



**ASX/Media Release**

**18 September 2018**

## **Acrux investor presentation**

**Melbourne, Australia; 18 September 2018:** Acrux Limited (ASX:ACR, “Acrux” or the “Company”) is pleased to release a new investor presentation.

### **Investment highlights**

- Diverse portfolio of 13 topical generic products, with an addressable market of US\$1.4bn+
- First ANDA submission to the FDA for a generic version of Jublia® in June which was accepted for review in early August
- Multiple upcoming value catalysts, first revenues expected in 2019
- Topical market is worth ~US\$18b in the US alone
- Generic product development is faster and lower risk when compared to branded products

**For more information, please contact:**

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### **About Acrux**

Acrux (ASX: ACR) is a pharmaceutical company dedicated to developing and commercialising topical pharmaceuticals. Incorporated in 1998 and using in house facilities and capabilities, Acrux has successfully developed and commercialised through licensees a number of topically applied pharmaceutical products in the US and Europe. Acrux is currently developing a range of generic products for the US market by leveraging its on-site laboratories, GMP manufacturing suite, clinical and commercial experience to bring affordable products to market. Acrux encourages collaboration and is well positioned to discuss partnering and product development.

For further information on Acrux, visit [www.acrux.com.au](http://www.acrux.com.au)

# ACRUX INVESTOR PRESENTATION (ASX: ACR)

September 2018



# INVESTMENT HIGHLIGHTS



## High potential topical generic portfolio

- **13 products** in the generic topical portfolio, up from **7** in October 2017
- Addressable market of pipeline assets is **>US\$1.4bn**



## Delivering on strategy

- **Strong execution building the topical generic pipeline since 2015, submitting first product in 2018**
- First submission to FDA in June, with acceptance for review in August, **in line with guidance**



## Attractive \$18bn market

- Generic products have **low development risk** and are typically **faster to develop** than branded products
- Topical generic market in the US alone worth **~US\$18bn**
- Generic manufacturers typically achieve **excellent EBITDA margins (+25%)**



## Multiple value catalysts

- **First revenues expected in calendar year 2019**
- Multiple new FDA ANDA submissions in **FY19** and beyond



## Commercialisation in progress

- Generic pharma companies place high value on generic portfolios
- Licensing interest received from several parties

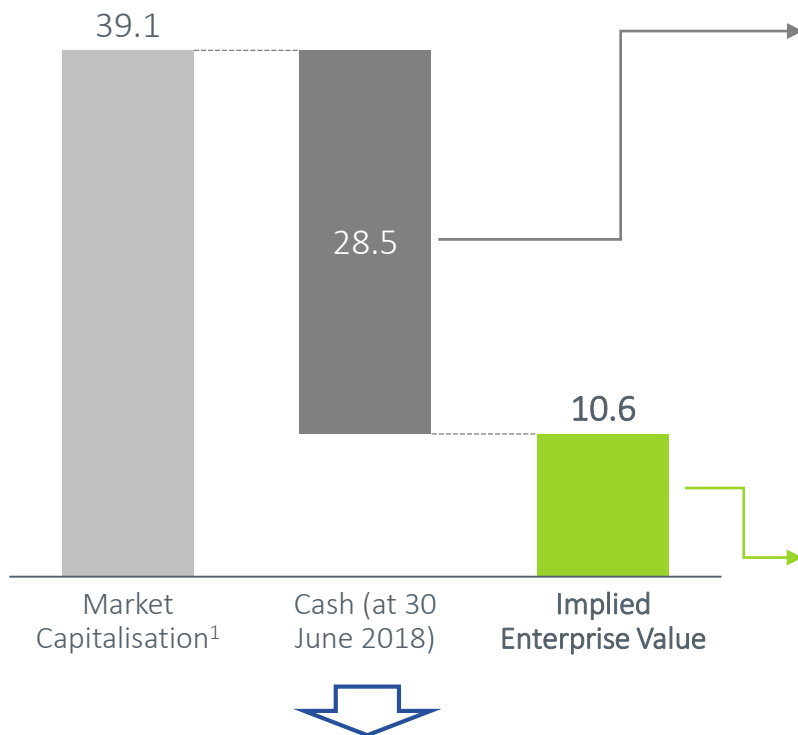


## Enterprise value of <\$11m

- Cash balance of \$28.5m at 30 June 2018
- Current market cap. of \$39.1m as at 14 September 2018
- Implied enterprise value of \$10.6m

