

# Acrux (ASX: ACR)

27 August 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 ~\$550m; 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
  - Declared second regular dividend (8 cents per share, total \$13m) in 2013
  - Interim 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

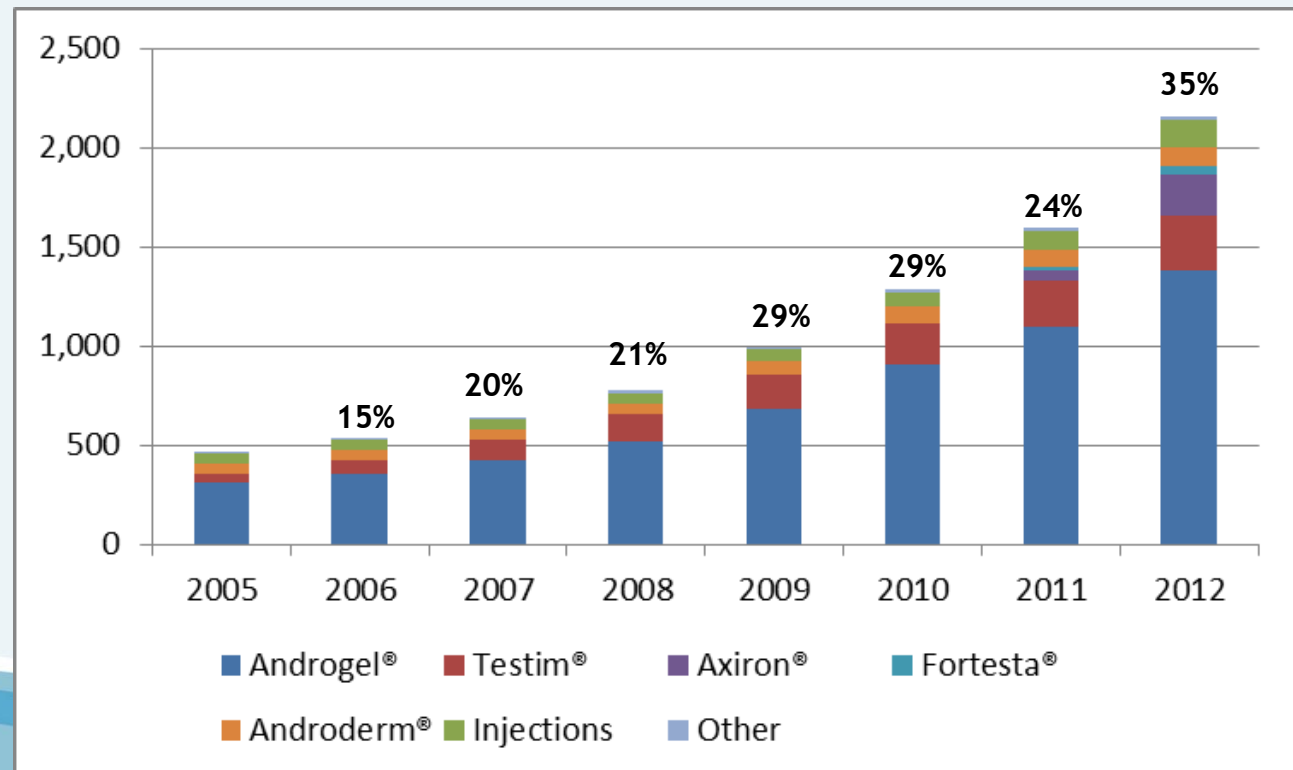


# Airon

# 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 July)
- 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

# EXPANDING KNOWLEDGE OF TESTOSTERONE

- 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

# 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
  - Number of potential patients is greater than in the US
  - Axiron already launched in Canada, Australia and approved in Brazil
  - Canada currently the largest ex-US market for testosterone
  - European submissions in progress - Germany second largest ex-US market

# US MARKET SHARE SINCE AXIRON LAUNCH



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

	April 2011	26 July 2013	Change
<i>Androgel</i> <sup>®</sup> 1%	77%	20.6%	-56.4%
<i>Androgel</i> <sup>®</sup> 1.62%	-	44.0%	+44.0%
Total <i>Androgel</i> <sup>®</sup>	77%	64.6%	-12.4%
<i>Axiron</i> <sup>®</sup>	-	14.1%	+14.1%
<i>Testim</i> <sup>®</sup>	22%	13.6%	-8.4%
<i>Fortesta</i> <sup>®</sup>	1%	7.7%	+7.6%
Total transdermal <sup>1</sup>	100%	100%	

