



Acrux (ASX: ACR)
FY2017 Annual Result
22 August 2017

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, the outcome of legal proceedings and the effectiveness of patent protection.

Agenda

FY17 outcomes

Full year P&L and Cashflow

Topical generic pipeline progress

Onychomycosis project progress

FY 2017 outcomes

Cash reserves	2017: \$34.0 million 2016: \$29.4 million
Net (Loss)/Profit After Tax	2017: \$(0.2) million includes a non-cash impairment loss of \$10.68 million 2016: \$11.1 million
Royalty revenue	2017: \$23.3 million 2016: \$25.4 million
Pipeline progress	8 products in active development including 7 generic products and 1 specialty product for onychomycosis

FY17 milestones

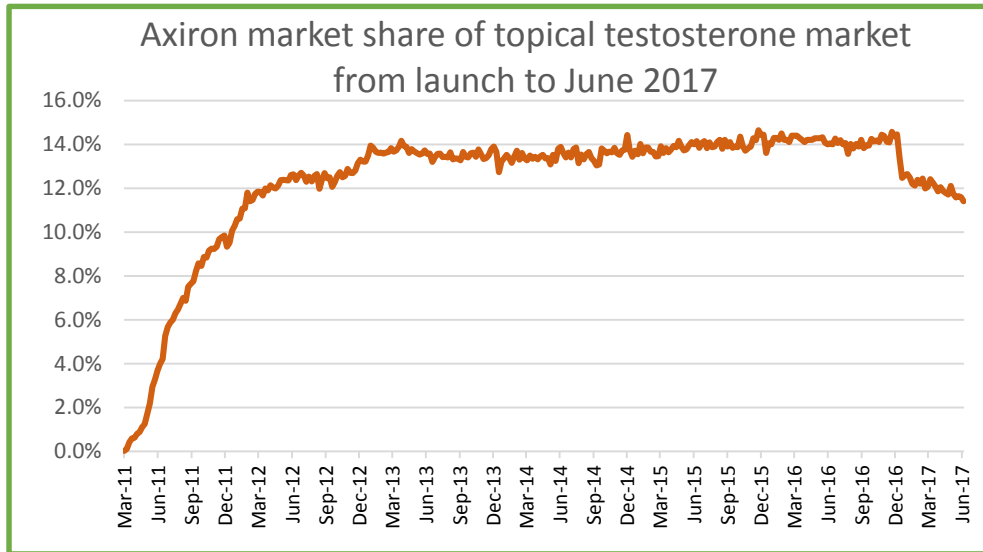
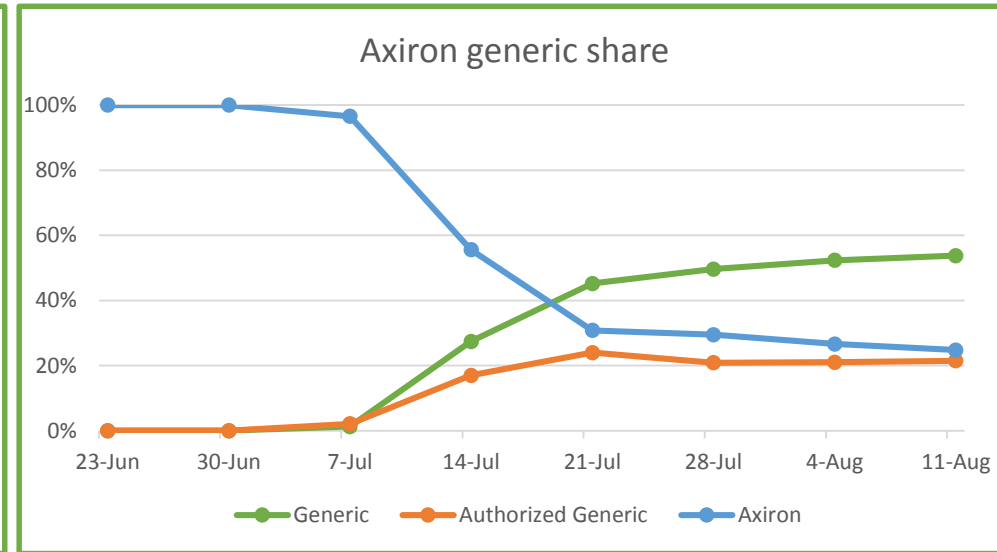
• Draft and submit patent application for ACR065 for onychomycosis	✓
• Gedeon Richter to continue country specific launches of Lenzetto in the European Union	✓
• Scale up activities to manufacture exhibit batches for initial generic products	✓
• Contract manufacturing organisation to be engaged to manufacture multiple generic products	✓
• Commence first bioequivalence study*	Trial planning on schedule
• Portfolio of 7 topical generics in development by end FY17	✓
• Axiron Appeal outcome	Court date yet to be scheduled

