

# ACRUX AGM PRESENTATION (ASX: ACR)

November 2018





## INTRODUCTION:

**ROSS DOBINSON  
NON-EXECUTIVE CHAIRMAN**



## OPERATIONAL REVIEW:

**MICHAEL KOTSANIS**  
**CEO & MANAGING DIRECTOR**



## 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.*

# STRONG OPERATIONAL AND COMMERCIAL PROGRESS



## Deliberate expansion & optimisation of portfolio

- **Successfully expanded generic topical portfolio from 7 to 13 products** and conducted ground work to add further products to the pipeline in FY19



## On-target regulatory submissions

- **Demonstrated successful execution of strategy** - achieving first and second submissions to the FDA (accepted for review in August and October 2018) and completion of a pharmacokinetic (PK) bioequivalence trial



## Continued excellence in research & development

- Significant progression and **increase in R&D projects** including **market screening** to identify high potential topical products and successful **formulation development of multiple products**



## Consistent operational execution

- **Successfully engaged additional Contract Manufacturing Organisations (CMO)** that are FDA approved and during FY19 will begin to scale up 6 projects from laboratory to exhibit batch manufacturing



## Attracted commercial interest

- Received **commercial interest** in the portfolio from several parties. Generic pharmaceutical companies place high value on generic portfolios



## Increased investor engagement

- Market responded to catalysts (generic Jublia® and testosterone solution FDA dossiers), share price increased in response
- Increased activity in investor engagement with increasing generic milestones and events



# INCREASING INVESTOR ENGAGEMENT

## Share price performance (last 12 months)



Key recent catalysts:  
02 August: Acrux has Paragraph IV generic of Jublia® accepted for review by FDA

Key recent catalysts:  
17 October: Acrux has generic testosterone solution submission accepted for review by FDA

Cash backing per share of 17c  
(as at 30 June 2018)

## OUR APPROACH



Market screening to  
**identify** high  
potential prescription  
topical products

**165**

*identified molecules,  
each with >US\$10m  
in sales*



R&D team with highly  
specific topical  
expertise drive  
development

**13**




*molecules in  
development*



**2 products already under FDA review,  
with several related commercial  
partnering discussions ongoing**

Acrux is developing a  
diversified portfolio of  
topically applied  
generic products

# MULTIPLE ADVANTAGES FOR GENERIC PRESCRIPTION PRODUCT DEVELOPMENT

	Traditional development	Acrux's generic development portfolio
<b>Market size</b> 	A new drug may have a significant market opportunity, however...	Attractive market and licensee terms
<b>Speed</b> 	...it takes <b>~10 years<sup>1</sup></b> to develop a new drug, involving <b>multiple expensive trials...</b>	Fast development and low cost
<b>Risk</b> 	...and typically less than <b>12% of drug candidates</b> make it into Phase I clinical trials <sup>1</sup>	Lower risk than branded development



# ACRUX IS MAKING EXCELLENT PROGRESS ACROSS ITS GENERIC TOPICAL PORTFOLIO

## In FY19, Acrux intends to:

- ✓ Submit 1 additional dossier to the FDA for review, in addition to dossier recently submitted
- ✓ Scale up 6 projects from Acrux laboratory to CMOs<sup>1</sup>
- ✓ Add additional products to the ACR generic topical portfolio



**Acrux expects to generate first revenues from its generic portfolio in CY19**

## Overview of Acrux's current generic topical portfolio of 13 assets

		Formulation Development	Process Development	Bioequiv. / clinical <sup>2</sup>	Regulatory Submission	Approved / Launched
Branded equivalent	Target area	Development phase			Commercialisation phase	
Jublia®	Toenail Infection	Progress as at FY17			Progress during FY18	
None	Testosterone	Progress as at FY17			Progress during FY18 *	
Not yet disclosed		Progress as at FY17			Progress during FY18	
Not yet disclosed		Progress as at FY17			Progress during FY18	
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Not yet disclosed		Progress as at FY17			Progress during FY18	

