Acrux (ASX: ACR)

FY18 Annual Results Presentation

17 August 2018

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

ACRUX
DRUG DELIVERY SOLUTIONS

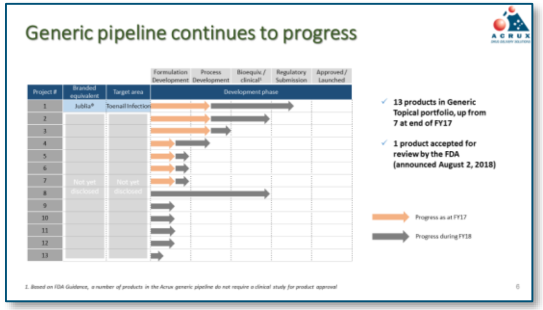
FY18 Achievements

Full Year P&L and Cashflow

FY19 Objectives

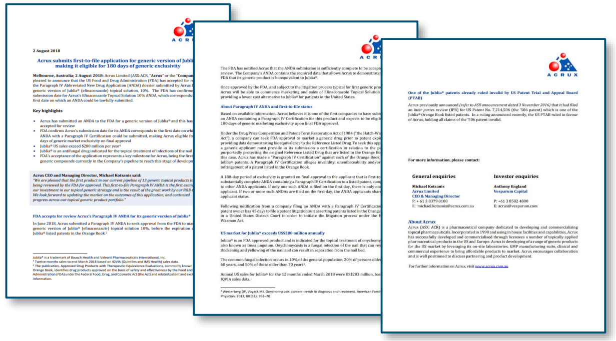
FY18 operational highlights

EXCELLENT R&D PROGRESS



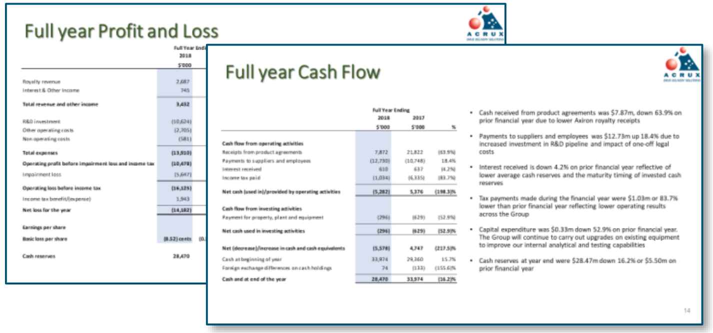
- Continued solid progress on our portfolio of generic topical drugs
- Engaged 4 contract manufacturing organisations (CMO) for different products in our pipeline
- Achieved successful completion of PK bioequivalence trial

ON-SCHEDULE FDA APPLICATION



- Acrux submitted its application to market a generic version of Jublia® in June 2018
- On August 2nd the application was accepted for review by the FDA

