

Acrux (ASX: ACR)

20 February 2014

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 ~\$334m; joined S&P/ASX 200 in September 2011
- Profitable for the last 4 years
 - Dividends paid annually since 2011: total of 76 cents per share
 - Further 12 cent per share special dividend declared 20 February 2014
- 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[®], partnered with Lilly globally
- Progressing pipeline of new products creating new intellectual property

ADVANCES MADE IN 2013

Axiron®

- Significant progress in US market share and international rollout of Axiron
 - 2013 sales milestone met; USD\$25 million receivable Q1 2014
 - Net sales for CY 2013 increased by 142% over CY 2012 (US\$178.7m vs US\$73.9m) and H2 CY 2013 net sales increased by 137% over H2 CY 2012
 - EU approval in Germany
 - Launched in Australia, Canada and Brazil

New Products

- New topical products introduced in pipeline
 - Antifungal therapeutic
 - Non-melanoma skin cancer (NMSC) therapeutic

CURRENT EXPECTATIONS FOR 2014

Axiron

- Continued growth in Axiron net sales for calendar 2014
 - Based on current knowledge, it is a reasonable expectation that the next sales milestone payment of US\$50 million will be earned
- Axiron launched in Germany Q1 2014
- Further regulatory approvals and launches in additional territories

New Products

- Additional data for both Anti-fungal therapeutic and Non-Melanoma Skin Cancer (NMSC) therapeutic products
- New patent filings
- Preparation and initiation of next development stages

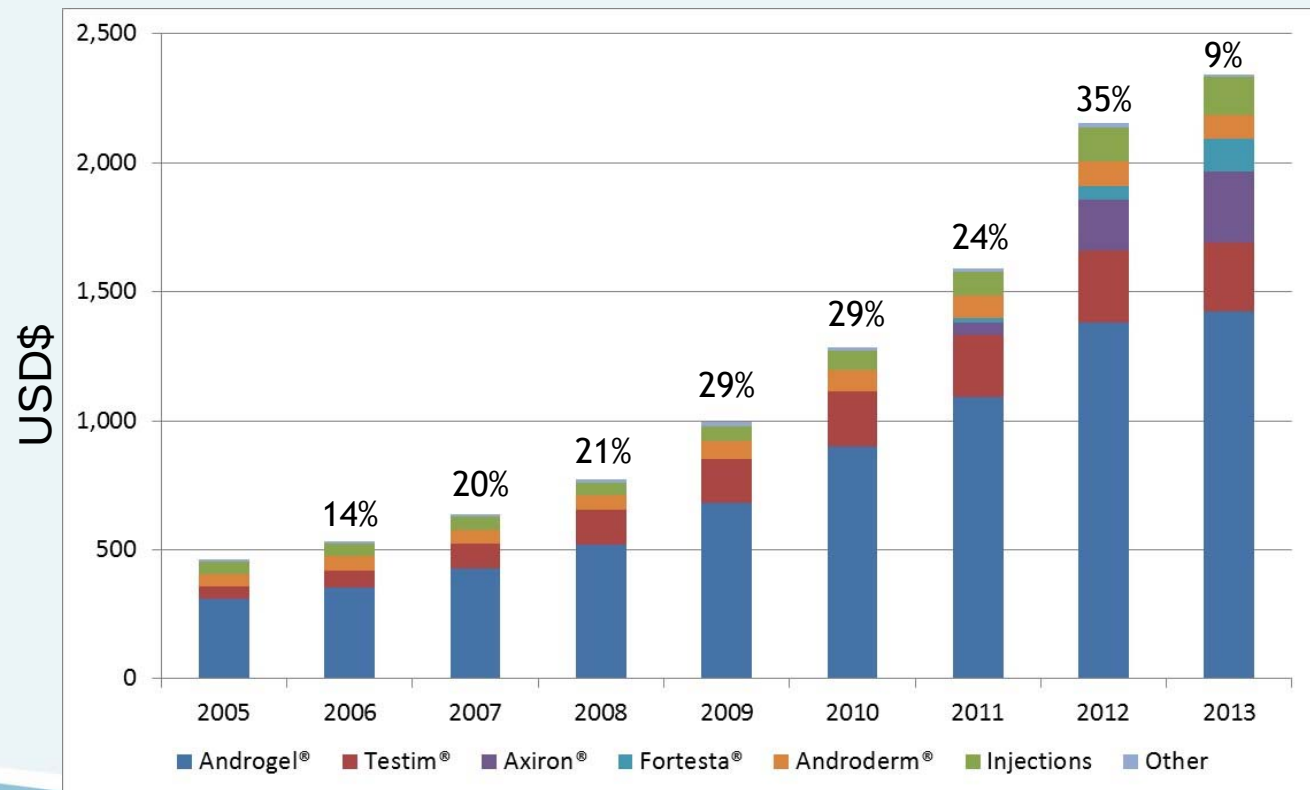
Distribution of cash in excess of medium term working capital requirements