# HIGH VALUE PIPELINE OF 13 PRODUCTS – IMPLIED ENTERPRISE VALUE OF <\$11M

## Implied enterprise value breakdown (A\$m)



With \$28.5m cash as at 30 June, management reasonably expects there to be sufficient funding to progress the current pipeline through to launch

- Typical costs for commercialisation of a generic product between ~\$3-4m
- Typical time to develop a generic product is ~3 years

The Board is of the view that Acrux's topical generic portfolio is being undervalued by the market

### Overview of Acrux's generic equivalent to Jublia®<sup>2</sup> (1 of 13 products)

- Accepted for review by the FDA (announced August 2<sup>nd</sup> 2018)
- Management believe it will be granted shared 'First-to-File' status, granting it shared sales exclusivity for 180 days
- Historically, generic products with 'First-to-File' status rapidly achieve ~50%+ market share<sup>3</sup>
- Addressable market - annual sales of Jublia® are ~US\$280m<sup>4</sup>
- Based on past experience management believes that significant double digit royalty rates are achievable<sup>5</sup>
- Several parties have already expressed interest in licensing agreements

**EV <\$11m despite pipeline of 13 drugs that has been developed over 3+ years**

1. Market capitalisation as at 14 September 2018

2. Jublia® (efinaconazole) Topical Solution, 10% is a prescription antifungal medicine indicated for the topical treatment of onychomycosis of the toenail(s).

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

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

5. Management estimates

## 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*



**1 product 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...	<b>Attractive market and licensee terms</b> <ul style="list-style-type: none"><li>• Market value of drugs in pipeline &gt;US\$1.4bn</li><li>• Future revenue derived from milestones and royalties</li></ul>
<b>Speed</b> 	...it takes <b>~10 years<sup>1</sup></b> to develop a new drug, involving <b>multiple expensive trials...</b>	<b>Fast development and low cost</b> <ul style="list-style-type: none"><li>• ~3 years to submission from project initiation</li><li>• ~\$3-4m (on average) to develop each generic</li></ul>
<b>Risk</b> 	...and typically less than <b>12% of drug candidates</b> make it into Phase I clinical trials <sup>1</sup>	<b>Lower risk than branded development</b> <ul style="list-style-type: none"><li>• Efficacy of drug has already been demonstrated</li></ul>