HEALTHY CASH BALANCE

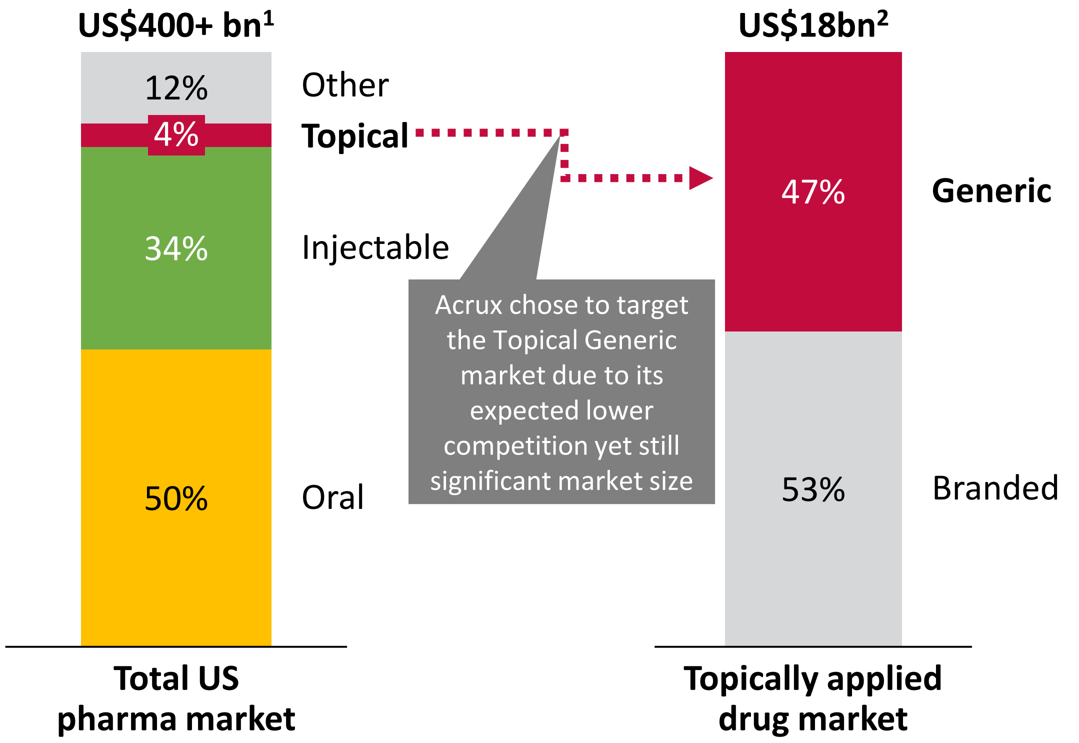


- Net cash spend on operating activities of ~A$5m in FY18
- Cash reserves as at 30 June of $28m in line with expectations

In FY18 Acrux expanded its high-potential portfolio of topical generic products

Strategy recap: Topical generic portfolio

SIGNIFICANT MARKET OPPORTUNITY (US$18bn)



ADVANTAGES OF GENERIC STRATEGY

Fast development and low cost

- $3-4m to develop each generic

Lower risk than branded development

- Efficacy of drug has already been demonstrated

Attractive market and licensee terms

- Market value of drugs in pipeline >$1.4 billion
- Future revenue derived from milestones and royalties

1. Source: US market by dosage form, IQVIA Q2, 2015 MAT. US market sales. US$; 2. Source: Market size for topically applied drugs IQVIA Q3, 2017 MAT US$

Generic pipeline continues to progress

Project #	Branded equivalent	Target area	Formulation Development	Process Development	Bioequiv. / clinical[1]	Regulatory Submission	Approved / Launched
			Development phase				
1	Jublia®	Toenail Infection					
2	Not yet disclosed	Not yet disclosed					
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							

- ✓ **13 products in Generic Topical portfolio, up from 7 at end of FY17**
- ✓ **1 product accepted for review by the FDA (announced August 2, 2018)**

Progress as at FY17

Progress during FY18

1. Based on FDA Guidance, a number of products in the Acrux generic pipeline do not require a clinical study for product approval

