

**Acrux (ASX: ACR)
1H FY17 Results**

February 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.

1H FY17 outcomes



Revenue	1H FY17: \$14.3 million 1H FY16: \$18.0 million
Net Profit After Tax	1H FY17: \$6.3 million 1H FY16: \$9.7 million
Cash	1H FY17: \$31.7 million 1H FY16: \$21.5 million
Pipeline progress	<ul style="list-style-type: none">• Solid progress on first five generic projects• Contract manufacturing agreements executed with Groupe Parima for initial generic projects• Selection of lead candidate for anti fungal development project and filing of new intellectual property

Half year profit & loss



	31 December 2016	31 December 2015	%
	\$'000	\$'000	
Royalty revenue	13,969	15,224	(8.2%)
Milestone revenue	-	2,534	(100.0%)
Interest & Other Income	359	246	46.0%
Total revenue and other income	14,328	18,004	(20.4%)
R&D investment	(3,572)	(2,427)	(47.2%)
Other operating costs	(888)	(1,506)	41.1%
Non-operating costs	(818)	(766)	(6.8%)
Total expenses	(5,278)	(4,700)	(12.3%)
Profit before income tax	9,050	13,304	(32.0%)
Income tax expense	(2,728)	(3,558)	23.3%
Net profit for the half-year	6,322	9,746	(35.1%)
Earnings per share			
Basic earning per share	0.04 cents	0.06 cents (0.02) cents	
Cash reserves	31,718	21,539	47.3%

- ➔ Royalty revenue largely comprises Axiron revenue via our licensee Eli Lilly with minor contributions from sales of Estradiol in America and Europe.
- ➔ Axiron revenue at \$13.7mil declined 10.5% from prior half-year reflecting a decline in Axiron global sales by our partner Eli Lilly. On a constant currency basis royalty revenue from Axiron declined 4.6% or \$0.7 million.
- ➔ Nil milestone income was received for the half-year compared to US\$2.0mil received from Gedeon Richter for Lenzetto launches in Europe during prior period.
- ➔ R&D investment up \$1.1mil or 47.2% over prior half-year, reflecting investment in the development of 5 generic drugs and one speciality product.
- ➔ Other operating costs have reduced 41.1% essentially driven by lower licence costs due to lower royalty revenue.
- ➔ Non-operating costs comprise depreciation and amortisation and unrealised foreign exchange movement.
- ➔ Income tax expense represents 30.1% of profit before tax, higher than last half-year 26.7% which was impacted by the utilisation of tax losses.
- ➔ Profit after tax down 35.1% or \$3.4mil over prior year

Half year cash flow



	31 December 2016	31 December 2015	%
	\$'000	\$'000	
Cash flow from operating activities			
Receipts from product agreements	10,420	14,657	(28.9%)
Payments to suppliers and employees	(5,244)	(3,873)	(35.4%)
Interest received	298	206	44.6%
Income tax paid	(2,924)	(2,619)	(11.7%)
Net cash provided by operating activities	2,550	8,371	(69.5)%
Cash flow from investing activities			
Payment for property, plant and equipment	(200)	(54)	(269.7%)
Net cash used in investing activities	(200)	(54)	(269.7)%
Cash flow from financing activities			
Dividends paid	-	(9,894)	100.0%
Net cash used in financing activities	-	(9,894)	100.0%
Net decrease in cash and cash equivalents	2,350	(1,577)	249.0%
Cash at beginning of half-year	29,360	23,068	27.3%
Foreign exchange differences on cash holdings	8	48	(83.6)%
Cash and at end of the half-year	31,718	21,539	47.3%

- Cash received from conduct of business activities \$10.4mil, down 28.9% or \$A4.2mil on prior half-year due to:
 - Lenzetto European launch milestones not re-occurring (USD2.0mil) and
 - Softer half on half Axiron royalty (A\$1.5mil)
- Increase in payments to suppliers & employees of 35.4% as investment in R&D is increased to drive pipeline program.
- Tax payments of \$(2.9)mil reflect payments for final FY16 tax liability and instalment payments for FY17.
- Payments for property, plant & equipment are A\$(200)k which is 269.7% higher than prior half-year and reflect investment in upgrading laboratory assets.
- As a result cash reserves at year end were \$31.7mil up 47.3% or \$10.2mil over prior year.