# ACRUX IS MAKING EXCELLENT PROGRESS ACROSS ITS GENERIC TOPICAL PORTFOLIO

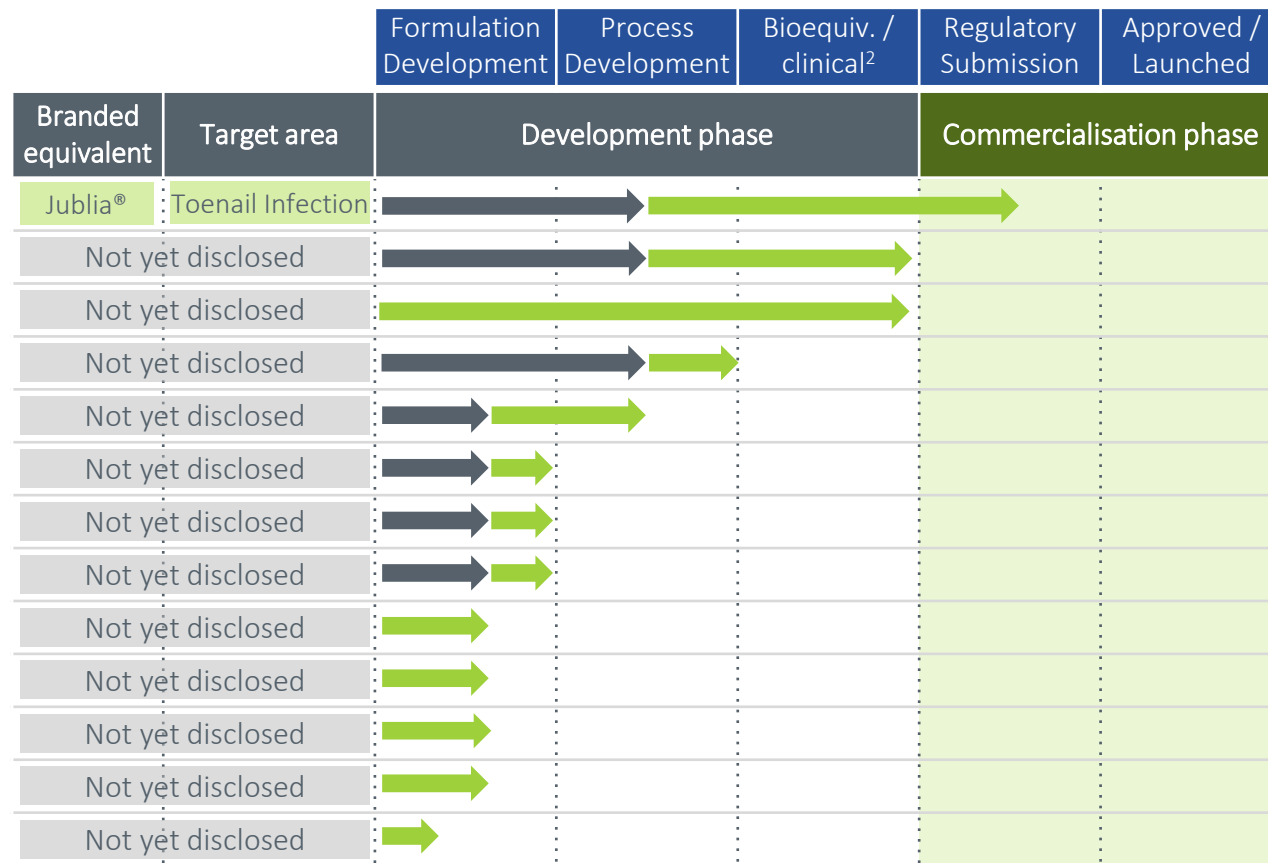
## In FY19, Acrux intends to:

- ✓ Submit 2 additional dossiers to the FDA for review
- ✓ Scale up 6 projects from Acrux laboratory to CMOs<sup>1</sup>
- ✓ Add additional products to the ACR generic portfolio



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

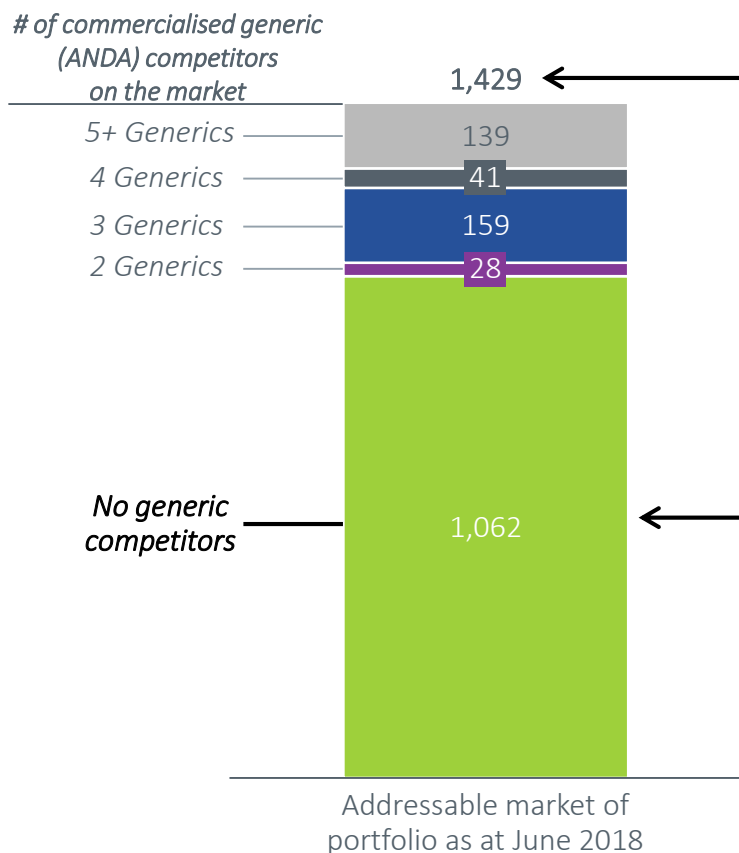
## Overview of Acrux's current generic topical portfolio of 13 assets