Legend: Progress as at FY17

Progress during FY18

# ACRUX PIPELINE REPRESENTS A LARGE MARKET WITH RELATIVELY LOW COMPETITION

## Addressable market value<sup>1</sup> (\$USm)

# of commercialised generic (ANDA)  
competitors on the market

5+ Generics

4 Generics

3 Generics

2 Generics

No generic  
equivalents

1,429

139

41

159

28

1,062

Addressable market of portfolio as at June 2018

Addressable market

**+US\$1.4 bn**

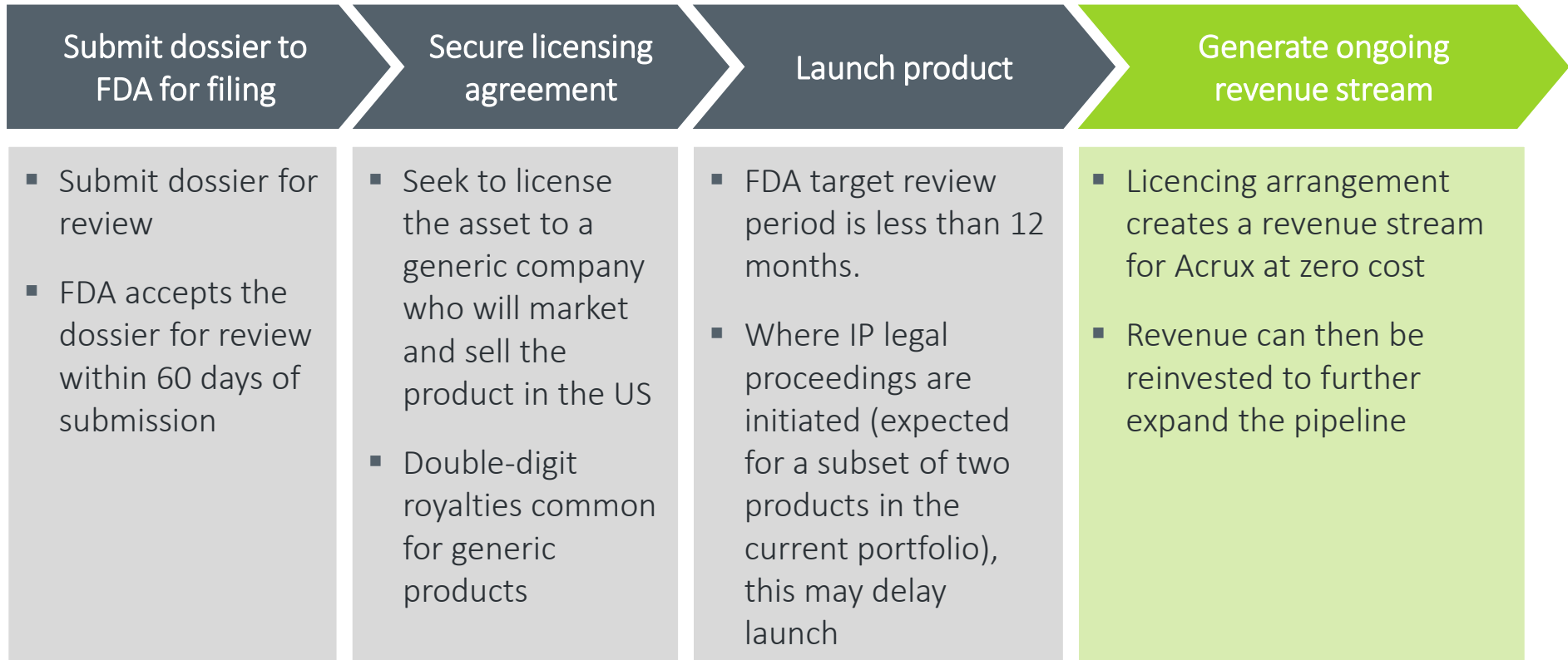
Based on 13 products currently in the Acrux  
topical generic pipeline

Fewer generic products on the  
market creates favourable  
economics

- ✓ Capture higher market share for products with lower competition
- ✓ More than half Acrux's portfolio have no commercialised generic equivalents

# EACH DRUG IN ACRUX'S GENERIC TOPICAL PORTFOLIO WILL FOLLOW THE SAME COMMERCIALISATION PATHWAY

An illustrative pathway for a successfully launched asset:



