Acrux (ASX: ACR)

28 April 2014

ACRUX
DRUG DELIVERY SOLUTIONS

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 ~$283m; joined S&P/ASX 200 in September 2011
- Profitable for the last 4 years
  - Dividends paid annually since 2011: total of 88 cents per share
- 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

KEY UPDATE

Axiron®

- Significant progress in international rollout of Axiron
  - Global net sales for the first 9 months of FY2014 increased by 74% over previous corresponding period
  - European launch in Germany
- FDA Drug Safety Communication (DSC) prompted in part by two recent publications on potential link between testosterone replacement therapy and cardiovascular events
  - criticised for misrepresentation of the study results
- Market response (decreased sales) - US$50 million milestone payment may be deferred from FY 2014-15 to FY 2015-16

Product Pipeline

- Antifungal therapeutic
  - Initial data suggests good penetration through human nail
- Non-melanoma skin cancer (NMSC) therapeutic
  - Further proof of concept data being pursued

Axiron®
(testosterone)
topical solution

Axiron

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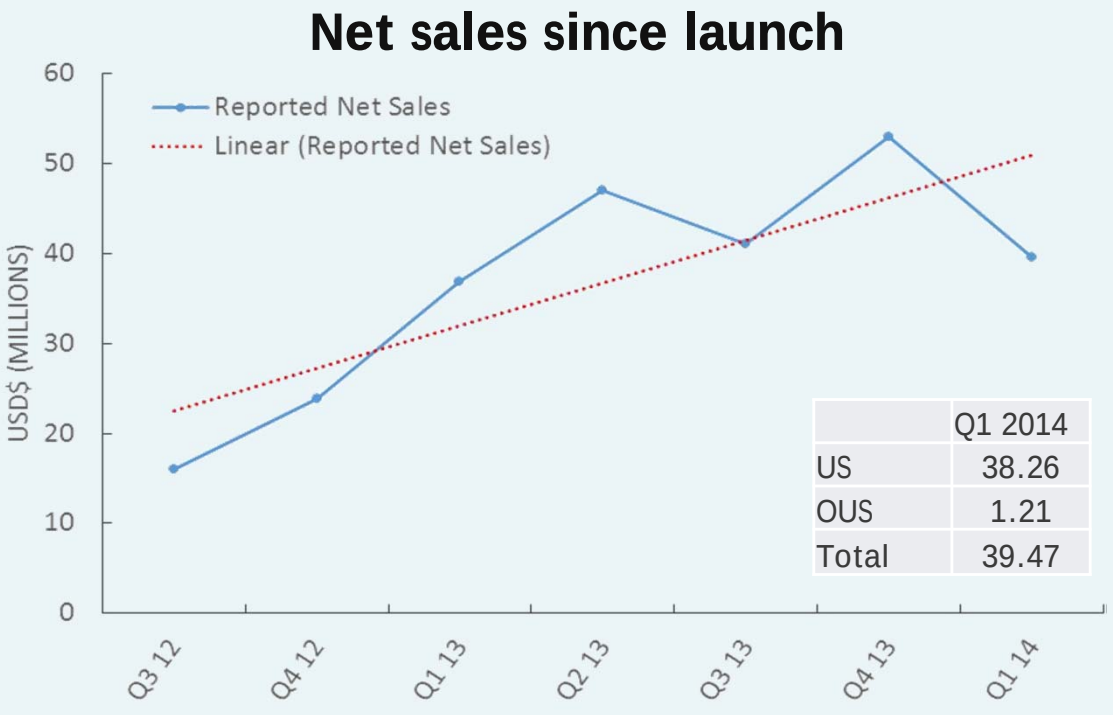
GLOBAL NET SALES SINCE LAUNCH