*some generic products in the Acrux pipeline do not require a clinical study for product approval

Axiron® IP status

- Acrux and Eli Lilly and Company appealed the United States District Court decision in August 2016
- Federal Circuit appeal expected to be scheduled in October / November 2017
- Perrigo announced the launch of a generic of Axiron on 5 July 2017 in the United States. An Authorized Generic marketed by Prasco was launched at the same time. Teva announced the launch of a generic of Axiron on 18 August in the United States.

Axiron volume and market share



- Axiron market share declined from start of CY2017
- A generic of Axiron launched in July 2017 eroding Axiron market share
- US District Court decision has been appealed. Federal Circuit in Washington DC will hear Appeal. Expected to be heard in the fourth quarter of 2017.

Full year profit and loss



	Full Year Ending		%
	2017	2016	
	\$'000	\$'000	
Royalty revenue	23,321	25,469	(8.4%)
Milestone revenue	-	2,540	(100.0%)
Interest & Other Income	613	548	11.9%
Total revenue and other income	23,934	28,557	(16.2%)
R&D investment	(9,247)	(5,536)	67.0%
Operating costs	(2,198)	(2,390)	(8.0%)
Non operating costs	(1,903)	(2,539)	(25.0%)
Total expenses	(13,348)	(10,465)	27.5%
Operating profit before impairment loss and income tax	10,586	18,092	(41.5%)
Impairment loss	(10,680)	-	-
Operating (loss)/profit before income tax	(94)	18,092	(100.5%)
Income tax expense	(149)	(5,111)	(97.1%)
Net (loss)/profit for the year	(243)	12,981	(101.9%)
Earnings per share			
Basic (loss)/earning per share	(0.15) cents	7.80 cents	(7.95) cents

- Royalty revenue largely comprises Axiron revenue of \$22.8m which is 10% down on prior year as global sales by our commercial partner were USD 143.0m down from USD 149.3m in the prior year
- Milestone income reflects multiple marketing approvals of Lenzetto in the European Union by our licensee Gedeon Richter, not recurring in financial year
- R&D investment was \$9.2m up 67% prior year due to the progression and increase in research and development projects and higher utilisation of external suppliers. Material investment increase in follow items:
 - contract manufacturing and procurement of API for exhibit batches \$1.7m
 - IP strategy costs \$1.1m
 - increased laboratory headcount \$0.3m
 - laboratory maintenance and facility costs \$0.2m
- Non-operating costs comprise amortisation of capitalised assets and foreign exchange loss
- Impairment loss is a result of a re-assessment of the estimated future discounted cashflows from Axiron® assessing variables including the current market data for the Testosterone market in the United States and generic market penetration since 6 July 2017
- Income tax expense is \$0.1m being 97.1% lower than prior year due to reversal of the deferred tax liability associated with the impaired portion of Axiron® capitalised development costs not being realised as initially contemplated
- Loss after tax was \$0.2m down \$13.2m from prior year