Legend: Progress as at FY17 Progress during FY18

# ACRUX PIPELINE REPRESENTS A LARGE MARKET WITH RELATIVELY LOW COMPETITION

## Acrux topical generic pipeline addressable market value <sup>1</sup> (\$USm)



### Acrux's portfolio (13 products) is targeting a significant addressable market

- ✓ Addressable market of +US\$1.4 billion (based on 13 products currently in the Acrux topical generic pipeline)
- ✓ Portfolio has increased from 7 products and addressable market of +US\$1.0 billion in October 2017

### Fewer generic products on the market creates favourable economics for Acrux

- ✓ Addressable market with no approved and commercialised generics exceeds US\$1bn
- ✓ FDA priority for review is given to applications with three or less approved generics
- ✓ Acrux expects to capture higher market share for products with lower competition and more than half of its portfolio has **no commercialised generics**



# FIRST GENERIC TOPICAL PRODUCT TO REACH 'FDA REVIEW' IS TARGETING A ~US\$280m MARKET

## What is Jublia®?



Jublia® (efinaconazole) Topical Solution, 10% is a prescription antifungal medicine used to treat fungal infections of the toenails (Onychomycosis)

## Development timeline overview

FEB-16:  
development  
program initiated

JUN-18:  
dossier submitted  
to FDA

NOTE: Acrux has submitted a 'Paragraph IV' filing, indicating that a patent litigation process is likely