Significant variation within topical generic pipeline

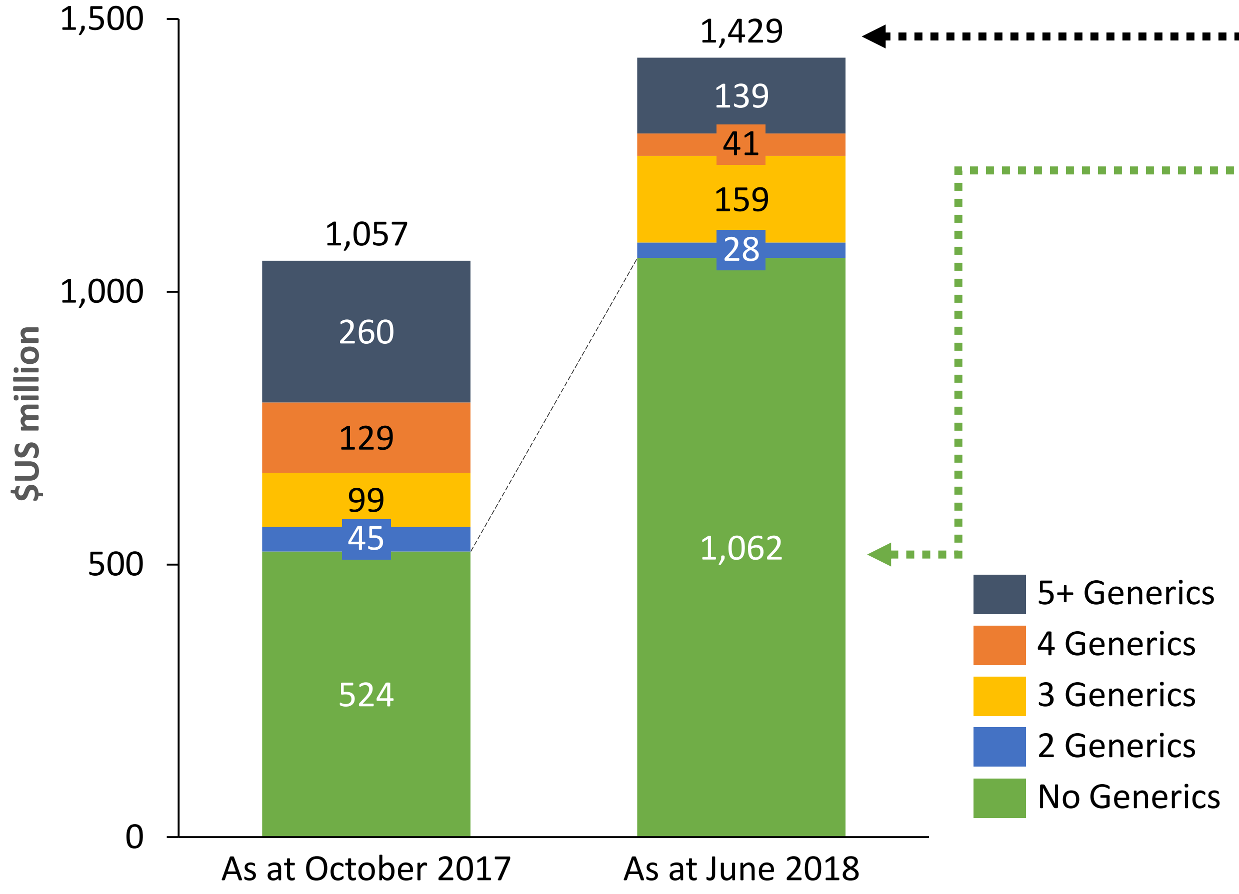
*Numerous **therapeutic areas***	
Antifungals	Anti-rheumatics
Acne	Analgesics
Hormones	Anti-inflammatories
Antivirals	…

*A range of **dosage forms***	
Ointments	Lotions
Creams	Pastes
Solutions	Sprays
Gels	…

No shortage of high value topical projects for Acrux to assess for inclusion in the portfolio

Market value of drugs in pipeline >US$1.4bn

ACRUX GENERIC PIPELINE ADDRESSABLE MARKET VALUE[1, 2]



