Implied gross sales (US\$m) <sup>1</sup>					68		
Implied rebates (%) <sup>2</sup>					65%		

<sup>1</sup> Estimated as total market multiplied by average market share

<sup>2</sup> Estimated as implied gross sales less net sales, divided by implied gross sales

## EX-US MARKETS

- Lilly distributes products into 125 countries
- Lilly responsible for obtaining marketing authorisations for Axiron in ex-US countries
  - Canada and Australia authorisations received in April/May 2012
  - Decisions in select European countries expected in 2012/13
  - Application filed in Brazil
- Royalties from ex-US sales will commence in 2012/13 financial year
- Ex-US markets for testosterone therapy underdeveloped
  - Annual sales approximately US\$250 million
  - US sales were ~US\$300 million ten years ago
  - Number of potential patients is greater than in the US

# PATENT PROTECTION

Formulation and delivery system  
Granted major markets; expiry 2017

Underarm administration  
Granted Au, Singapore, South Africa;  
expiry 2026; Other markets pending



Applicator  
Granted US (expiry 2030),  
Eurasia, South Africa, Au;  
Other markets pending

Composition  
Granted AU, NZ, Canada, Eurasia,  
India, Singapore; expiry 2023

Designs  
Applications pending  
Anticipated expiry 2029

## ANIMAL HEALTH

- Exclusive global licence for animal health products utilising Acrux's delivery technology
- Acrux earns royalties plus product approval milestones
- First product Recuvyra<sup>®</sup> approved for marketing in US and Europe - launch Q3 2012
- Further products in clinical development



**Elanco**

# ESTRADIOL SPRAY

- Actively seeking distributor for Europe
- Marketing applications under review in South Africa and South Korea
- US rights held by KV Pharmaceutical - in August 2012 KV filed for Chapter 11 bankruptcy protection

# REPORTED FINANCIALS

	FY 2009/10 \$m	FY 2010/11 \$m	FY 2011/12 \$m
Revenue	56 <sup>1</sup>	93 <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	30 <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

- Multiple factors combining to drive future growth of Axiron royalties from US\$6m in 2011/12:

$$\text{Royalty} = (\text{US market size} \times \text{US market share} - \text{Rebates} + \text{Ex-US sales}) \times \text{average royalty \%}$$

Trend:            ↑                                    ↑                                    ↓                                    ↑                                    ↑

- Axiron milestone payments:
  - US\$25 million expected 2013/14 (net sales ≥ US\$100m in calendar year)
  - US\$50 million expected 2014/15
  - US\$120 million expected 2018/19 to 2021/22
- Royalties and milestone payments from animal health and estradiol spray
- Current expenditure ~ \$5m per year plus Monash royalty 3.5% of product revenues (expires 2017) and amortisation, partly offset by Lilly technical support





# 2012/13 MILESTONES

- Axiron:
  - US net sales growth
  - underarm 2026 patent - response to USPTO in H2 2012
  - marketing application decisions in Europe
  - launch in Australia and Canada
- Other products:
  - Recuvyra launch in US and Europe
  - Estradiol spray distributor in Europe
  - Resolution of US estradiol spray distribution
  - Evaluation of new product opportunities



 **Axiron**<sup>®</sup>  
(testosterone)  
topical solution 