APR-17:  
CMO<sup>1</sup> transfer

AUG-18: application  
accepted for review

Several parties already  
expressed interest in  
licensing agreements

## Product and market highlights

**US\$280m**  
addressable  
market<sup>2</sup>

**~10%**  
of population  
affected<sup>3</sup>

**First-to-File**  
180 days sales exclusivity on  
approval by FDA<sup>4</sup>

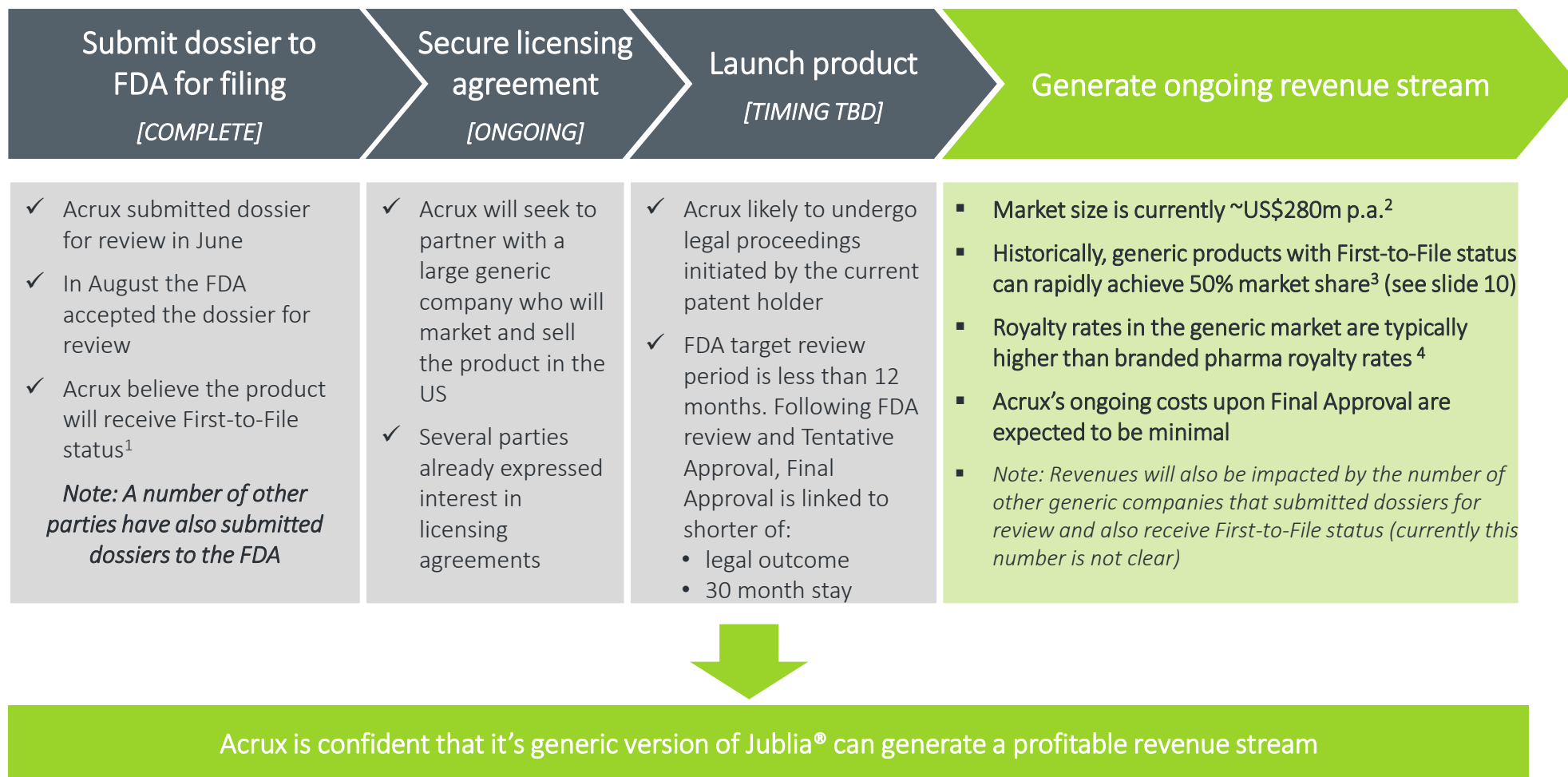
1. CMO: Contract Manufacturing Organisation

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

3. Westerberg DP, Voyack MJ (Dec 1, 2013). "Onychomycosis: current trends in diagnosis and treatment". American Family Physician. 88 (11): 762–70. PMID 24364524.

4. Market exclusivity is shared with any other companies that submitted a generic dossier (ANDA with Paragraph IV certification) on the same day with the FDA, and are also granted First-To-File Status