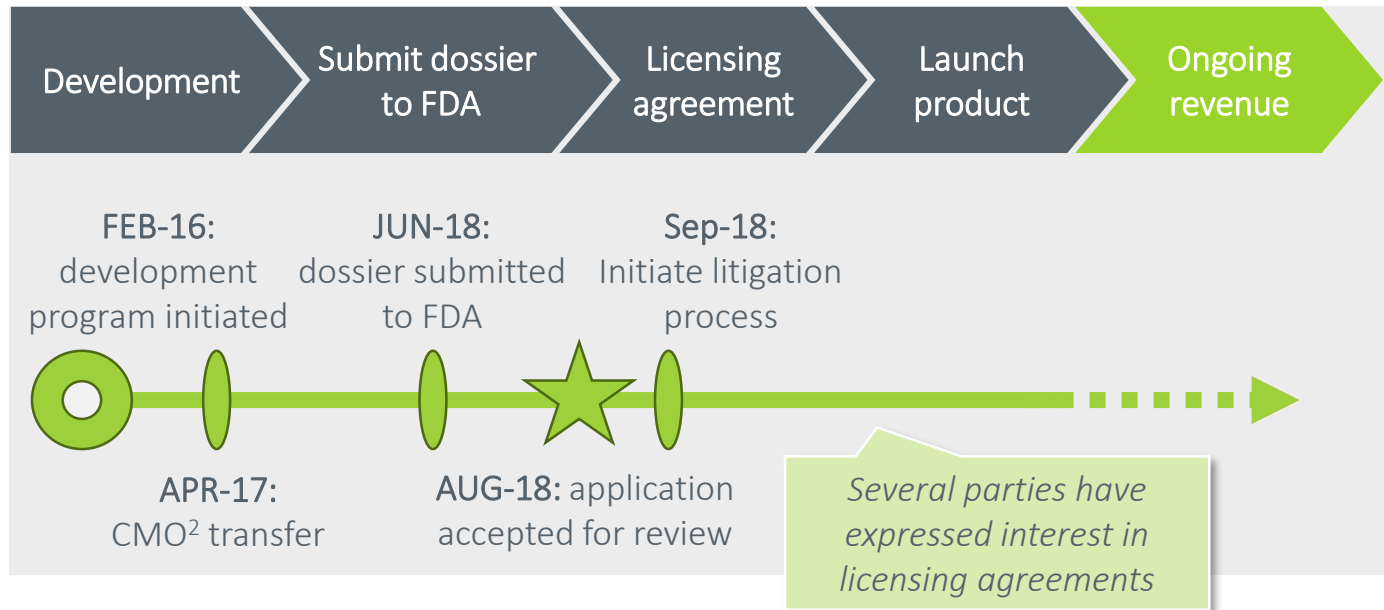
# FIRST GENERIC TOPICAL PRODUCT TO REACH 'FDA REVIEW'

## What is Jublia®?



Jublia® (efinaconazole) Topical Solution, 10% is a prescription antifungal medicine used to **treat fungal infections of the toenails** (Onychomycosis), which affects 10% of the population<sup>1</sup>