Acrux is targeting a large and growing addressable market

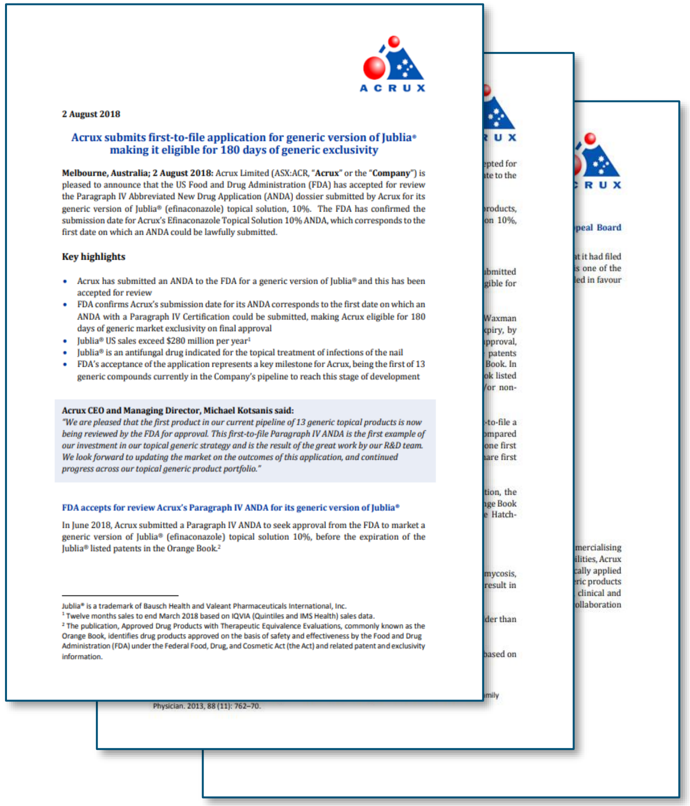
- ✓ Addressable market of +US$1.4 billion*

Fewer generic products on the market creates favourable economics for Acrux

- ✓ **Addressable market with no generics has grown from US$524 million at October 2017 to +US$1 Bn at end FY18**
- ✓ For markets with lower competition, Acrux expects to capture relatively higher market share
- ✓ Over half of the portfolio's addressable market has zero generic competitors at this point in time
- ✓ Over half of the portfolio has zero generic competitors at this point in time
- ✓ FDA priority for review is given to generic applications with three or less approved generics

1. *June 2018 pipeline addressable market based on twelve months sales to end March 2018 based on IQVIA (Quintiles and IMS Health) sales data*
2. *October 2017 pipeline addressable market based on twelve months sales to end March 2017 based on IQVIA (Quintiles and IMS Health) sales data*

First-to-file Generic of Jublia®



2 August 2018

Acrux submits first-to-file application for generic version of Jublia® making it eligible for 180 days of generic exclusivity

Melbourne, Australia; 2 August 2018: Acrux Limited (ASX:ACR, "**Acrux**" or the "**Company**") is pleased to announce that the US Food and Drug Administration (FDA) has accepted for review the Paragraph IV Abbreviated New Drug Application (ANDA) dossier submitted by Acrux for its generic version of Jublia® (efinaconazole) topical solution, 10%. The FDA has confirmed the submission date for Acrux's Efinaconazole Topical Solution 10% ANDA, which corresponds to the first date on which an ANDA could be lawfully submitted.

Key highlights

- Acrux has submitted an ANDA to the FDA for a generic version of Jublia® and this has been accepted for review
- FDA confirms Acrux's submission date for its ANDA corresponds to the first date on which an ANDA with a Paragraph IV Certification could be submitted, making Acrux eligible for 180 days of generic market exclusivity on final approval
- Jublia® US sales exceed $280 million per year[1]
- Jublia® is an antifungal drug indicated for the topical treatment of infections of the nail
- FDA's acceptance of the application represents a key milestone for Acrux, being the first of 13 generic compounds currently in the Company's pipeline to reach this stage of development

Acrux CEO and Managing Director, Michael Kotsanis said:
"We are pleased that the first product in our current pipeline of 13 generic topical products is now being reviewed by the FDA for approval. This first-to-file Paragraph IV ANDA is the first example of our investment in our topical generic strategy and is the result of the great work by our R&D team. We look forward to updating the market on the outcomes of this application, and continued progress across our topical generic product portfolio."

FDA accepts for review Acrux's Paragraph IV ANDA for its generic version of Jublia®

In June 2018, Acrux submitted a Paragraph IV ANDA to seek approval from the FDA to market a generic version of Jublia® (efinaconazole) topical solution 10%, before the expiration of the Jublia® listed patents in the Orange Book.[2]

Jublia® is a trademark of Bausch Health and Valeant Pharmaceuticals International, Inc.
[1] Twelve months sales to end March 2018 based on IQVIA (Quintiles and IMS Health) sales data.
[2] The publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information.