# ILLUSTRATIVE VIEW OF COMMERCIALISATION PATH FOR ACRUX'S GENERIC VERSION OF JUBLIA®



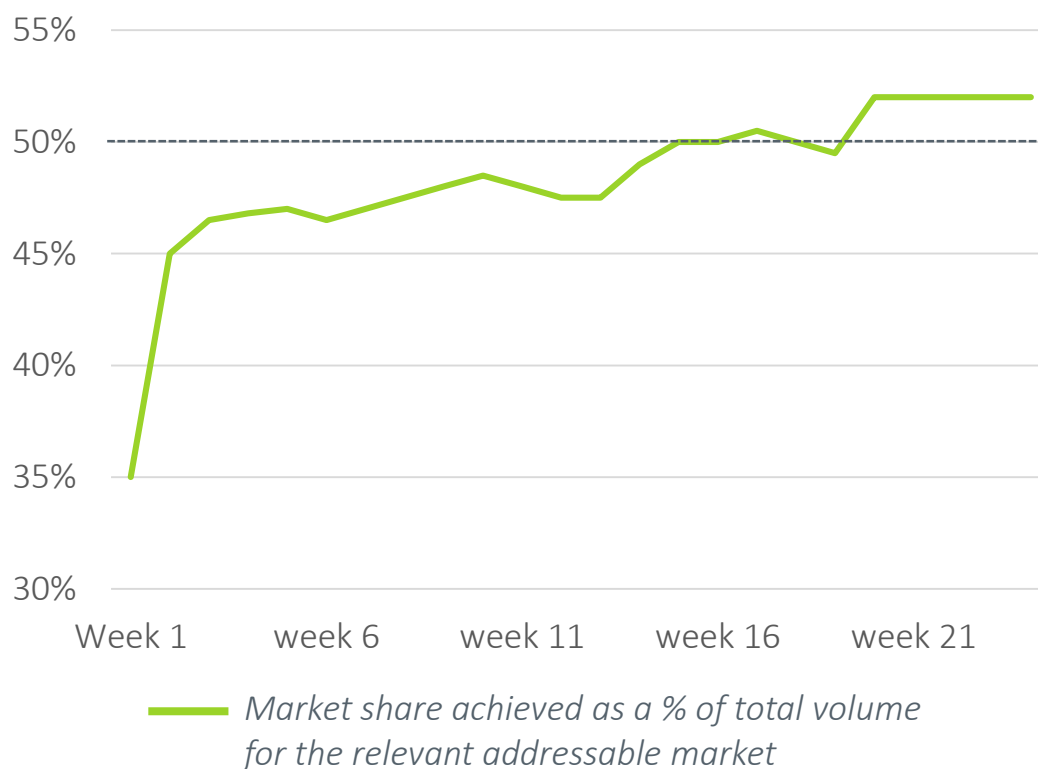
1. First-to-File status grants Acrux with 180 days exclusivity on approval by the FDA. First-to-file status and subsequent exclusivity period can be shared with other Paragraph IV ANDAs filed on same day  
2. Twelve months sales to end March 2018 based on IQVIA (Quintiles and IMS Health) sales data (US\$)  
3. Citi Research – Generics Landscape Chart Pack (Jan 2017);  
4. Management estimates

# RAPID MARKET SHARE GAINS TYPICALLY ACHIEVED BY NEW GENERIC PRODUCTS

Acrux's generic version of Jublia® is expected to be granted First-to-File status and benefit from exclusivity

- ✓ Acrux is confident that if approved, it should be granted First-to-File status which would lead to 180 days of generic market exclusivity<sup>2</sup>
- ✓ Rapid market share gains are usually achieved during this exclusivity period
- ✓ Citi Research suggests that 50% market share is possible within weeks (see graph)