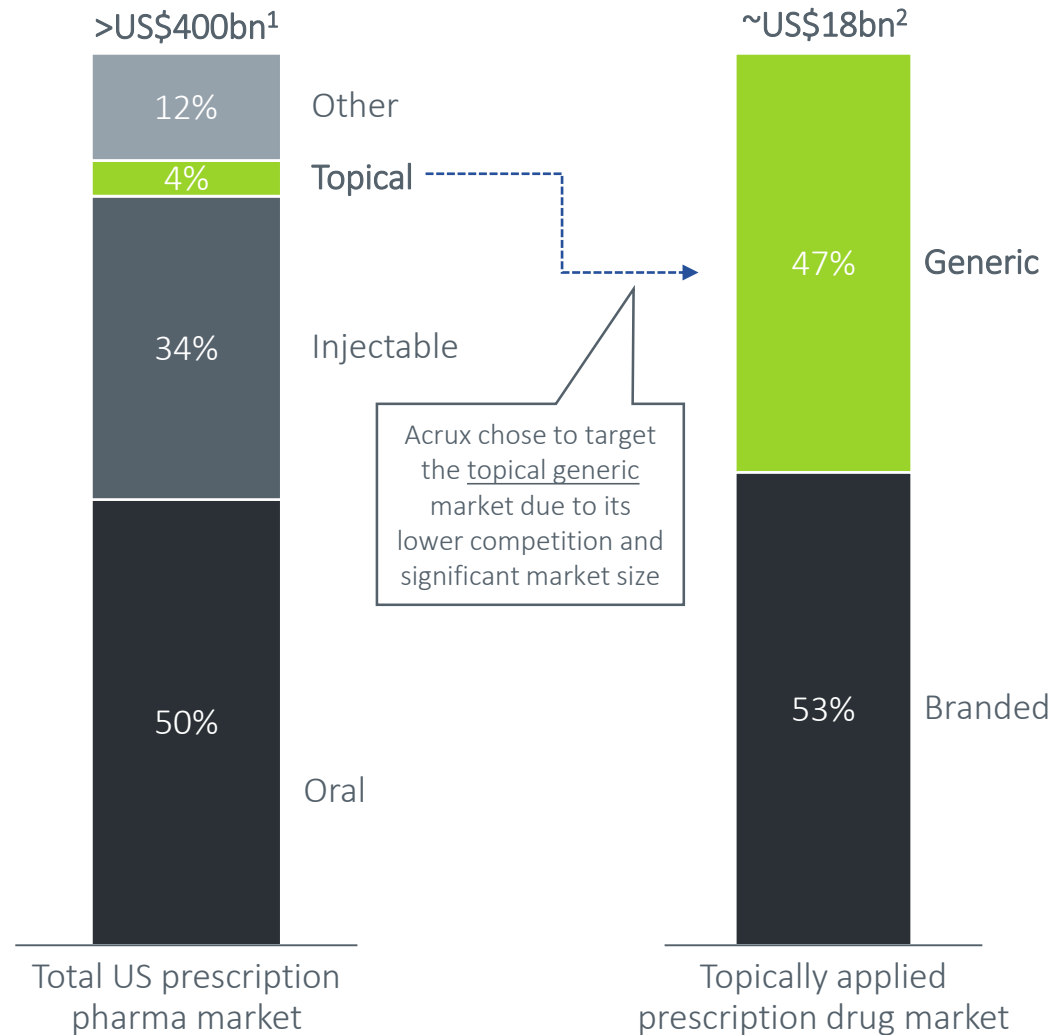
## Development timeline overview



# ACRUX IS OPERATING IN AN ATTRACTIVE US\$18bn MARKET

*Topical generics represent an attractive and significant market opportunity*

- ✓ US\$18bn market opportunity
- ✓ Currently, generics make up only 47% of the topical market, this is expected to grow
- ✓ Technical expertise required to develop and manufacture topicals as products can come in many different forms, **increasing barriers to entry**
- ✓ Acrux has established in-house development capabilities
- ✓ Generic manufacturers achieve **excellent EBITDA margins (+25%)<sup>3</sup>**



1. US market by dosage form, IQVIA Q2, 2015 MAT. US market sales (US\$)

2. Market size for topically applied drugs IQVIA Q3, 2017 MAT (US\$)

3. Citi Research – Generics Landscape Chart Pack (Jan 2017)

# EXPERIENCED MANAGEMENT TEAM WITH A PROVEN HISTORY OF MEETING OPERATIONAL MILESTONES

## Management team



**Michael Kotsanis BSc, MBus**  
*CEO & Managing Director*



Experienced leader in the pharmaceuticals industry with demonstrated success commercialising generic products



**Felicia Colagrande, BSc(Hons), MBA**  
*Product Development and Technical Affairs Director*



Deep experience in pharmaceutical operations, dermal drug development, analytical development and production. Felicia leads and facilitates all technical aspects of pharmaceutical product development including R&D, analytical development, project management and CMC development



**Charles O'Sullivan, B. Pharm**  
*Portfolio Director*



Experienced healthcare executive with senior and international leadership roles in scientific affairs, medical affairs, health economics and government affairs. Previously Asia Pacific Director of Medical and Government Affairs for Hospira Inc (now Pfizer)



**Tim Bateman CA**  
*CFO & Company Secretary*



Extensive financial experience and senior finance role. Tim was the Group Chief Financial Officer at Vix Technology for 10 years where his responsibilities included financial management, corporate governance, supporting strategic planning, M&A activities and capital raising

## World class topical R&D team

*"I am extremely proud to lead an **expert topical drug development team**. Our in-house skill set provides us with an **unique advantage**, supported by robust processes, competent regulatory acumen and our ability to **deliver products through development to commercialisation**."*