Announcement released August 2, 2018

KEY HIGHLIGHTS

- **Acrux has submitted an ANDA to the FDA for a generic version of Jublia® and this has been accepted for review**
- **Acrux eligible for 180 days of generic market exclusivity on final approval**
- **Jublia® US sales exceed $280 million per year[1]**
- Jublia® is an **antifungal drug** indicated for the topical treatment of **infections of the nail**
- FDA's acceptance of the application **represents a key milestone for Acrux**, being the **first of 13 generic compounds** currently in the Company's pipeline to reach this stage of development

1. Twelve months sales to end March 2018 based on IQVIA (Quintiles and IMS Health) sales data

Lenzetto® update: Consistent royalty growth

Lenzetto® overview

- Estradiol spray (Lenzetto® and Evamist®) represents the first commercialised product to be developed by Acrux
- Lenzetto® used to treat patients who are suffering from menopausal symptoms

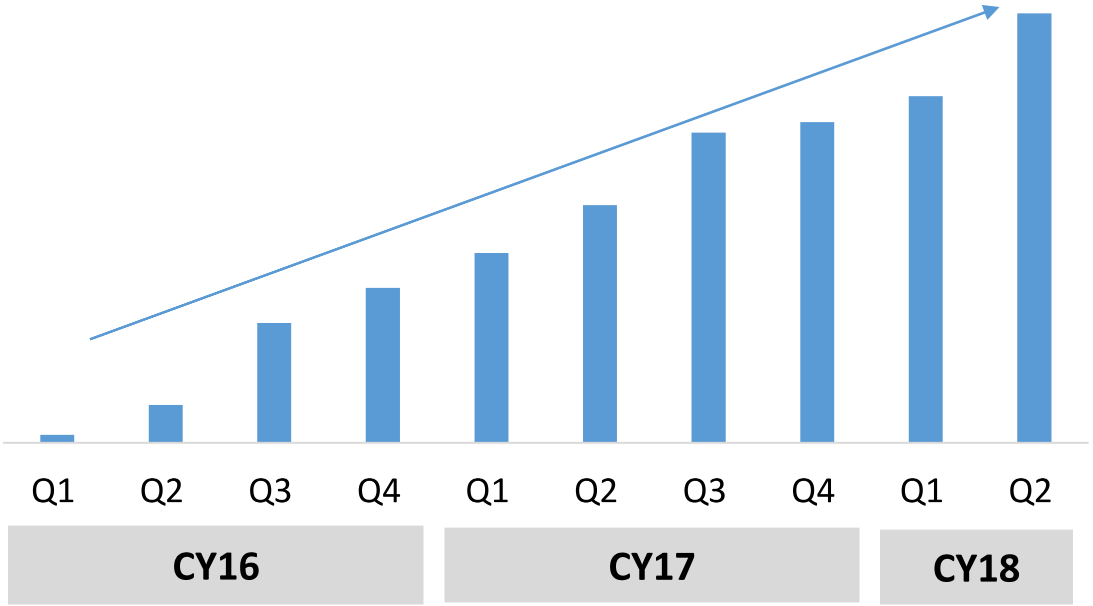
Effective partnering

✓ Product has been **licensed to Gedeon Richter in Europe**, who own the Lenzetto® Trademark

✓ Rollout of Lenzetto® commenced in **Q1 2016** and has since **successfully launched in 24 countries** across the European Union and other markets

✓ **Strong growth in revenue royalty expected to continue** as Lenzetto® is progressively launched in ex-US territories

Growing royalty revenues



Lenzetto provides evidence of Acrux's ability to execute on favourable B2B licensing agreements