Axiron



US TESTOSTERONE MARKET 2013

- Total TRT \$ sales increased ~9% for 2013 versus 2012
- Total transdermal testosterone replacement therapy (TRT) \$ sales increased 5.8% (year on year December);
- Transdermal market remains a substantially larger market in the US compared to other dosage forms



US TRANSDERMAL PRODUCT PRICING

- Consistent price increases in major US transdermal TRT products occurred throughout 2013, partially offsetting the slower market growth
- Several manufacturers increased the price of their products by a further 9-10% in December 2013/January 2014, including Axiron
- Price rises are implemented the day after they are announced
- There is no seasonality in price: when prices are increased the increases are maintained until the next price rise is implemented
 - There has never been a price reduction since Axiron was launched
- Pricing power remains strong, and regular price increases seen across the sector

US MARKET SHARE SINCE AXIRON LAUNCH



Share of Total Prescriptions (TRx) for transdermal products¹ in United States

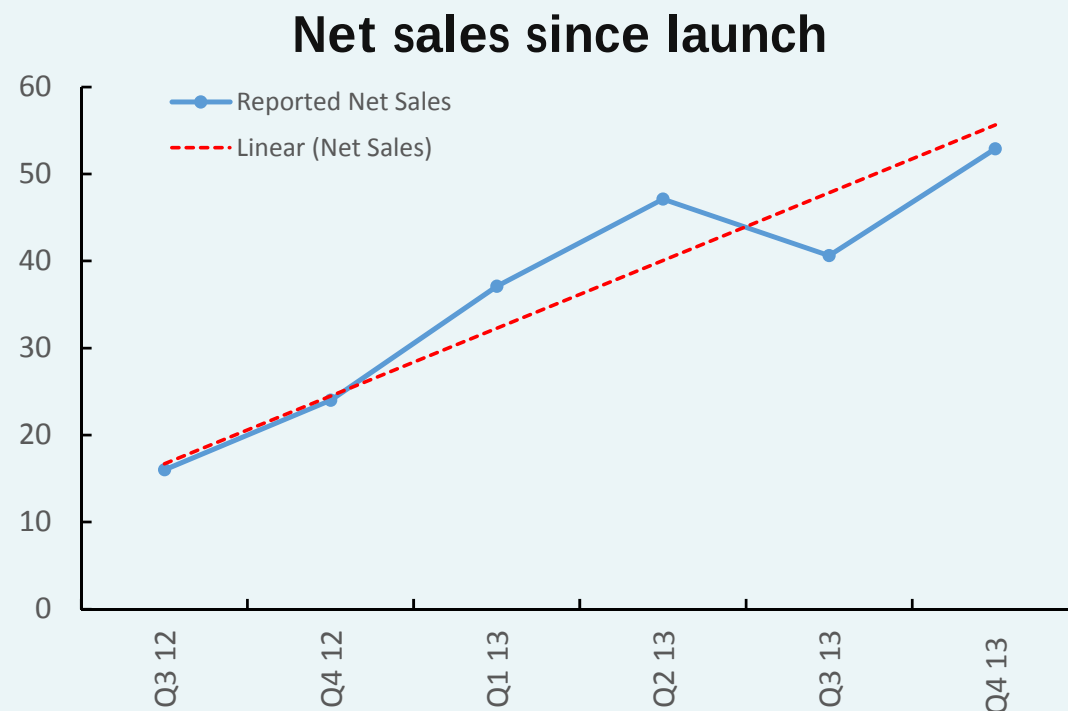
	30 Jun 13	31 Jan 14	Change
<i>Androgel</i> [®] 1%	21.1%	18.7%	-2.4
<i>Androgel</i> [®] 1.62%	42.9%	47.6%	+4.7
Total Androgel [®]	64.0%	66.3%	+2.3
Axiron [®]	14.3%	14.3%	+0.0
Testim [®]	13.8%	12.7%	-1.1
Fortesta [®]	7.9%	6.7%	-1.2
Total transdermal ¹	100%	100%	

