

# Acrux (ASX: ACR)

18 February 2013

# FORWARD-LOOKING STATEMENTS

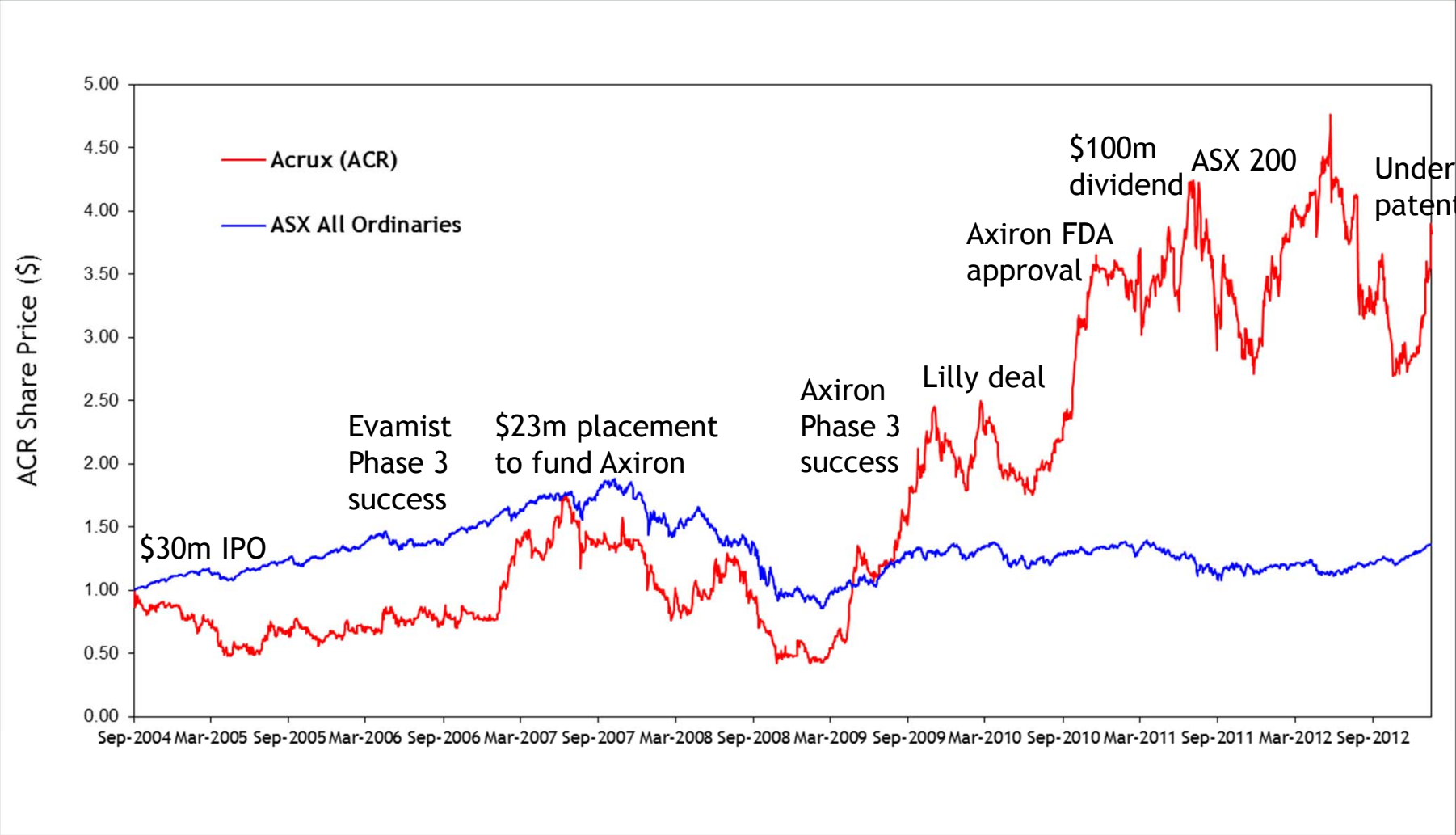
This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of Acrux to be materially different from the statements in this presentation.

