

# Acrux (ASX: ACR)

14 November 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 ~\$450m; joined S&P/ASX 200 in September 2011
- Profitable for the last 4 years
  - Paid special dividend (60 cents per share, total \$100m) in 2011
  - Paid first regular dividend (8 cents per share, total \$13m) in 2012
  - Paid second regular dividend (8 cents per share, total \$13m) in 2013
  - Dividend to be declared in Q1 2014 subject to milestone receipt
- 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 Lilly globally



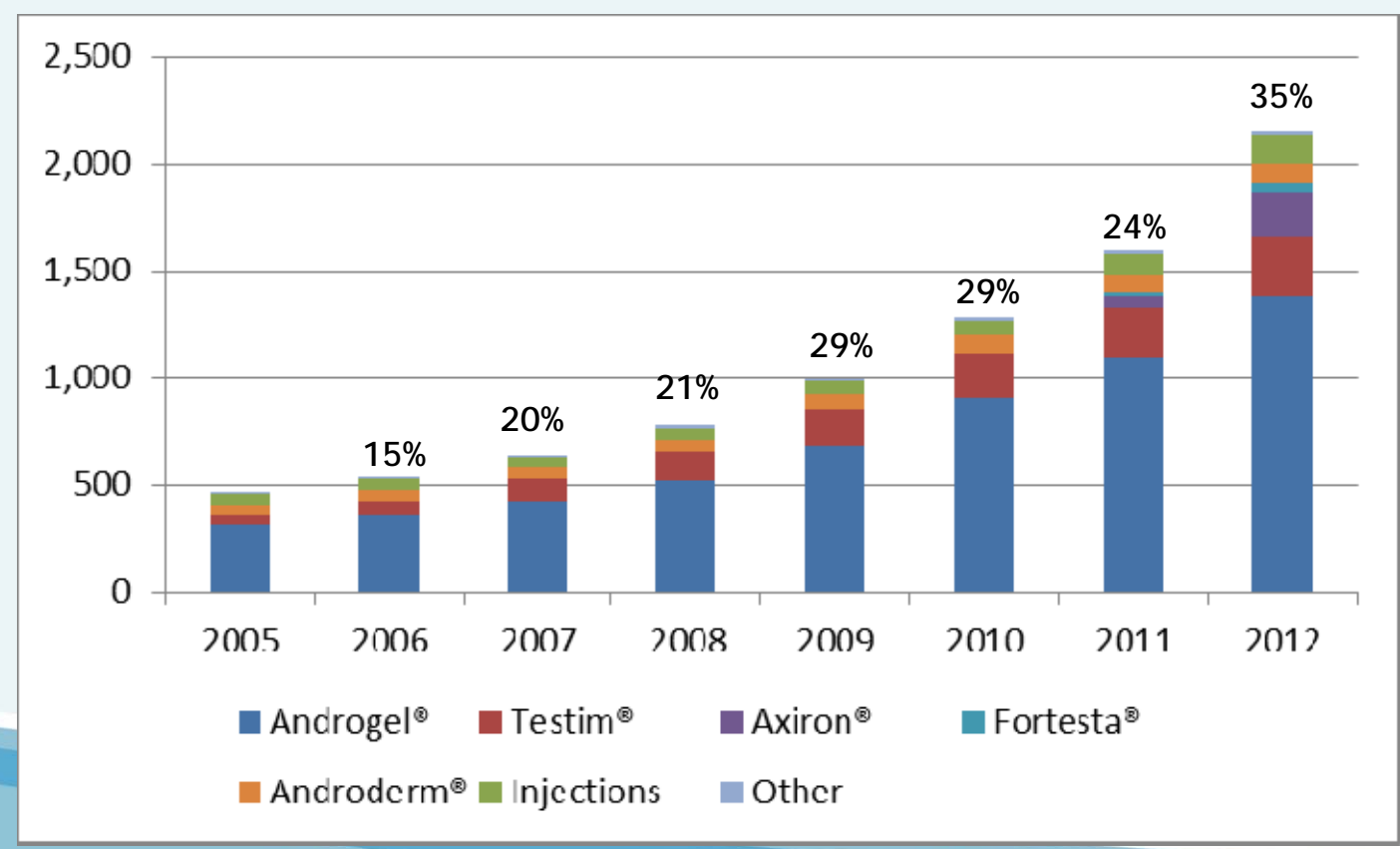
# Axiron



# US TESTOSTERONE MARKET

- The topical market continues to grow but has slowed to a lower rate than the last two years, currently at 6% (YTD over YTD August)
- The injectable market has shown recent growth, however the topical market is still a substantially larger market in the US