¹ excluding Androderm[®] patch

GLOBAL NET SALES SINCE LAUNCH



- Net sales = invoiced sales less rebates, discounts, returns
- Trajectory of quarterly net sales remains very positive
- Based on current knowledge, sales in 2014 expected to trigger a US\$50 million milestone payment in early 2015



	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	Q4 2013	Total 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	53.9	178.7
Average market share (%)	0%	2%	6%	9%	4.6%	11%	12%	12%	13%	12%	14%	14%	14%	14%	14%

Transdermal gel market share, excluding Androderm

COMMERCIAL MANAGED CARE*



- Competitors indicated Q4 2013 rebates were at the lowest level experienced in 2013
 - e.g. 20.5% for Androgel in Q4 2013 reported
- Q1 2014: Axiron is the only transdermal TRT to register as a preferred product on both ESI and CVS Caremark National Formularies

	Included
ESI	Axiron AndroGel
CVS Caremark	Axiron Fortesta

CO-PAY CARD/VOUCHER

- New Savings Card system initiated 1 January 2014
- Savings Card can only be used by patients that have commercial insurance coverage
 - i.e. not eligible for use with Medicare, Medicaid, Tricare or any government (state or federal) healthcare plan



Patient Savings

1 Card, 2 Ways to Save* - AXIRON Savings Card

30-day FREE trial	Save for 11 more months
Get your first month's prescription FREE	Eligible patients pay no more than \$25 a month with up to \$75 monthly savings

The graphic is a promotional card for AXIRON. It features a dark red header with the text 'Patient Savings' in white. Below this, a white section contains the text '1 Card, 2 Ways to Save* - AXIRON Savings Card'. The bottom half of the card is divided into two columns by a white arrow pointing from left to right. The left column has a dark red header '30-day FREE trial' and a white body with the text 'Get your first month's prescription FREE'. The right column has a dark red header 'Save for 11 more months' and a white body with the text 'Eligible patients pay no more than \$25 a month with up to \$75 monthly savings'.

2014 AXIRON US MARKET SHARE DRIVERS

- Direct to Consumer marketing; optimised marketing message initiated 01 January 2014
- Impact of a committed men's health sales force - operational from August 2013
- Marketing initiatives: including Savings Card
- Increased presence with the leading formularies (ESI and CVS Caremark); the two leading PBMs, accounting for approximately 2/3 of the market
- Perception of coverage achieved to drive share of Market - being number 2 product on market and being 1 of 2 choices on Lowest Branded Co-Pay (LBC) with key formularies
- Brand loyalty developed among both consumers and physicians
- Price increase impact (last price rise of 9% put through in December 2013), no meaningful impact on Q4 2013 result

FUTURE US 1% GENERIC INTRODUCTION

- First 1% generic product expected in 2015
- Not expected to have a significant impact on the market
 - Branded 1% products have been losing market share to the higher strength products (Axiron and 1.62% Androgel)
 - Volume of 1% strength gels reimbursed by formularies has decreased significantly since the introduction of the higher strength gels

FUTURE US HIGH STRENGTH GENERIC INTRODUCTION

- No analogue for the impact of generics in this market
 - Each product has different dosing requirements and the topical gels require titration, which could make switching between treatment regimens complex
- Consumer and physician resistance to switching once steady state dosing is achieved
 - Born out by significant number of consumers staying on medication after formulary reimbursement is withdrawn

POTENTIAL BEYOND THE US MARKET

- Ex-US markets for testosterone therapy underdeveloped
 - Axiron already launched in Canada, Australia and Brazil
 - Germany launch anticipated end of February 2014
 - Canada, Australia, Germany and Brazil comprise more than half the ex-US \$ market
 - o Canada currently the largest ex-US market for testosterone
- Additional regulatory approvals and launches are expected

EXPANDING KNOWLEDGE OF TESTOSTERONE

Lilly is conducting clinical studies to evaluate other benefits of Axiron treatment

- studying sex drive/energy levels, ejaculatory dysfunction and suboptimal responders to other testosterone gels

Studies conducted by other medical institutes expand knowledge about men with testosterone deficiency:

- 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

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

FDA DRUG SAFETY COMMUNICATION

- US FDA issued a Drug Safety Communication (DSC) on 31 January 2014, prompted by two recent publications^{1,2}, which stated:
 - FDA is investigating the risk of stroke, heart attack and death in men taking FDA-approved testosterone products
- At this point, FDA has not concluded that FDA-approved testosterone treatments increase the risk of stroke, heart attack, or death;
 - patients should not stop taking prescribed products without consulting their healthcare professional

FDA DRUG SAFETY COMMUNICATION Cont.