Agenda

- FY18 Achievements
- **Full Year P&L and Cashflow**
- FY19 Objectives

Full year Profit and Loss

	Full Year Ending 2018 $'000	2017 $'000	%
Royalty revenue	2,687	23,321	(88.5%)
Interest & other Income	745	613	21.5%
Total revenue and other income	**3,432**	**23,934**	**(85.7%)**
R&D investment	(10,624)	(9,247)	14.9%
Other operating costs	(2,705)	(2,198)	23.1%
Non operating costs	(581)	(1,903)	(69.5%)
Total expenses	**(13,910)**	**(13,348)**	**4.2%**
Operating (loss)/profit before impairment loss and income tax	**(10,478)**	**10,586**	**(199.0%)**
Impairment loss	(5,647)	(10,680)	-
Operating loss before income tax	**(16,125)**	**(94)**	**17065.7%**
Income tax benefit/(expense)	1,943	(149)	(1404.0%)
Net loss for the year	**(14,182)**	**(243)**	**5737.8%**
Loss per share			
Basic loss per share	**(8.52) cents**	**(0.15) cents**	**(8.37) cents**
Cash reserves	**28,470**	**33,974**	**(16.2%)**

- Royalty revenue decreased 88.5% to $2.7m reflecting a decline in Axiron® global sales by our partner Eli Lilly and Company due to generic competition and the termination of the licensing agreement
- R&D investment increased by $1.4m, up 14.9% on prior financial year due to the increase in expenditure on our generic pipeline and nature of development costs
- Other operating costs increased by $0.5m, up 23.1% on prior financial year materially due to non-recurring legal fees of $0.7 million associated with the Axiron® patent appeal litigation
- Non operating costs are comprised of depreciation and amortisation
- Impairment loss is a result of a reassessment of the estimated future discounted cashflows from Axiron®. The assessment included consideration of termination of Axiron® licensing agreement and U.S. Court of Appeals for the Federal Circuit decision.
- Income tax benefit of $1.9m is attributable to the lower operating profit (excluding the impairment loss) and the reversal of the deferred tax liability associated with the impaired portion of Axiron® capitalised development costs not being realised as initially contemplated

Full year Cashflow

	Full Year Ending 2018 $'000	2017 $'000	%
Cash flow from operating activities			
Receipts from product agreements	7,872	21,822	(63.9%)
Payments to suppliers and employees	(12,731)	(10,748)	18.4%
Interest received	610	637	(4.2%)
Income tax paid	(1,033)	(6,335)	(83.7%)
Net cash (used in)/provided by operating activities	**(5,282)**	**5,376**	**(198.3%)**
Cash flow from investing activities			
Payment for property, plant and equipment	(296)	(629)	(52.9%)
Net cash used in investing activities	**(296)**	**(629)**	**(52.9%)**
Net (decrease)/increase in cash and cash equivalents	**(5,578)**	**4,747**	**(217.5%)**
Cash at beginning of year	33,974	29,360	15.7%
Foreign exchange differences on cash holdings	74	(133)	(155.6%)
Cash and at end of the year	**28,470**	**33,974**	**(16.2%)**

- Cash received from product agreements was $7.9m, down 63.9% on prior financial year due to lower Axiron royalty receipts
- Payments to suppliers and employees was $12.7m up 18.4% due to increased investment in R&D pipeline and impact of one-off legal costs
- Interest received is down 4.2% on prior financial year reflective of lower average cash reserves and the maturity profile of invested cash reserves
- Tax payments made during the financial year were $1.0m or 83.7% lower than prior financial year reflecting lower operating results across the Group
- Capital expenditure decreased by $0.3m or 52.9% on prior financial year reflecting the timing of expenditure as the Group carries out upgrades of existing equipment to improve our internal analytical and testing capabilities
- Cash reserves at year end were $28.5m down 16.2% or $5.5m on prior financial year

Agenda

- FY18 Achievements
- Full Year P&L and Cashflow
- **FY19 Objectives**

Outlook and objectives

FY19

2 dossiers

Submit 2 additional dossiers to the FDA for review

6 Technical Transfers

Scale up 6 projects from Acrux laboratory to Contract Manufacturing Organisations (CMOs)

Additional new products

Add additional products to the ACR generic portfolio

CY19

First generic revenues

Generate first revenues from generic portfolio

Acrux (ASX: ACR)

FY18 Annual Results Presentation

17 August 2018