



# **Acrux (ASX: ACR)**

**HY15 Results Presentation**

**26 February, 2015**

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**Sharon Papworth – Chief Financial Officer**

# 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.*

# Summary of Financials



*Profitable and with a strong balance sheet to execute our future growth strategy, aimed to provide income diversification and shareholder return*

- Total revenue \$14.2m, down 67.5% on prior year
  - Nil Product Milestones received, \$28.8m received in the prior year
  - Product royalties \$13.7m, down 5.5% on prior year and influenced by the US Food and Drug Administration (FDA) Drug Safety Communication issued on 31 January 2014.
- Operating expenses \$3.9m, down 26.4% on prior year
- Net Profit After Tax \$7m, down 71.5% on prior year
- Net Cash at half year-end \$15.8m

# Axiron® - United States

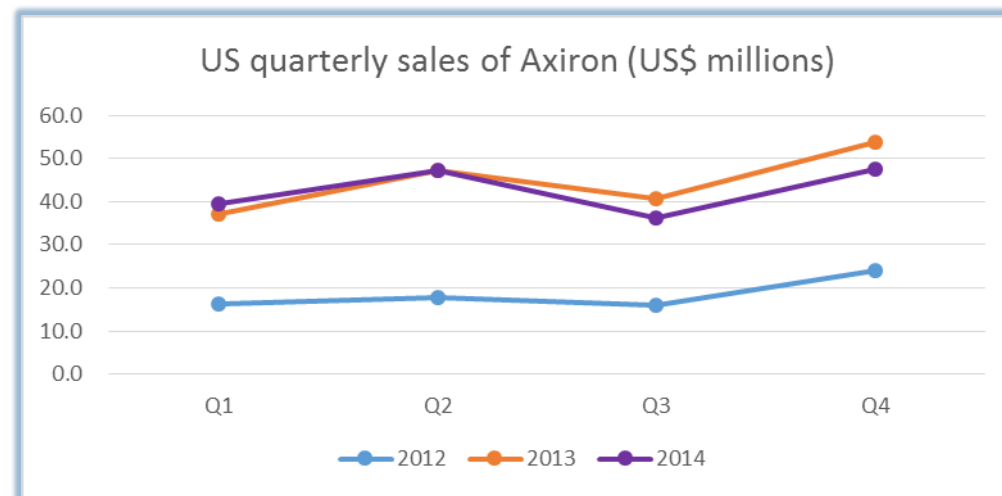


## Highlights

- Market share consistent throughout 2014
  - share of market for December 2014 was 13.9%
  - sales volume decline in US market partially offset by increased net realised price
  - Second largest (in US\$) brand in US testosterone replacement market

## Outlook

- FDA Statement following September 2014 Advisory Committee is expected in the near future
- Favourable exchange rate will buoy royalty due to Acrux in comparison to prior year
- Results from a large placebo-controlled Phase 3 study (NCT01816295) of the effects of Axiron on testosterone levels, sex drive, and energy due 1H, 2015