Axiron® IP Appeal



- United States District Court for the Southern District of Indiana judgment
 - Formulation and axilla application patents granted by the US Patent Office for Axiron® were invalidated
 - Patents therefore would not be infringed by the commercialisation of generic versions of Axiron by the generic companies that have challenged these patents
 - The applicator patent is valid but not infringed by the majority of parties
- Acrux and Eli Lilly and Company have appealed the District Court decision
- Federal Circuit appeal outcome expected Q1 FY18

Axiron® sales



- AXIRON is used to treat adult males who have low or no testosterone due to certain medical conditions
- Approved in the United States and selected other countries
- Testosterone replacement therapy market is \$1 billion+ in United States
- Licensed globally to Eli Lilly and Company
- Acrux receives royalties and milestones on sales from Lilly
- To date, there has been no launch of a generic of Axiron

Lenzetto® (estradiol) spray Launched in Europe

- Lenzetto® is a hormone replacement therapy for women
- Lenzetto® has been launched in a number of territories throughout 2016, through our licensee Gedeon Richter:

Belgium	Hungary
Bulgaria	Latvia
Croatia	Lithuania
Czech Republic	Poland
Estonia	Romania
Germany	Slovakia



- Progressive European roll-out to other new markets expected through 2017
- Topical estrogen-only HRT market is valued at over EURO 85 million

Growth Strategy

Acrux is building a sustainable business model with a broader portfolio which leverages its existing topical expertise in compelling market segments

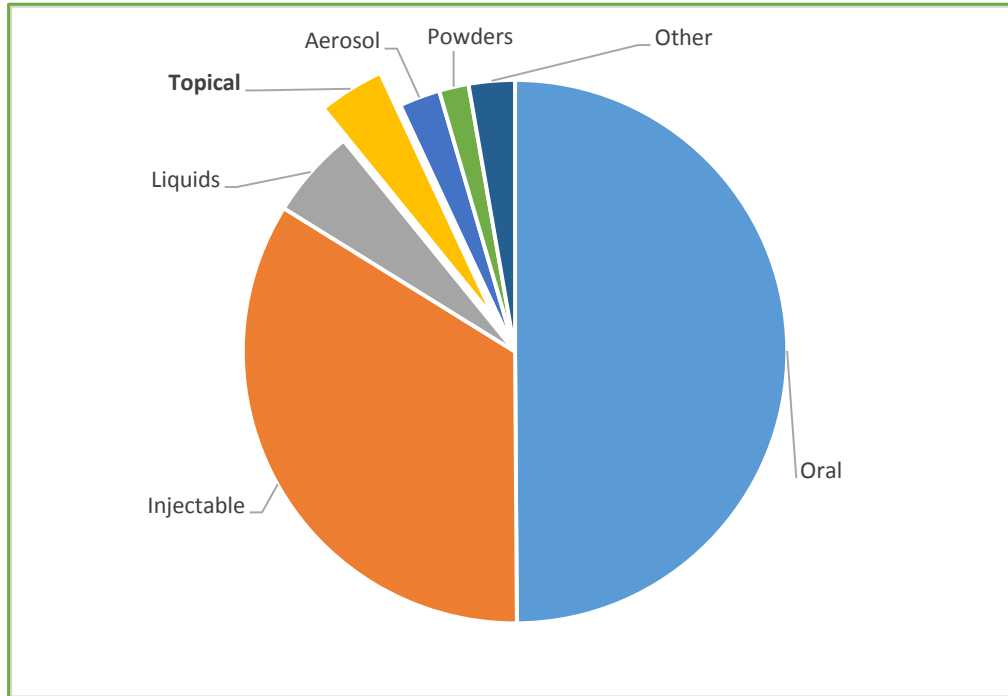
How:

- Core competency – utilise current technology, skills and capabilities
- Highly experienced formulation team
- Product development focused on commercially compelling opportunities
- Partner with strong and capable licensees