Felicia Colagrande, Product Development and Technical Affairs Director



**25** *researchers with experience in developing pharma products*

**350+** *years of combined experience in drug development*

**1** *common goal: develop high-value topical generics*



# STRATEGIC DIRECTION LED BY A BOARD WITH HIGHLY RELEVANT EXPERTISE



**Michael Kotsanis**  
*CEO & Managing Director*



- Experienced leader in the pharmaceuticals industry with demonstrated success **commercialising generic products**
- Michael was formally the Chief Commercial Officer for Synthon Holding BV, an international pharmaceutical company and a **leader in the field of generic medicines**
- Prior to Synthon Michael was President, Europe for Hospira Inc - the **largest global generic injectable company**



**Ross Dobinson**  
*Non-Executive Chairman*



Capital markets expert with a wealth of experience advising and establishing life science companies



**Simon Green**  
*Non-Executive Director*

- Extensive biotech drug development and commercial manufacturing experience
- Formerly senior vice president and general manager, CSL Ltd



**Geoff Brooke**  
*Non-Executive Director*

- Founded GBS Venture Partners
- Former president of Medvest Inc, a venture capital group he founded with Johnson & Johnson



**Tim Oldham**  
*Non-Executive Director*

- Former CEO of Cell Therapies Pty Ltd
- Former president of Asia Pacific for Hospira Inc and previously held a variety of senior management roles with Mayne Pharma Ltd

# MULTIPLE UPCOMING VALUE CATALYSTS

## Acrux objectives

### FY19



Submit 2  
additional  
dossiers to FDA



Scale up 6 projects  
from Acrux  
laboratory to  
CMOs



Add further  
products to  
generic portfolio

### CY19



First generic  
revenues

*Acrux expects to generate  
first revenues from its  
generic portfolio in CY19*



## FINANCIAL REVIEW:

**TIM BATEMAN**  
**CFO**

# FULL YEAR PROFIT AND LOSS

	Full Year Ending		
	2018	2017	
	\$'000	\$'000	%
Royalty revenue	2,687	23,321	(88.5%)
Interest & other Income	745	613	21.5%
<b>Total revenue and other income</b>	<b>3,432</b>	<b>23,934</b>	<b>(85.7%)</b>
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%)
<b>Total expenses</b>	<b>(13,910)</b>	<b>(13,348)</b>	<b>4.2%</b>
<b>Operating (loss)/profit before impairment loss and income tax</b>	<b>(10,478)</b>	<b>10,586</b>	<b>(199.0%)</b>
Impairment loss	(5,647)	(10,680)	-
<b>Operating loss before income tax</b>	<b>(16,125)</b>	<b>(94)</b>	<b>17065.7%</b>
Income tax benefit/(expense)	1,943	(149)	(1404.0%)
<b>Net loss for the year</b>	<b>(14,182)</b>	<b>(243)</b>	<b>5737.8%</b>
<b>Loss per share</b>			
<b>Basic loss per share</b>	<b>(8.52) cents</b>	<b>(0.15) cents</b>	<b>(8.37) cents</b>
<b>Cash reserves</b>	<b>28,470</b>	<b>33,974</b>	<b>(16.2%)</b>

# FULL YEAR CASHFLOW

	Full Year Ending		
	2018	2017	
	\$'000	\$'000	%
<b>Cash flow from operating activities</b>			
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%)
<b>Net cash (used in)/provided by operating activities</b>	<b>(5,282)</b>	<b>5,376</b>	<b>(198.3%)</b>
<b>Cash flow from investing activities</b>			
Payment for property, plant and equipment	(296)	(629)	(52.9%)
<b>Net cash used in investing activities</b>	<b>(296)</b>	<b>(629)</b>	<b>(52.9%)</b>
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>(5,578)</b>	<b>4,747</b>	<b>(217.5%)</b>
Cash at beginning of year	33,974	29,360	15.7%
Foreign exchange differences on cash holdings	74	(133)	(155.6%)
<b>Cash and at end of the year</b>	<b>28,470</b>	<b>33,974</b>	<b>(16.2%)</b>

## THANK YOU

Michael Kotsanis

Acrux Limited

CEO & Managing Director

P: + 61 3 8379 0100

E: michael.kotsanis@acrux.com.au

Visit our website: <http://www.acrux.com.au/>

Follow us on LinkedIn:



## Investor enquiries

Anthony England

Vesparum Capital

Director

P: + 61 3 8582 4800

E: Acrux@vesparum.com