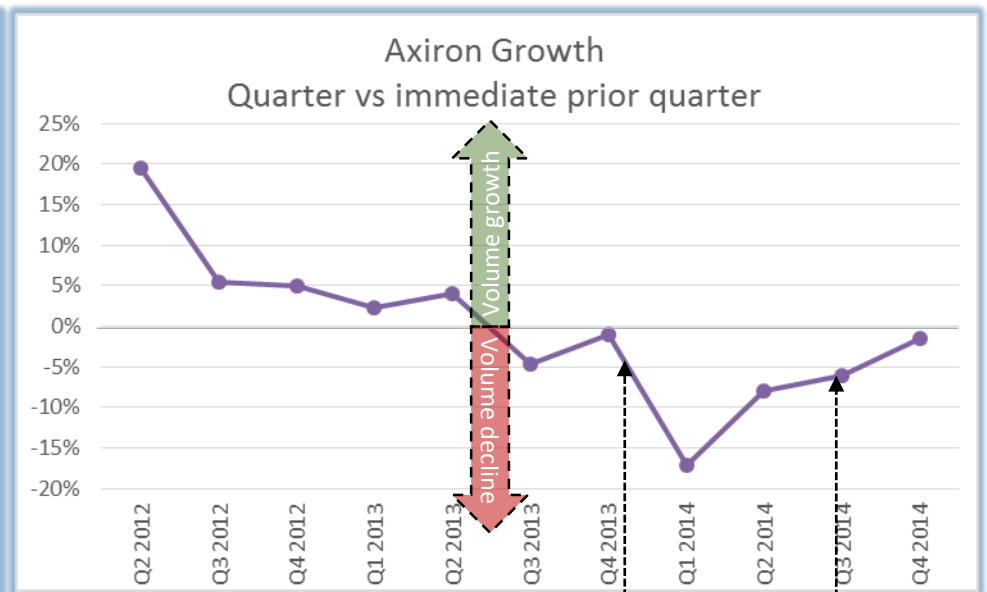
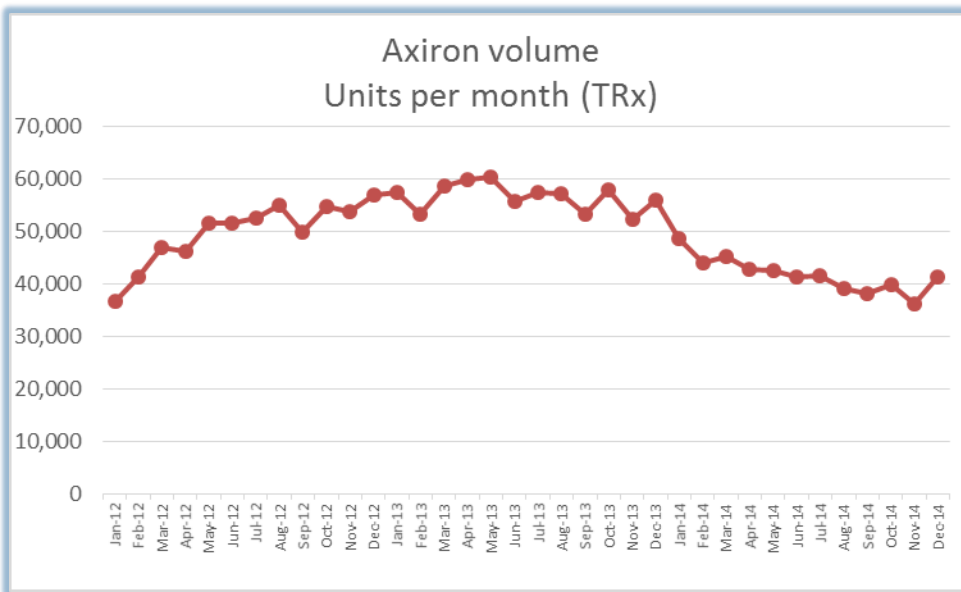


# Axiron® - United States (continued)



## Axiron volume and growth

- Axiron volume stabilising over recent months
- Market declines have slowed for the topical testosterone market and for Axiron
- Future market direction dependent on FDA Statement



FDA Safety Communication      FDA Advisory Committee Meeting

# Axiron® - Rest of World

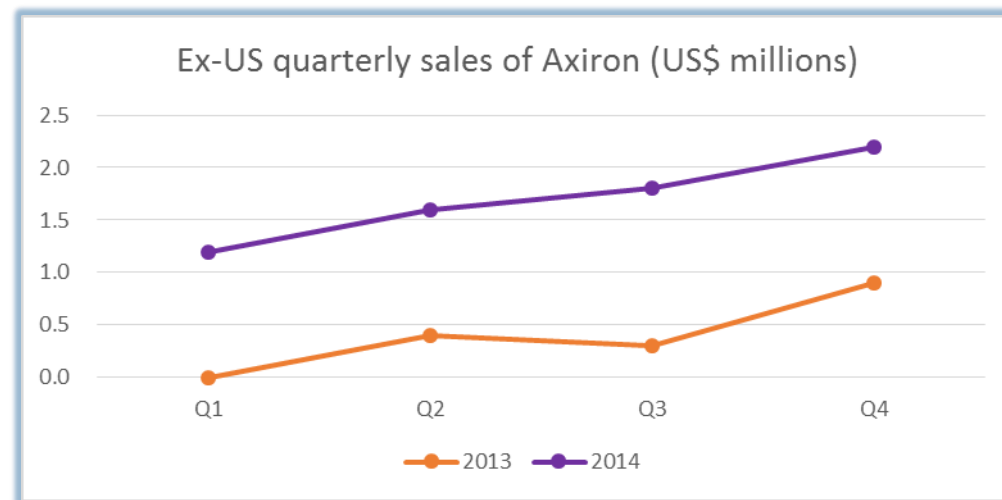


## Highlights

- Strong volume growth in launched markets
- European Medicines Agency testosterone statement released in November, 2014