- FDA will continue to evaluate, and communicate conclusions once their evaluation is complete
 - Could take some time to reach a conclusion
- Axiron product label and medication guide already includes warnings and precautions relating to cardiovascular risk
- FDA DSC relates to all FDA approved testosterone formulations
 - including injection, transdermal patch, topical gel, and buccal system (applied to upper gum or inner cheek)

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

COMPETITOR AWARENESS

- Other testosterone delivery systems in development - nasal gel, capsules, depot injection
 - 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 ease of administration and 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
 - US\$600K received for first regulatory filing
 - Up to US\$2m 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® in US and Europe
 - Other products in clinical development

PIPELINE PRODUCTS

- New products
 - Low cost proof of concept development progressing for two new topical products:
 - Non-melanoma skin cancer (NMSC) therapeutic
 - Anti-fungal therapeutic
 - Both products address unmet need in large (billion dollar+) markets
 - New intellectual property developed and patent applications currently being filed
 - Topical pain relief product also in formulation development

CANCER THERAPEUTICS

Aim:

- To develop novel therapeutics for non-melanoma skin cancers (NMSC) using proprietary anti-cancer molecules developed by Hexima Limited

NMSC Market:

- The total number of NMSC treatments in Australia increased from 412,000 in 1997 to 767,000 in 2010
- In 2015 NMSC will be the most costly cancer in Australia, with 938,000 treatments expected, when the diagnosis, treatment and pathology costs are estimated to be \$700 million in 2015
- The incidence of NMSC is expected to increase substantially in all Western developed economies

CANCER THERAPEUTICS

Progress:

- A collaboration agreement is in place with Hexima Limited
 - combine Hexima's lead molecules with Acrux's transdermal delivery technology
- Collaborative relationships established with leading Melbourne based medical and research institutions
 - human skin samples that contain NMSC lesions are being collected
 - in-vitro testing of formulations on normal and cancerous skin to assess the ability to permeate human skin is in progress
- Initial proof of concept data positive; initiating next stage of development
- Currently preparing new patent applications

HUMAN ANTIFUNGAL THERAPEUTICS

Aim:

To develop novel therapeutics for fungal infections using proprietary fungicidal molecules developed by Hexima Limited

Antifungal Market:

- The market for human antifungal therapies was valued at US\$10.2 billion in 2008
 - US\$7.8 billion were over-the-counter (OTC) sales
 - US\$4 billion were topically applied products
- Fungal nail infections affect 20-25% of the population and >50% of individuals over 70 years of age
- Current therapies for fungal nail infections are ineffective and require long treatment regimes
 - Many of these have associated liver toxicity

HUMAN ANTIFUNGAL THERAPEUTICS

Progress:

- A collaboration agreement is in place with Hexima Limited
 - combine Hexima's lead molecules with Acrux's transdermal delivery technology
- Lead compounds are active against the pathogens that cause fungal skin and nail infections
- Source of human nails identified and ethics approval received
- In-vitro testing of formulations in progress to assess the ability to permeate human nails
- Positive preliminary data received
- Proof of concept data expected Q2 2014 (subject to supply of nails)
- New patent filings currently being prepared

HALF YEAR FINANCIALS

- Revenue \$43.7 million (2012: \$5.1 million)
- Profit before tax \$38.4 million (2012: \$2.0 million)
- Operating cash inflow \$7.7 million (2012: inflow \$2.3 million)
- Cash reserves \$17.5 million (30 June 2013: \$22.8 million)

- Declared unfranked special dividend of 12 cents per share (exempt from tax):
 - Record date - 3 March 2014
 - Payment date - 20 March 2014



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 achieved as net sales $\geq$ US\$100m in the 2013 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 - \$0.6m
- Minimising costs, but retaining core competencies to exploit new product opportunities and support Lilly



Axiron[®]
(testosterone)
topical solution 