Measures of success:

- Portfolio with multiple products in various stages of development
- Valuable products licensed and commercialised
- Profitable and sustainable business

Total US pharma market size



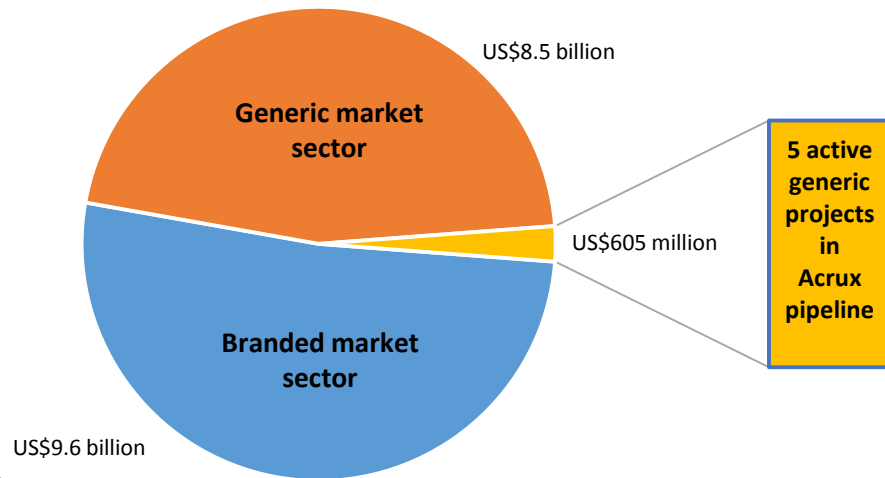
Source: Acrux analysis. IMS June 2015 MAT. US market sales in US\$.

- Oral market exceeds \$200 billion
- Injectable market exceeds \$130 billion
- Both oral and injectable markets are heavily competitive.
- Topical transdermal market exceeds \$18 billion

**Topically applied drugs generated sales of over \$18 billion in 2015.
Oral and injectable markets account for 84% of total market.**

Topical Generic Portfolio

US Transdermal and Topical market size



Source: IMS June 2015 MAT. US Transdermal and Topical generic and branded market segments

- First three generic formulations completed. CMO selected and contracted.
- 5 generic projects in active development
- Topically applied generic products in commercially attractive market segments
- Reduced development timeframes compared to topical speciality portfolio
- Building portfolio of topical generic programs with sustainable returns
- Targeting US market
- Generic market sector grew by 17% year on year. Branded market sector declined by 2%

Our topical generic pipeline is growing and is commercially compelling

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
- IPR Petition for review of existing Jublia patent filed

Market

- New topical products growing market volume
- Over 30 million Americans with onychomycosis
- Efficacy of currently marketed topicals is low

Acrux is targeting best in class efficacy in an attractive growing market

Future milestones

<ul style="list-style-type: none"> Draft and submit patent application for ACR065 for onychomycosis 	<ul style="list-style-type: none"> Patent filing submitted
<ul style="list-style-type: none"> Gedeon Richter to continue country specific launches of Lenzetto in the European Union 	<ul style="list-style-type: none"> Ongoing
<ul style="list-style-type: none"> Scale up activities to manufacture exhibit batches for initial generic products 	<ul style="list-style-type: none"> Scale up activities underway and exhibit batches scheduled over coming months
<ul style="list-style-type: none"> Contract manufacturing organisation to be engaged to manufacture multiple generic products 	<ul style="list-style-type: none"> Contract executed
<ul style="list-style-type: none"> Commence first bioequivalence study 	<ul style="list-style-type: none"> Planning underway
<ul style="list-style-type: none"> Portfolio of 7 topical generics in development by end FY17 	<ul style="list-style-type: none"> 5 active projects. On schedule to have 7 active generic projects by mid 2017
<ul style="list-style-type: none"> Axiron Appeal outcome 	<ul style="list-style-type: none"> Outcome expected 1Q FY18
<ul style="list-style-type: none"> Onychomycosis phase 1 trial 	<ul style="list-style-type: none"> First patient recruited 1H FY18