## Outlook

- Continued revenue growth across countries where Axiron has been launched



# Key Financials

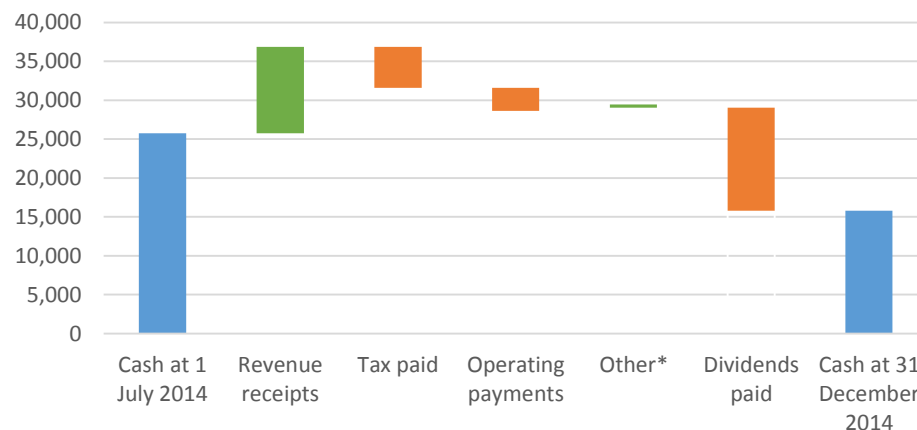
- Revenue of \$14.2m, down 67.5% on pcp
  - Nil Milestone revenue generated (pcp \$28.8m)
  - Royalty income driven by testosterone market decline in the US
- Operating expenditure decline is aligned with sales and non operating costs:
  - Monash Royalty reduced \$1m to \$0.5m
  - Nil share options were issued during the period (pcp: \$0.6m)
  - \$0.2m operating cost increase, aligned with execution of strategic priorities
- Income Tax expense reduced \$10.5M to \$3.3m
- NPAT \$7m, down 71.5% on pcp
- Net cash at 31 December 2014 \$15.8m

A\$m	31 Dec 2014	31 Dec 2013	% Decline
Product Royalties	13.7	14.5	5.5%
Product Milestones & other revenue	0.5	29.2	98.3%
<b>Total Revenue</b>	<b>14.2</b>	<b>43.7</b>	<b>67.5%</b>
Operating Expenses	3.9	5.3	26.4%
<b>Profit Before Tax</b>	<b>10.3</b>	<b>38.4</b>	<b>73.2%</b>
Income Tax	3.3	13.8	76.1%
<b>Net Profit After Tax</b>	<b>7.0</b>	<b>24.6</b>	<b>71.5%</b>
<b>Net cash on hand</b>	<b>15.8</b>	<b>17.5</b>	<b>9.7%</b>
<b>Earnings per share</b>	<b>4 cents</b>	<b>15 cents</b>	

# Cash Flow

- Cash and cash equivalents \$15.8m at 31 December 2014
- Operating cash inflow \$3.2M, comprising
  - Royalty receipts \$11.1M
  - Interest on cash investment \$0.4M
  - Tax paid (\$5.3M)
  - Payments to suppliers & employees (\$3M)
- Final Dividend for the year ended 30 June 2014 paid in September, \$13.2M (8 cents, fully franked)
- Strong cash position to enable execution of growth strategy

Cash flow by category: period ended  
31 December 2014



## Outlook

- Full year cash forecast will be influenced by:
  - Deployment of R&D projects
  - Acquisition and / or partnering execution
- The market will be updated when material events occur.



# Pipeline Update



Indication(s)	Commercial Partners	Formulation Design	Non-Clinical Development	Pre-Clinical Design	Phase 1	Phase 2	Phase 3	Registration	Commercial
MARKETED									
Hypogonadism	Eli Lilly	AXIRON® (testosterone)							
Hormone Deficiency	Lumara Health	EVAMIST® (oestradiol)							
Post-operative Pain	Elanco	RECUVYRA® (fentanyl)							

PRODUCT PIPELINE									
Hormone Deficiency	Gedeon Richter	OESTRADIOL MDTS*							
Hormone Deficiency	Aspen, Vifor, Alvogen	OESTRADIOL MDTS*							
Companion Animal Health	Elanco	UNDISCLOSED PRODUCTS							
Onychomycosis		[Progress bar]							
Pain and Inflammation 1		[Progress bar]							
Non Melanoma Skin Cancer		[Progress bar]							
Pain and Inflammation 2		[Progress bar]							

- Ellavie® - Europe:
  - Gedeon Richter continues on track for launch in Europe
  - Aspen achieved regulatory approval in South Africa

- Active program to in-license or acquire new technologies
- Unique pain and inflammation product concepts in early testing
  - additional patent filings anticipated
- Acrux continues to investigate antifungal and NMSC opportunities



**ACRUX**

# Appendix – Acrux (ASX: ACR) at a glance

- Market cap ~A\$220 million<sup>1</sup>
- Unique, patented technology for delivering drugs through the skin
- Products developed by Acrux, approved and launched in major markets:
  1. Axiron<sup>®</sup>, marketed by Lilly for hypogonadism in the US and other territories
  2. Estradiol Spray, marketed for menopausal hot flushes by Perrigo in the US; Licensed to Gedeon Richter in Europe and other commercialisation partners in RoW
  3. Recuvyra<sup>®</sup>, marketed by Elanco for post operative pain (in dogs) in the US and Europe
- Profitable for the last 5 years
  - Dividends paid total 96 cents per share including 2 special dividends paid on milestones received (totalling 72 cents)
- Pooled Development Fund – capital gains and dividends exempt from tax
- Pipeline of patient-preferred product candidates exploiting Acrux’s proven capabilities