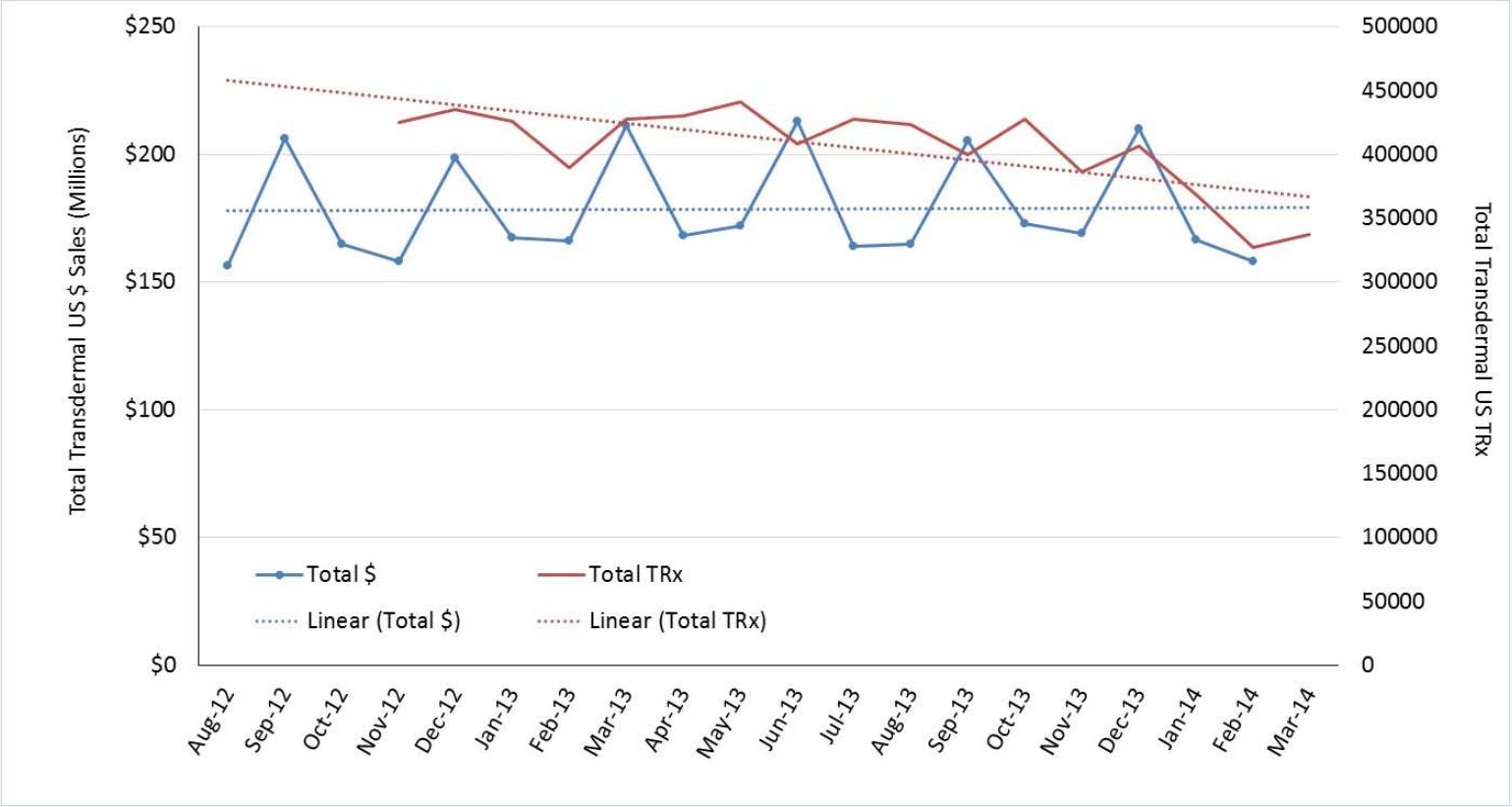
- Net sales = invoiced sales less rebates, discounts, returns
- Unless overall market TRx volume (translating to $US) and/or Axiron Share of Market improve in CY2014, the US$50 million milestone payment may not be received until the 2015-16 financial year
- US$50 million milestone is payable in the first calendar year that the global sales hurdle is met



Financial Year	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*	Q1 2014
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*	39.5
Avg market share (%)	0%	2%	6%	9%	*4.6%*	11%	12%	12%	13%	*12%*	14%	14%	14%	14%	*14%*	14%