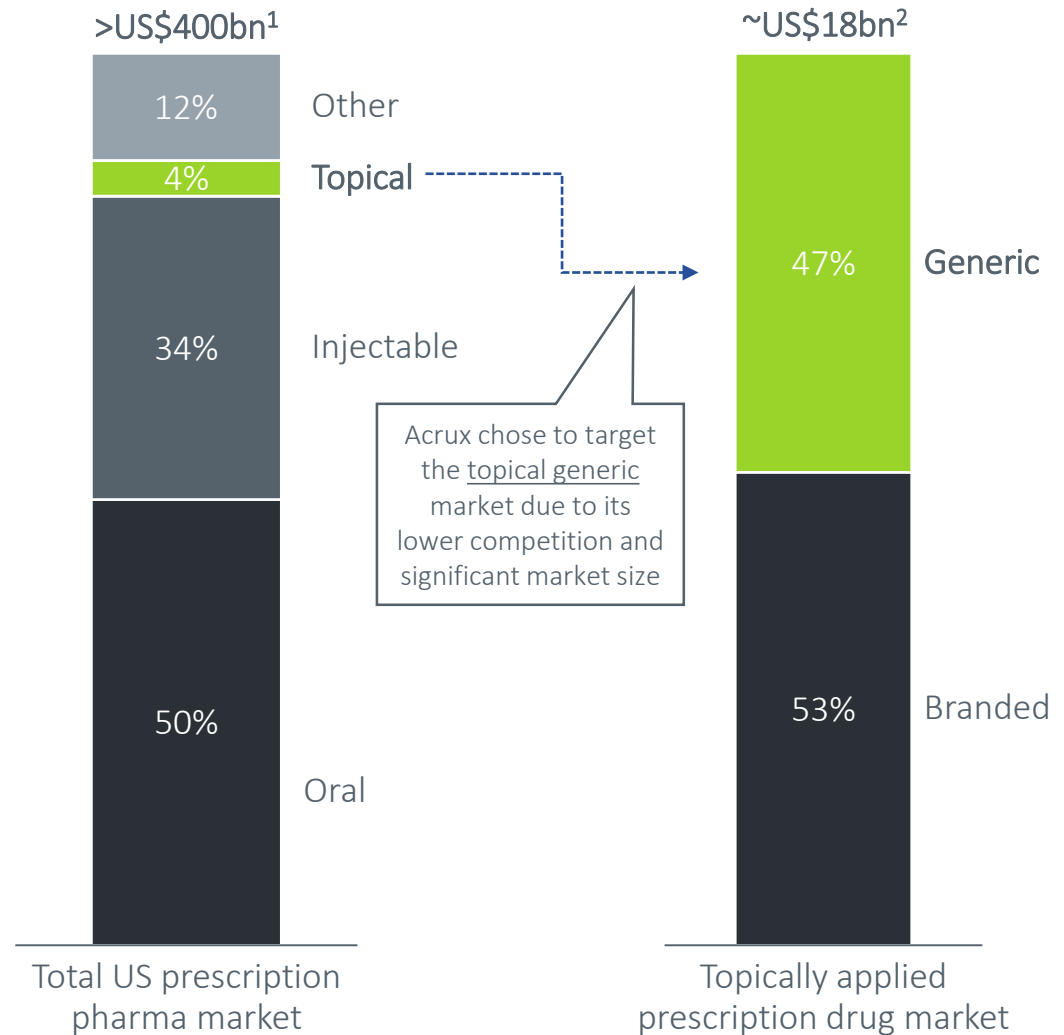
Generics with exclusivity reached a peak market share of >50%<sup>1</sup> on average during the exclusivity period