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



Source: IMS data



# US MARKET SHARE SINCE AXIRON LAUNCH



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

	April 2011	25 Oct 2013	Change
<i>Androgel</i> <sup>®</sup> 1%	77%	19.4%	-57.6%
<i>Androgel</i> <sup>®</sup> 1.62%	-	45.3%	+45.3%
Total Androgel <sup>®</sup>	77%	64.7%	-12.3%
Axiron <sup>®</sup>	-	14.3%	+14.3%
Testim <sup>®</sup>	22%	13.5%	-8.5%
Fortesta <sup>®</sup>	1%	7.5%	+6.5%
Total transdermal <sup>1</sup>	100%	100%	

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

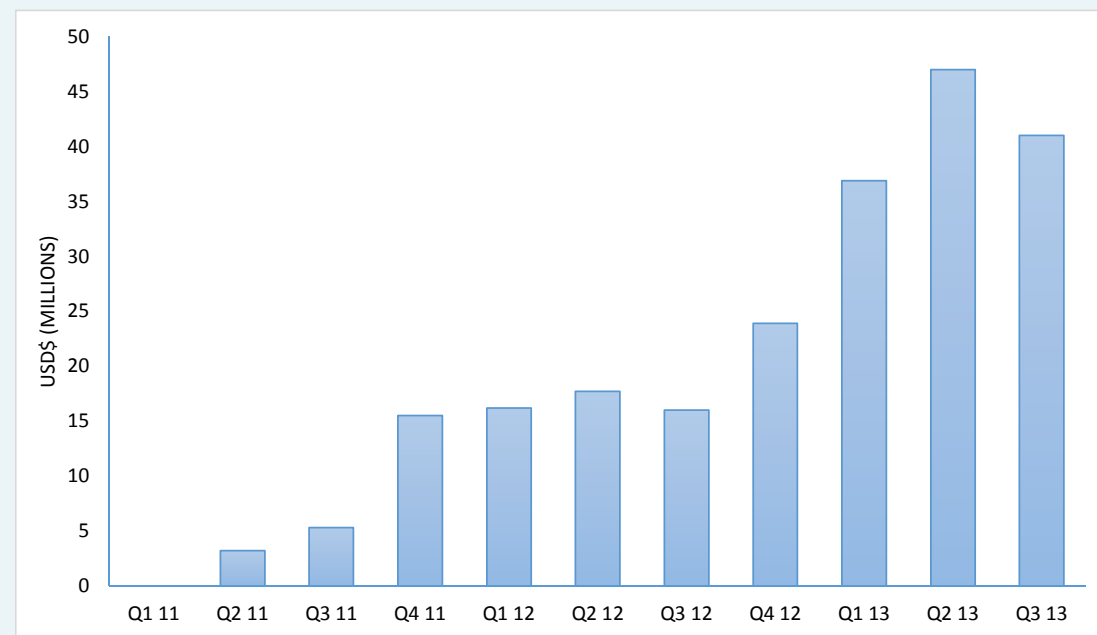
Source: internal

# GLOBAL NET SALES SINCE LAUNCH



- Net sales = invoiced sales less rebates, discounts, returns
- Formulary rebates typically accrued, as invoiced 6mths+ in arrears\*
- Q3 net sales typically adjusted to account for actual versus forecast rebate for Q1 and Q2

## 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	Q1 2013	Q2 2013	Q3 2013
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	37.1	47.1	40.6
Average market share (%)	0%	2%	6%	9%	4.6%	11%	12%	12%	13%	12%	14%	14%	14%

Transdermal gel market share, excluding Androderm



\*Details can be found on FDA website (Pharmacy Benefit Management Companies (PBMs) process) and ESI white paper on formulary implementation

# MANAGED CARE FORMULARIES



- 82% of MHRT Volume flows through Commercial Managed Care plans
  - at least 87% of all commercially insured lives now have some form of access to Axiron (including prior authorisations and step-edits)
- Tier 2 access to Express Scripts/Medco formularies from July 2012 (~23m lives)
- Axiron has highest unrestricted access in Commercial Managed Care as of January 1, 2014



# POTENTIAL BEYOND THE CURRENT US MARKET

- Current ex-US markets for testosterone therapy underdeveloped
  - Current annual sales approximately US\$300 million
  - Annual US sales were ~US\$300 million ten years ago
  - Axiron already launched in Canada, Australia and approved in Brazil and Germany
  - Canada, Australia, Germany and Brazil comprise more than half the OUS \$ market
    - Canada currently the largest ex-US market for testosterone
    - Germany, the first European approval, currently the second largest ex-US market