US Transdermal gel market share, excluding Androderm

US TESTOSTERONE MARKET



Total transdermal US market demonstrates decline in total TRx, however total $ sales remains steady

Effect of FDA Drug Safety Communication (DSC) and journal articles flowing through to TRx

Based on IMS data

US MARKET SHARE SINCE AXIRON LAUNCH

Axiron® (testosterone) topical solution

Share of Total Prescriptions (TRx) for transdermal products[1] in United States

	30 Jun 13	31 Jan 14	04 Apr 14	Change since 31 Jan
Androgel® 1%	21.1%	18.7%	18.0%	*-0.7*
Androgel® 1.62%	42.9%	47.6%	48.8%	*+1.2*
Total Androgel®	64.0%	66.3%	66.8%	*+0.5*
Axiron®	14.3%	14.3%	14.2%	*-0.1*
Testim®	13.8%	12.7%	12.4%	*-0.3*
Fortesta®	7.9%	6.7%	6.6%	*-0.1*
Total transdermal[1]	100%	100%	100%	

[1] excluding Androderm® patch

IMS now has access to Walmart for their prescription level data (previously estimated) – this has led to a restatement of the SOM

Source: internal

FDA DRUG SAFETY COMMUNICATION

- US FDA issued a Drug Safety Communication (DSC) on 31 January 2014, prompted by two recent observational studies[1,2], which stated:
  - FDA is investigating the risk of stroke, heart attack and death in men taking FDA-approved testosterone products
- FDA has not concluded that FDA-approved testosterone treatments increase the risk of stroke, heart attack, or death;
  - FDA has stated that patients should not stop using prescribed products without consulting their healthcare professional
- FDA evaluation will take some time
- The European Medicines Agency (EMA) announced on 11 Apr 2014 that, based on the JAMA publication[1], it will review all available data, and issue an opinion – no timeframe given

1.Vigen R, O'Donnell CI, Baron AE, et al. Association of testosterone therapy with mortality, myocardial infarction, and stroke in men with low testosterone levels. JAMA. 2013;310(17):1829-1836.
2.Finkle W, et al. Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men. PLOSONE. 2014;9(1): e85805

FDA DRUG SAFETY COMMUNICATION Cont.

- The observational studies were found to contain multiple inaccuracies and misreporting of results
- 3 professional medical societies and an international group of over 160 scientists and physicians have petitioned the Journal of the American Medical Association to retract one of the study articles stating that it is "*no longer credible*"[3,4]
- The DSC has created some concern amongst patients which, along with the 2 articles, is impacting TRT prescriptions
- FDA approved 10-weekly injectable product after issuing DSC, quoting "*The FDA's current view is that the benefits of testosterone therapy outweigh the known risks when used as directed in patients for whom the drug is indicated*"

3. http://androgenstudygroup.org/press-releases/91-2014-03-25
4. http://androgenstudygroup.org/press-releases/92-2014-04-10

2014 AXIRON US MARKET SHARE DRIVERS

- Direct to Consumer marketing; optimised marketing message initiated 01 January 2014
- Men's health sales force, operational since August 2013, making good progress with specialists and directing effort to Primary Care Physicians (PCPs)
- Savings Card for commercially insured patients launched, with transition from existing co-pay card and voucher in progress
- Perception of coverage achieved is expected 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
- Good progress in development of brand loyalty among both consumers and physicians

COMMERCIAL MANAGED CARE*

- Q1 2014: Axiron is the only transdermal TRT to register as a preferred product on both ESI and CVS Caremark National Formularies (2/3rds of market)

	Included
ESI	Axiron
	AndroGel
CVS Caremark	Axiron
	Fortesta

- Step edits and prior authorisations impact greater than anticipated
- Physicians must submit a request form for all prior authorisation and step edit medications

**Note: the National formulary is one of multiple formularies offered to commercial members*

EXPANDING KNOWLEDGE OF AXIRON

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

- Sex drive/energy levels – Phase III, 618 men, currently recruiting with estimated completion June 2015
- Ejaculatory dysfunction – Phase II, 76 men, completed December 2013; data analysis in progress then clinical study report during 2014
- Suboptimal responders to other testosterone gels – Phase IV, 75 men, completed January 2014; data analysis in progress then clinical study report during 2014