# 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>**

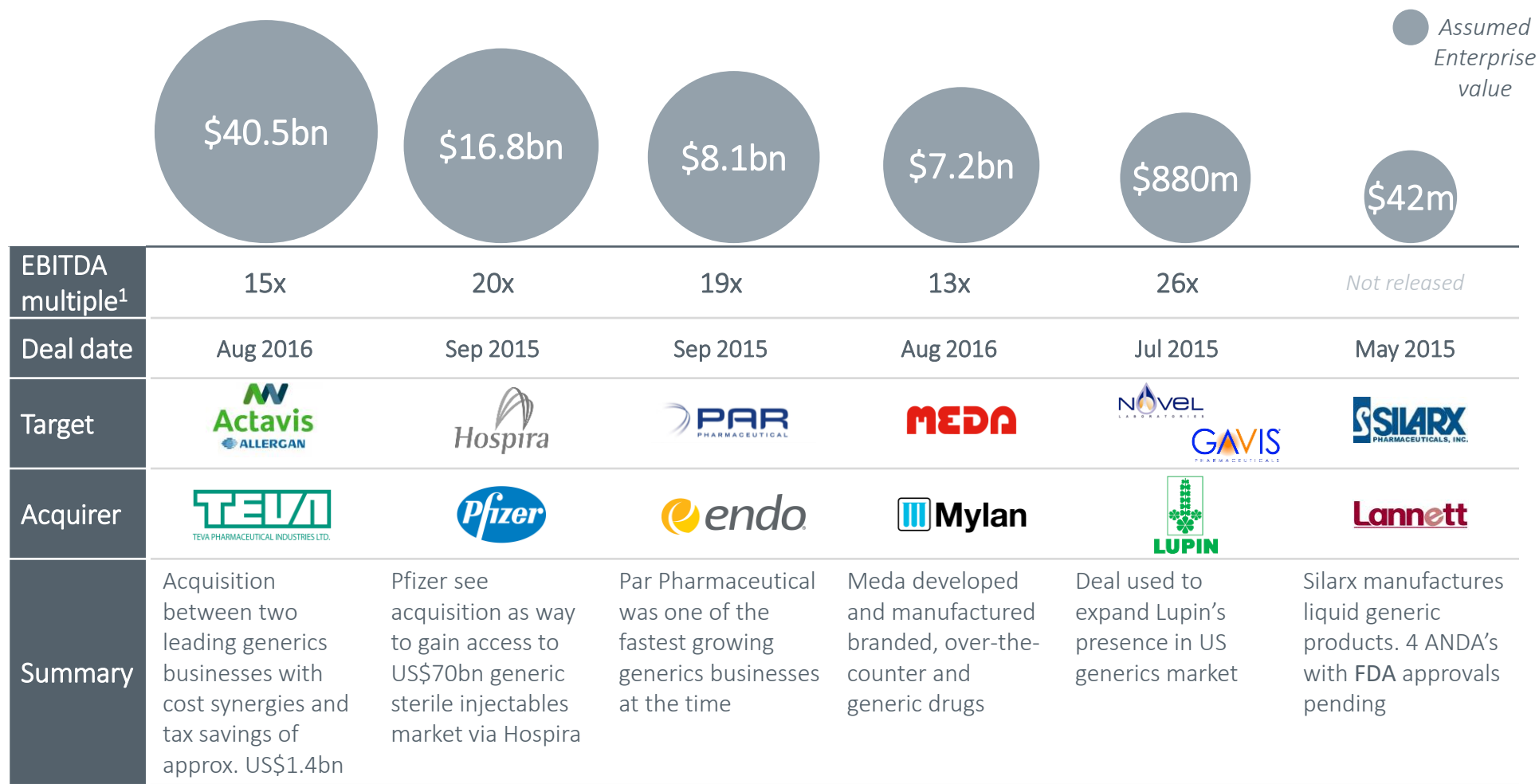


1. US market by dosage form, IQVIA Q2, 2015 MAT. US market sales (US\$)

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

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

# GLOBAL GENERIC COMPANIES PLACE HIGH VALUE ON GENERIC PRODUCTS AND GENERIC PORTFOLIOS



1. Enterprise values and multiples shown assume that the target's enterprise value is equal to the size of the transaction  
Source: Company releases; annual reports; literature review; Cogent Valuation Q3, 2017 Pharmaceuticals Generic Report  
Note: Analysis not exhaustive

# 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 (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 - 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

# CORPORATE OVERVIEW

## Trading Information

Share price (as at 14 September 2018)	A\$0.235
Shares outstanding <sup>1</sup>	166.5m
Market capitalisation	A\$39.1m
Cash (as at 30 June 2018)	A\$28.5m
Implied enterprise value	A\$10.6m

## Major Shareholders

Shareholder	%
Samuel Terry Asset Management	6.14
Mr Paul Cozzi <sup>2</sup>	3.87
Mr Christopher M Abbott <sup>2</sup>	2.94
Ashwood River Pty Ltd <sup>2</sup>	1.56

## Share price performance (last 12 months)



Source: IRESS & Acrux 2018 Appendix 4E & Financial Results

1. Excludes 1m options expiring in July 2019

2. As at 25 July 2018

# MULTIPLE UPCOMING VALUE CATALYSTS

## Upcoming news flow

Acrux will keep the market updated as it continues development of its current pipeline of 13 generic topical drugs.

### Potential news flow includes:

- ✓ Dossier acceptance for review by the FDA
- ✓ Acrux securing a deal with a key partner (licensing, etc.)
- ✓ Litigation initiation by patent holders following Paragraph IV filing<sup>2</sup>
- ✓ Product approvals
- ✓ Product launches

1. CMO: Contract Manufacturing Organisation
2. Acrux pipeline contains products that will not require a Paragraph IV certification

## Acrux objectives

### FY19



#### 2 additional dossiers

*Submit 2 additional  
dossiers to the FDA  
for review*



#### 6 technical transfers

*Scale up 6 projects  
from Acrux  
laboratory to CMOs<sup>1</sup>*



#### Additional new products

*Add further  
products to the ACR  
generic portfolio*

### CY19



#### First generic revenues

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

# THANK YOU

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## Investor relations

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