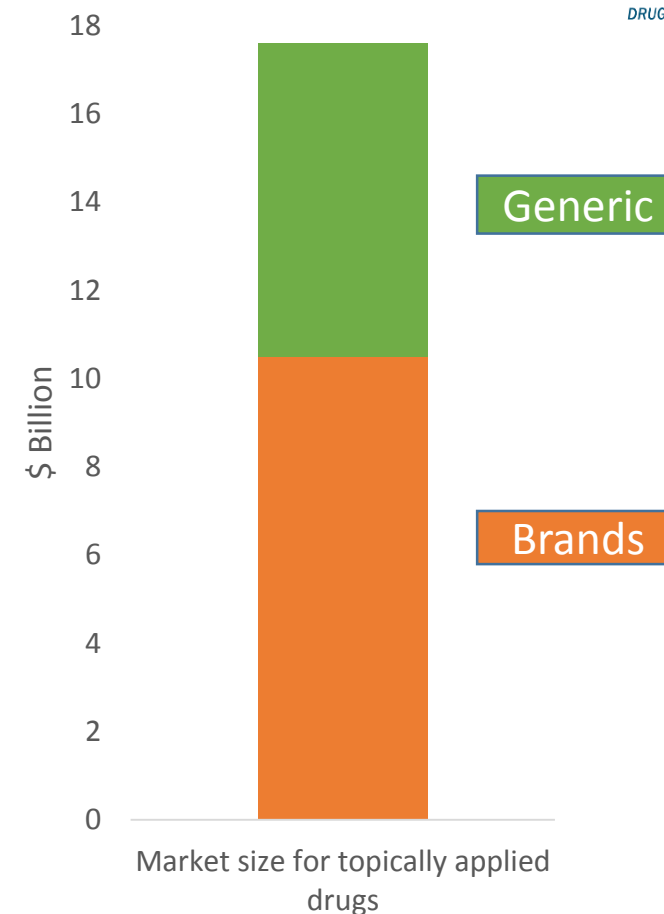