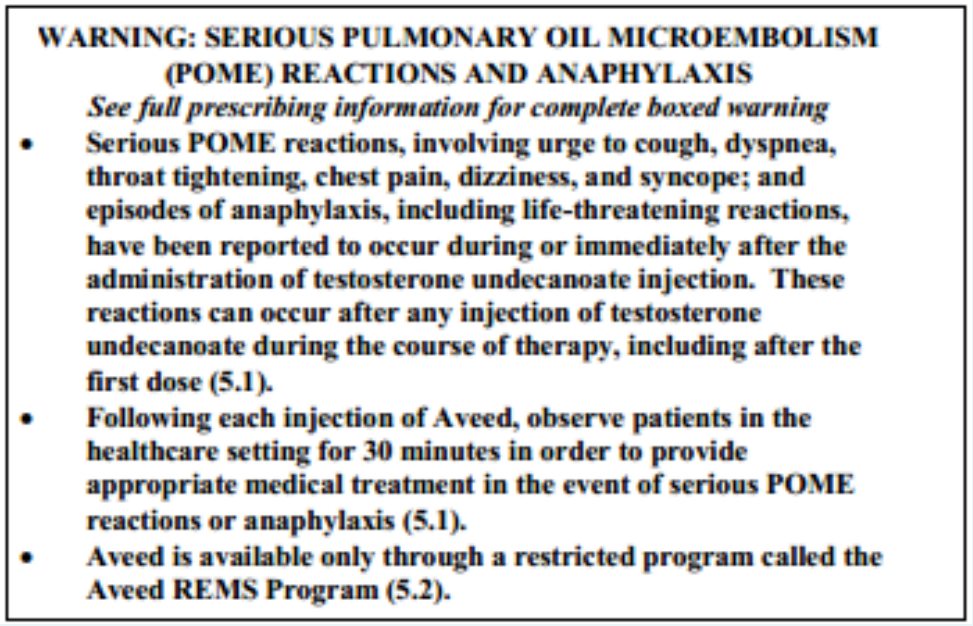
EXPANDING KNOWLEDGE OF TESTOSTERONE

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
  - the Overseas Development Institute reports that the number of overweight and obese adults is 550 million in high-income countries and 900 million in the developing world
- Exploratory clinical studies have been publicised investigating testosterone effects in Alzheimer's and in Multiple Sclerosis

COMPETITOR AWARENESS

- Other testosterone delivery systems in development – nasal gel and oral capsules
- Aveed approved by FDA (after the DSC was issued) : an intramuscular injection in the buttock given once to begin therapy, once four weeks later, and every 10 weeks after that



WARNING: SERIOUS PULMONARY OIL MICROEMBOLISM (POME) REACTIONS AND ANAPHYLAXIS

See full prescribing information for complete boxed warning

- **Serious POME reactions, involving urge to cough, dyspnea, throat tightening, chest pain, dizziness, and syncope; and episodes of anaphylaxis, including life-threatening reactions, have been reported to occur during or immediately after the administration of testosterone undecanoate injection. These reactions can occur after any injection of testosterone undecanoate during the course of therapy, including after the first dose (5.1).**
- **Following each injection of Aveed, observe patients in the healthcare setting for 30 minutes in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis (5.1).**
- **Aveed is available only through a restricted program called the Aveed REMS Program (5.2).**

Boxed warning on Aveed prescribing information leaflet

- Acrux remains confident that the clinical profile and ease of administration of the product will enable the product to remain competitive in the market for testosterone replacement therapy

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
  - Upsher Smith won appeal against Auxilium patent in Dec 2013; Vogelxo, a generic Testim gel, may be launched in late 2014/early 2015 – Auxilium launched further appeal
  - Lilly/Acrux litigation against both Perrigo and Actavis (Watson) for infringement of Axiron patents by ANDA filing