# LILLY'S INVESTMENTS IN AXIRON

- Payments to Acrux (to date ~ AUD\$166m)
- Men's health sales force within Lilly fully operational
- Supply chain improvements and significant manufacturing capacity expansion
- Continuing product launch preparations
- Substantial and ongoing
  - Direct-to-consumer advertising in the US.
  - Improved promotion to specialist physicians and PCPs, including increase in sample penetration rate
  - Clinical studies on the benefits of Axiron treatment
    - e.g. initiated clinical trials studying sex drive/energy levels, ejaculatory dysfunction and suboptimal responders to other testosterone gels

# EXPANDING KNOWLEDGE OF TESTOSTERONE

Studies conducted by medical institutes demonstrate potential for testosterone market growth:

- Growing incidence of Type II Diabetes and obesity with associated higher incidence of low testosterone
  - current studies indicate 50% of obese men (including obese diabetics) and ~30% of lean diabetics have low testosterone
  - World Health Organisation predicts 700 million obese adults by 2015
- Exploratory clinical studies have been publicised investigating testosterone effects in Alzheimer's and in Multiple Sclerosis
- Potential application in treating cachexia in cancer patients, chronic opioid use and renal disease

# PATENT PROTECTION IN UNITED STATES

Formulation and delivery system  
4 granted patents, expiry 2017

Underarm administration  
1 granted patent, expiry 2027  
1 allowed patent, expiry 2026  
1 patent application pending



Applicator  
2 granted patents, expiry 2026 and 2030  
1 patent application pending

# COMPETITIVE LANDSCAPE IN UNITED STATES

- Existing transdermal products
  - Patent expiries - Androgel 2020(1%)/2026(1.62%), Testim 2023/25, Fortesta 2018
  - Androgel, Testim and Fortesta patents challenged by substitutable (ANDA) and non-substitutable (NDA) products - multiple litigations
  - Lilly/Acrux litigation against both Perrigo and Actavis (Watson) for infringement of Axiron patents by ANDA filing
- Other testosterone delivery systems in development - nasal gel, capsules, depot injection
  - Significant clinical, regulatory and commercial hurdles to be overcome by prospective entrants, particularly those without distribution networks
- Acrux confident of Axiron's sustainable competitive advantage, including clinical studies on the benefits of Axiron treatment

# Other products and outlook

# OTHER PRODUCTS

- Estradiol spray
  - Gedeon Richter contracted for ex-US distribution
    - US\$1m upfront and up to US\$2.6m in further regulatory milestones for the EU
    - Royalties on sales expected to commence in 2015
  - Marketing applications under review in South Africa and South Korea
  - KV Pharmaceutical has emerged from Chapter 11 bankruptcy protection
- Animal health products
  - Licensed to Elanco (Eli Lilly)
  - First royalties received from Recuvyra<sup>®</sup> in US and Europe
  - Other products in clinical development

# PIPELINE PRODUCTS

- New products
  - Low cost proof of concept development initiated for two new topical products:
    - Non-melanoma skin cancer (NMSC) therapeutic
    - Anti-fungal therapeutic
  - Both products address unmet need in large (billion dollar+) markets
  - In collaboration with Hexima Limited and a leading Melbourne based cancer institute
  - Concept using Acrux proven delivery technology
  - Proof of concept data is anticipated Q4 13/Q1 14
  - Topical pain product also in formulation development



# FINANCIAL OUTLOOK - REVENUE

Royalty = (US market size x US market share - Rebates + Ex-US sales) x average royalty %

- Axiron royalties:
  - Percentages of worldwide net sales
  - Tiered structure with average rate increasing as sales increase
  - Multiple factors combining to drive future growth
- Axiron milestone payments:
  - US\$25 million due 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 estradiol spray and animal health

# FINANCIAL OUTLOOK - EXPENDITURE

- Expenditure maintained at ~\$5m in 2013/14 (2012/13: \$4.8m) excluding:
  - Monash royalty (3.5% of product revenues until February 2017)
  - Non-cash amortisation of capitalised R&D costs - \$1.2m per annum
  - One-off non-cash expense for issue of employee share options - \$1.2m
- Minimising costs, but retaining core competencies to exploit new product opportunities and support Lilly

# SUMMARY OF 2013/14 MILESTONES

- Axiron:
  - Net sales growth - royalties and first sales milestone payment
  - Product launches in Brazil and Europe
  
- Other products:
  - Gedeon Richter regulatory milestones
  - Results of proof of concept for two new topical product opportunities



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