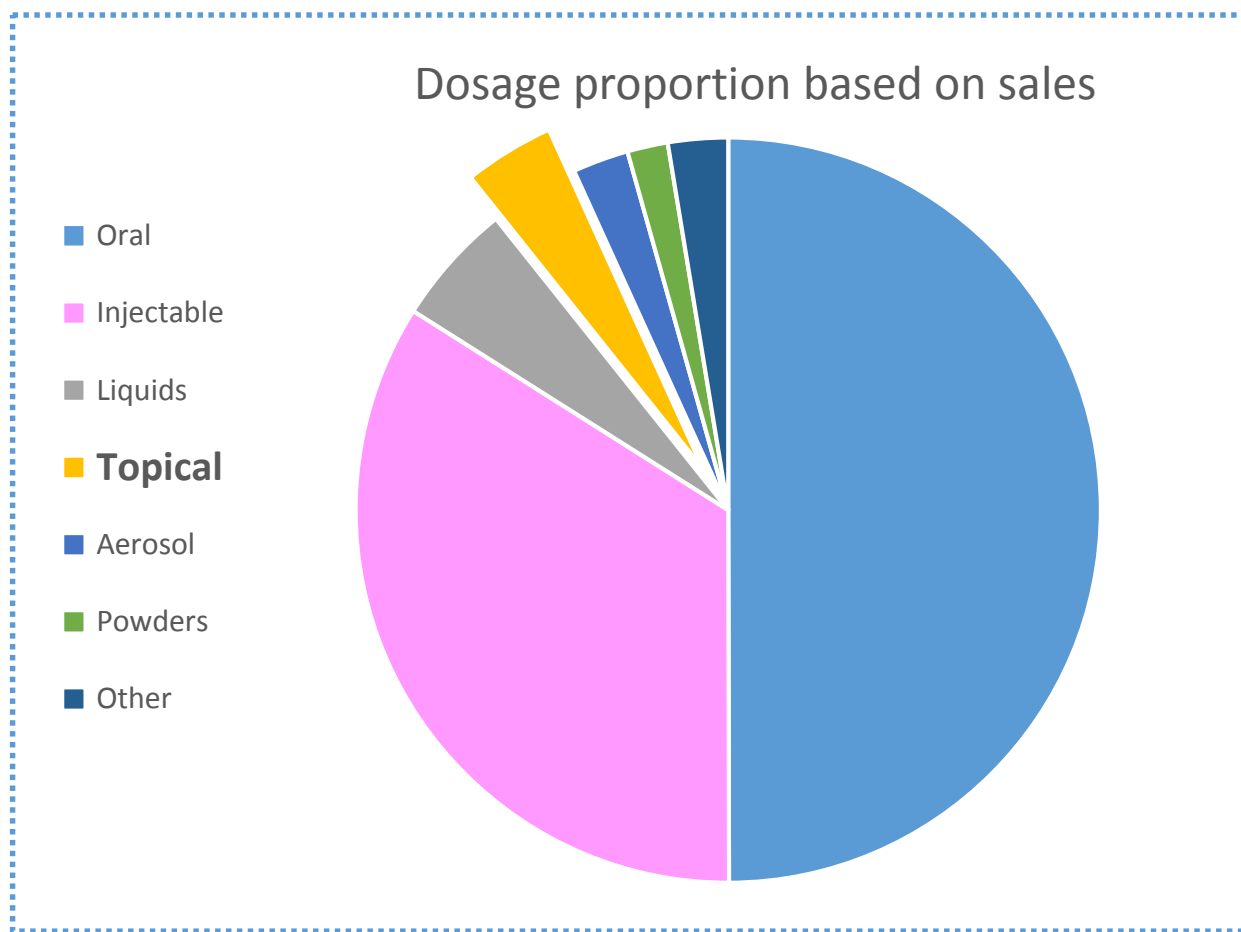
Full year cash flow