POTENTIAL BEYOND THE US MARKET

- Ex-US markets for testosterone therapy underdeveloped
  - Axiron recently launched in Canada, Australia, Germany and Brazil
  - Q3 FY14 net sales were US$1.21 million, an increase of 75% over Q2 FY14 sales
  - Canada, Australia, Germany and Brazil comprise more than half the ex-US $ market
    - Canada currently the largest ex-US market for testosterone
- Approved in Korea and launch is planned by end of June

Product Pipeline

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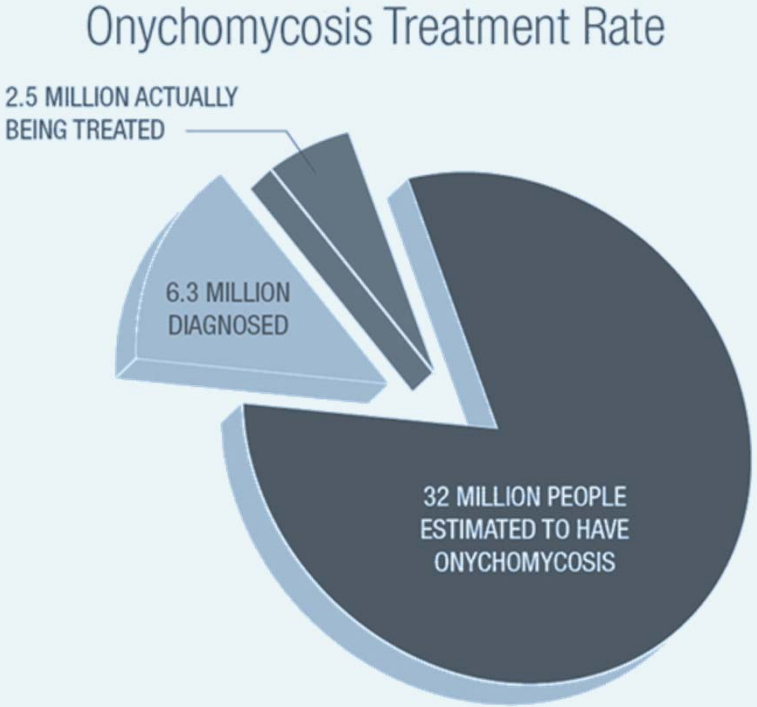
HUMAN ANTIFUNGAL THERAPEUTICS

- Human antifungal therapies market was valued at US$10.2 billion in 2008 (US$4 billion were topically applied products)
- Fungal nail infections affect 20-25% of the population, and is increasing
- Many antifungal treatments are fungistatic rather than fungicidal, i.e. temporarily halt the infection rather than eliminate it
- Only around 20% of the people that suffer from a toenail fungal infection have actually been diagnosed
- Many fungicides (particularly systemic) have severe side effects



TOPICAL ANTIFUNGAL STATUS

- ✓ In collaboration with Hexima Limited (Hexima's lead molecules with Acrux's new topical delivery technology)
- ✓ Lead compounds are active against the pathogens that cause fungal skin and nail infections
- ✓ In-vitro testing using human nails in progress
- ✓ Progress is promising
- ✓ Initiating next stage of development
- ✓ New patent filings currently being prepared

NON-MELANOMA SKIN CANCER (NMSC)

- Growing market in developed nations with over 2.15 million cases in the US in 2006. Expect a million cases in Australia in 2015 costing $700 million
- Treatment of non-melanoma skin cancers increased by ~77% since early 1990's
- Skin cancer is the most common form of cancer in the United States. More than 3.5 million skin cancers in over two million people are diagnosed annually
- According to IMS Health, US sales for Solaraze gel (which causes inflammation, irritation, burning, pain, redness, stinging, crusting, scabbing) were USD$92 million for calendar year 2012
- Global market estimated to be worth ~ USD$1.7 billion by 2020

TOPICAL NMSC STATUS

- In collaboration with Hexima Limited (Hexima's lead molecules with Acrux's new topical delivery technology)
- Relationships established with leading Melbourne based medical and research institutions
  - In-vitro testing using human skin samples containing NMSC lesions in progress
- Further proof of concept data being pursued
- Currently preparing new patent applications

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(testosterone)
topical solution