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
- Profitable for the last 3 years
  - Paid special dividend (60 cents per share, total \$100m) in 2011
  - Paid first regular dividend (8 cents per share, total \$13m) in 2012
- 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> testosterone therapy, partnered with Lilly globally

# ACR SHARE PRICE PERFORMANCE SINCE IPO

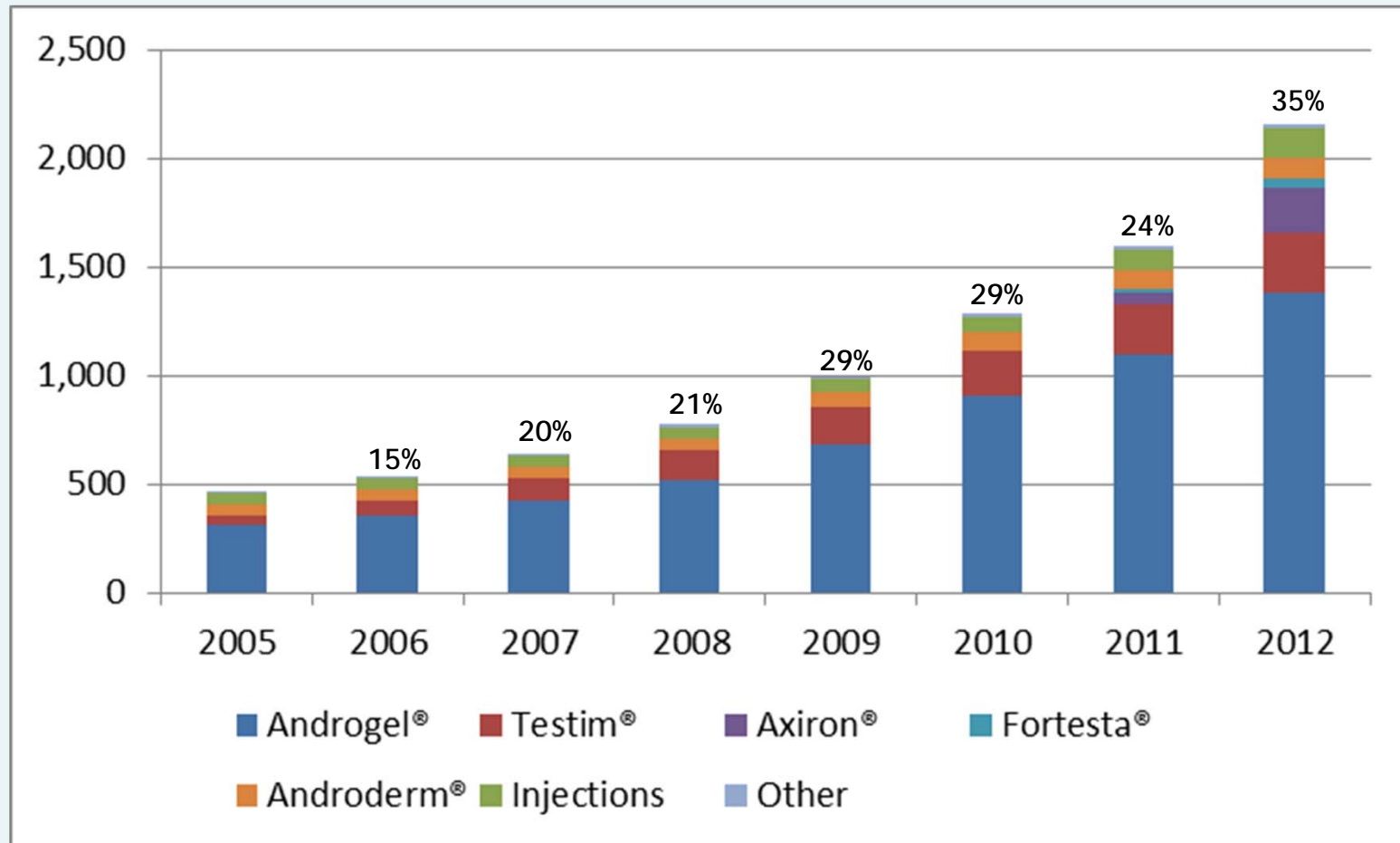


# Axiron



# US TESTOSTERONE MARKET

Male Testosterone Therapy Market, United States 2005 to 2012 (US\$ million)



Source: internal

- Transdermal therapies excluding Androderm® comprise ~89% of sales value
- Transdermal prescriptions in 2012 ~28% higher than 2011

# US MARKET SHARE SINCE AXIRON LAUNCH



Share of Total Prescriptions (TRx) for transdermal products<sup>1</sup> in United States

	April 2011	30 Nov 2012	1 Feb 2013	Change in 2 months
<i>Androgel</i> <sup>®</sup> 1%	77%	26.5%	23.9%	-2.6%
<i>Androgel</i> <sup>®</sup> 1.62%	-	41.1%	40.9%	-0.2%
Total <i>Androgel</i> <sup>®</sup>	77%	67.6%	64.8%	-2.8%
<i>Testim</i> <sup>®</sup>	22%	15.5%	15.0%	-0.5%
<i>Axiron</i> <sup>®</sup>	-	13.3%	14.6%	+1.3%
<i>Fortesta</i> <sup>®</sup>	1%	3.6%	5.6%	+2.0%
Total transdermal <sup>1</sup>	100%	100%	100%	