	Full Year Ending		%
	2017	2016	
	\$'000	\$'000	
Cash flow from operating activities			
Receipts from product agreements	21,822	28,208	(22.6%)
Payments to suppliers and employees	(10,748)	(7,923)	35.7%
Interest received	637	515	23.7%
Income tax paid	(6,335)	(4,294)	47.5%
Net cash provided by operating activities	5,376	16,506	(67.4)%
Cash flow from investing activities			
Payment for property, plant and equipment	(629)	(236)	166.5%
Net cash used in investing activities	(629)	(236)	166.5%
Cash flow from financing activities			
Dividends paid	-	(9,992)	(100.0%)
Net cash used in financing activities	-	(9,992)	(100.0)%
Net increase in cash and cash equivalents	4,747	6,278	(24.4)%
Cash at beginning of year	29,360	23,068	27.3%
Foreign exchange differences on cash holdings	(133)	14	(1050.0)%
Cash and at end of the year	33,974	29,360	15.7%

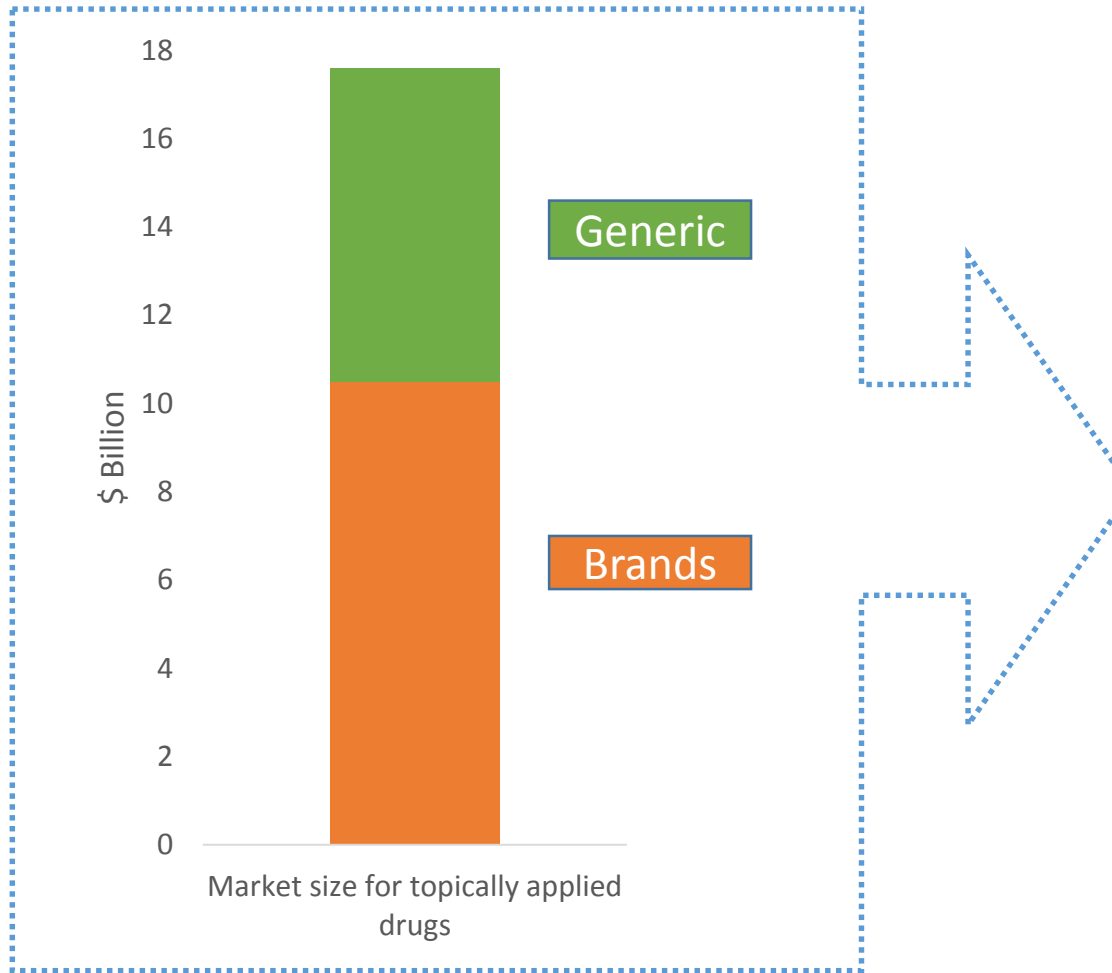
- Cash received from product agreements was \$21.8m down 22.6% on prior year due to:
 - lower Axiron royalty receipts \$21.5m
 - non recurrence of Lenzetto European approval milestones of USD 2.0m
- Payments to suppliers & employees was \$10.7m up 35.7% due to increased investment in R&D pipeline. Material payments:
 - contract manufacturing and procurement of API for exhibit batches
 - IP strategy costs
 - increased laboratory headcount to align with planned pipeline activity
- Interest received is up 23.7% on prior year due to higher average cash reserves held during year
- Tax payments for the financial year were \$6.3m or 47.5% higher than prior year reflecting the timing of tax payments
- Capital expenditure was \$0.6m up 166.5% on prior year as the company refreshes its existing equipment and internalises analytical and testing capability
- Cash reserves at year end were \$34.0m up 15.7% or \$4.6m on prior year