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

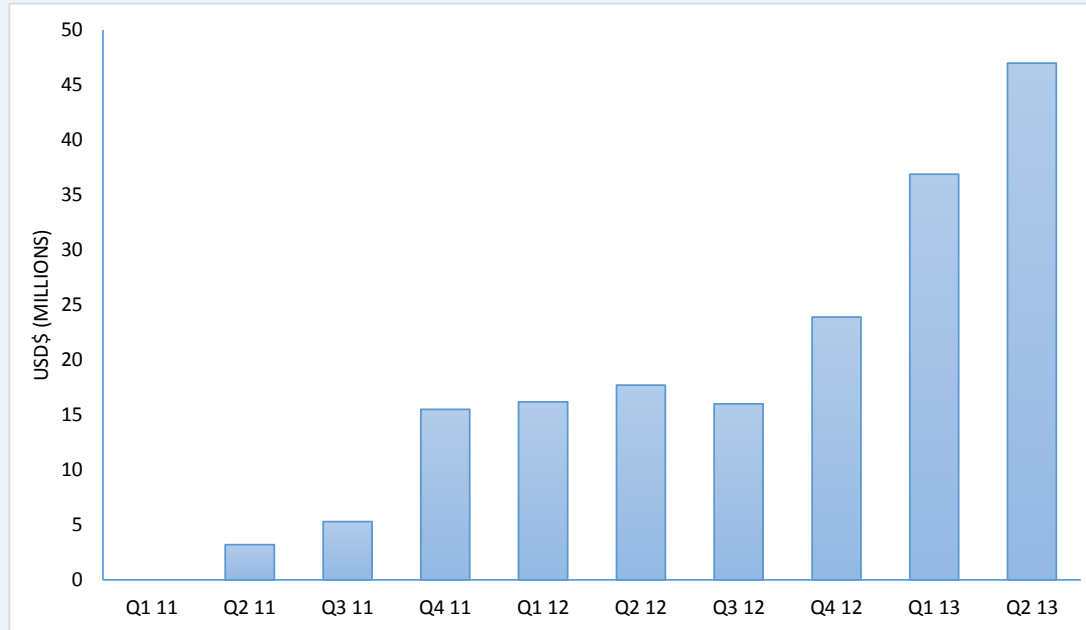
Source: internal



# 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, but reduced in 2013 - now comparable with market leader

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
Reported net sales (US\$m)	0.0	3.2	5.3	15.5	<b>24.0</b>	16.2	17.7	16.0	23.9	<b>73.9</b>	37.1	47.1
Average market share (%)	0%	2%	6%	9%	<b>4.6%</b>	11%	12%	12%	13%	<b>12%</b>	14%	14%

# MANAGED CARE FORMULARIES

- 88% of MHRT Volume flows through Commercial Managed Care plans
  - ~87% of all commercially insured lives have some form of access to Axiron
- Tier 2 access to Express Scripts/Medco formularies from July 2012 (~23m lives)
- Improvements in access to both National and Regional Managed Care formularies from 1 January 2013

# 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, 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 Perrigo 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 further clinical studies on the benefits of Axiron treatment

# 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
- Ex-US marketing applications and continuing product launch preparations
- Substantial and ongoing
  - Direct-to-consumer advertising
  - Improved promotion to specialist physicians and PCPs Further clinical studies on the benefits of Axiron treatment
    - e.g. initiated clinical trials studying sex drive/energy levels, ejaculatory dysfunction and suboptimal responders to testosterone gels

# 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
  - Resolution of US rights - KV Pharmaceutical in Chapter 11 bankruptcy protection
- Animal health products
  - Licensed to Elanco (Eli Lilly)
  - First royalties received from Recuvyra® in US and Europe
  - Other products in clinical development
- New products
  - Low cost proof of concept development initiated for two new topical products, including cancer treatment
  - Topical pain product in formulation development

# REPORTED FINANCIALS

	FY 2010/11 \$m	FY 2011/12 \$m	FY 2012/13 \$m
Revenue	93 <sup>1</sup>	11	<b>16.7</b>
Profit before tax	82	4.9	<b>10.0</b>
Tax (charge)/benefit	(25)	2.5	<b>(3.1)</b>
Profit after tax	57	7.4	<b>6.9</b>
Earnings per share	35 cents	4 cents	<b>4 cents</b>
Dividend (tax-free)	60 cents	8 cents	<b>8 cents</b>
Cash at 30 June	33	30 <sup>2</sup>	<b>22.8<sup>3</sup></b>
Franking account at 30 June		10	<b>12.4</b>

<sup>1</sup> Included US\$87m from Lilly on FDA approval of Axiron

<sup>2</sup> Prior to dividend payment of \$13.3m

<sup>3</sup> Prior to dividend payment of \$13.3m



# FINANCIAL OUTLOOK - REVENUE

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

- 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 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 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
  - 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
  - Marketing application decisions in Europe
  - Product launches in Brazil and Europe (subject to approval)
- Other products:
  - Gedeon Richter regulatory milestones for Europe
  - Resolution of US Estradiol spray distribution
  - Results of proof of concept for two new topical product opportunities



**Axiron<sup>®</sup>**

(testosterone)

topical solution 