<sup>1</sup> excluding Androderm<sup>®</sup> patch

Source: internal

# NET SALES

- Royalties and milestone payments depend on worldwide net sales
- Net sales = invoiced sales less rebates, discounts, returns
- Rebates in launch period were high - this is expected to reduce through 2013
- Rebates assisted patients prior to securing access to health plan formularies

## US Net sales since launch

	Q1 2011	Q2 2011	Q3 2011	Q4 2011	Total 2011	Q1 2012	Q2 2012	Q3 2012	Q4 2012	Total 2012
Reported net sales (US\$m)	0.0	3.2	5.3	15.5	24.0	16.2	17.7	16.0	23.9	73.9
Average market share (%)	0%	2%	6%	9%	4.6%	11%	12%	12%	13%	12%



# MANAGED CARE FORMULARIES

- Improvements in access to both National and Regional Managed Care formularies from 1 January 2013:
  - CVS Caremark
    - Axiron upgraded from not reimbursed to preferred formulary status (~22m lives)
  - Capital Blue Cross
  - Sanford Health
  - BCBS Louisiana
  - Gateway
  - First Care
  - Fidelis
- Further improvements expected during 2013

# AXIRON OUTLOOK FOR 2013

- Continuing US market growth
  - Transdermal prescriptions in January 2013 were ~18% higher than January 2012
- US market share growth
  - Axiron weekly share of Total Prescriptions (TRx) increased from 13.3% on 30 November 2012 to 14.6% on 1 February 2013
  - Share of weekly New Prescriptions (NRx) higher than TRx at 16.4% on 1 February
  - 2<sup>nd</sup> largest share of NRx in January 2013, 21 months after launch
- Significant increase in US net sales
  - Impact of already improved formulary coverage compared with 2012
  - Further improvements in coverage during 2013
  - Reducing gross to net deductions
- Initiating global commercialisation
  - Launches in Australia and Canada
  - Marketing application decisions in Europe

# PATENT PROTECTION IN UNITED STATES

Formulation and delivery system  
4 granted patents, expiry 2017

Underarm administration  
1 allowed patent, expiry 2027  
1 pending patent



Applicator  
1 granted patent, expiry 2030  
1 pending patent

# COMPETITIVE LANDSCAPE IN UNITED STATES

- Transdermal gels
  - Patent expiries - Androgel 2020, Testim 2023/25, Fortesta 2018
  - Androgel and Testim patents challenged by substitutable (ANDA) and non-substitutable (NDA) products - multiple litigations in progress
  - US Supreme Court reviewing past Solvay/Watson/Par agreements regarding Androgel ANDAs
- Other testosterone delivery systems in development - nasal gel, capsules, depot injection
  - Significant regulatory, clinical and commercial hurdles still to be overcome by new entrants, particularly those without distribution networks
- Acrux confident of Axiron's sustainable competitive advantage

# LILLY'S INVESTMENTS IN AXIRON

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

# POTENTIAL 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
- Expanding knowledge of testosterone
  - Growing incidence of Type II Diabetes, obesity, metabolic disease with associated high incidence of low testosterone
  - Exploratory clinical studies have been publicised investigating testosterone effects in Alzheimer's and in Multiple Sclerosis

# Other products and outlook

# OTHER PRODUCTS

- Animal health products
  - Licensed to Elanco (Eli Lilly)
  - First royalties in 2013 from Recuvyra<sup>®</sup> in US and Europe
  - Other products in clinical development
- Estradiol spray
  - Actively seeking distributor for Europe
  - Marketing applications under review in South Africa and South Korea
  - Resolution of US rights - KV Pharmaceutical in Chapter 11 bankruptcy protection
- New products
  - Formulation development in progress for new transdermal products
  - Licensing opportunities expected in 2013





## 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

# SUMMARY OF 2013 MILESTONES

- Axiron:
  - US net sales growth - royalties and first sales milestone payment
  - marketing application decisions in Europe
  - launch in Australia and Canada
- Other products:
  - Recuvyra first royalties
  - Estradiol spray distributor in Europe
  - Resolution of US estradiol spray distribution
  - Licensing opportunities for new products



**Axiron**<sup>®</sup>

(testosterone)

topical solution 