United States market – sales by dosage form

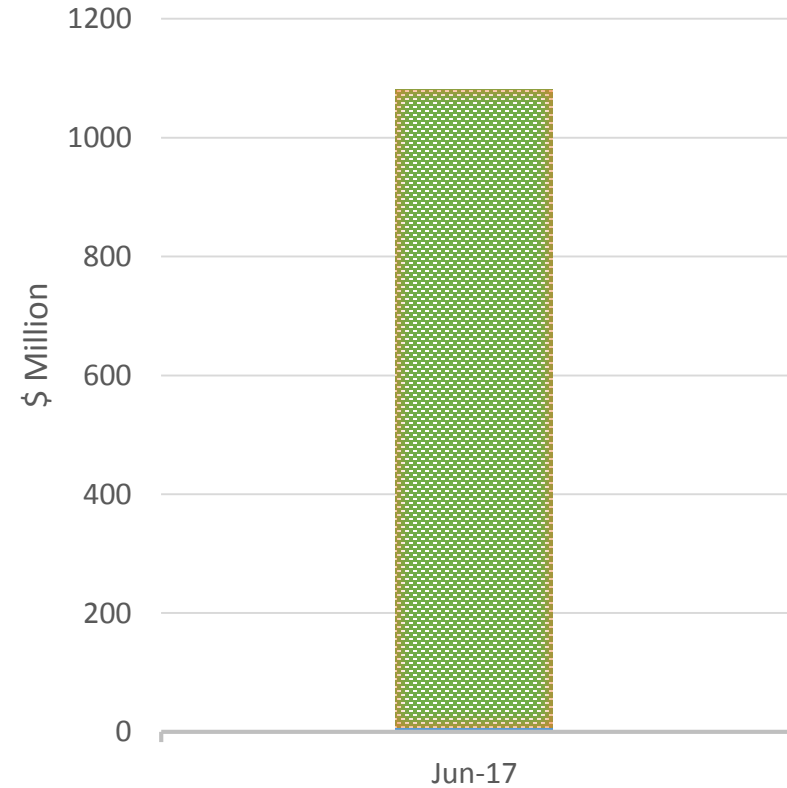


Topically applied drugs generate almost \$18 billion in sales in the United States
Acrux pipeline is focussed on the development of generic topical/transdermal products

The Acrux market opportunity

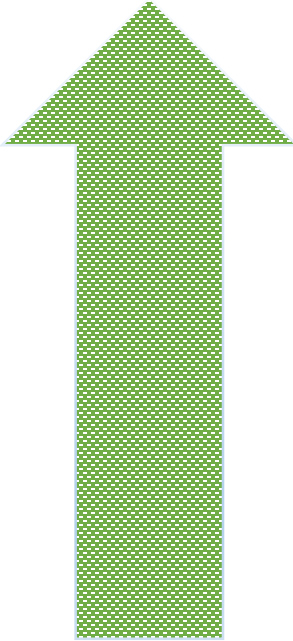


Acrux generic pipeline addressable market value



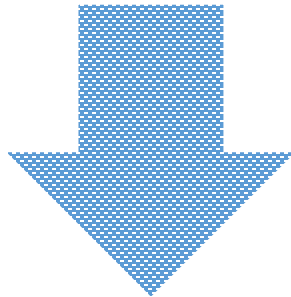
Acrux has 7 generic products in active development
Acrux expects to increase this to 12 generic products in active development by end FY18

Acrux generic portfolio opportunities and challenges



Opportunities

- Low project risk for generic pipeline compared to branded products
- Considered project selection including products with biowaiver potential or Paragraph IV opportunity
- Avoid commoditised market segments with significant pricing pressure
- Commercialise a diversified broad topical generic portfolio
- FDA costs lower for ANDAs compared to 505(b)(2) or NDA submissions



Challenges

- Undisclosed pipelines for generic companies

Acrux plans to file ANDA regulatory submissions mid 2018 for its initial generic products

Acrux antifungal development

Onychomycosis



Indication

For treatment of fungal infection (onychomycosis) of toenails and fingernails

Formulation and intellectual property

- Solution for topical administration
- Improved formulation of efinaconazole selected
- New patent has been filed
- In May 2017, the US Patent and Trademark Office (PTO) has instituted an *inter partes* review (IPR) proceeding filed by Acrux against a Jublia patent

Development progressing

- Pre-IND meeting scheduled with the FDA in October to inform clinical program direction
- External pre-clinical studies underway
- Preferred formulation manufactured and indicative lab scale stability initiated

Acrux is targeting best in class efficacy

Future milestones

- Submit first generic dossiers during FY18
- Initial revenue from generic pipeline expected 2019
- Portfolio of 12 topical generics in development by end FY18
- Initiate clinical program for onychomycosis following FDA Pre-IND meeting
- Axiron Appeal outcome



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