



**ASX/Media Release**

**29 July 2019**

## **Acrux's approach to competition (Bioshares Biotech Summit 2019)**

**Melbourne, Australia; 29 July 2019:** Acrux Limited (ASX:ACR, "Acrux" or the "Company") presented at the Bioshares Biotech 2019 Summit over the weekend in Queenstown, New Zealand.

The presentation follows this announcement and provides additional detail on Acrux's approach to competition. Topics addressed include:

- Rationale behind Acrux's strategic focus on the identification and development of topical generic drugs
- Considerations to be weighed when selecting and prioritising product opportunities
- Product selection criteria that leverages Acrux's inherent competitive advantages
- Case study of successful topical generic drug commercialisation
- Medium term view as Acrux shifts towards a greater commercial focus

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### **About Acrux**

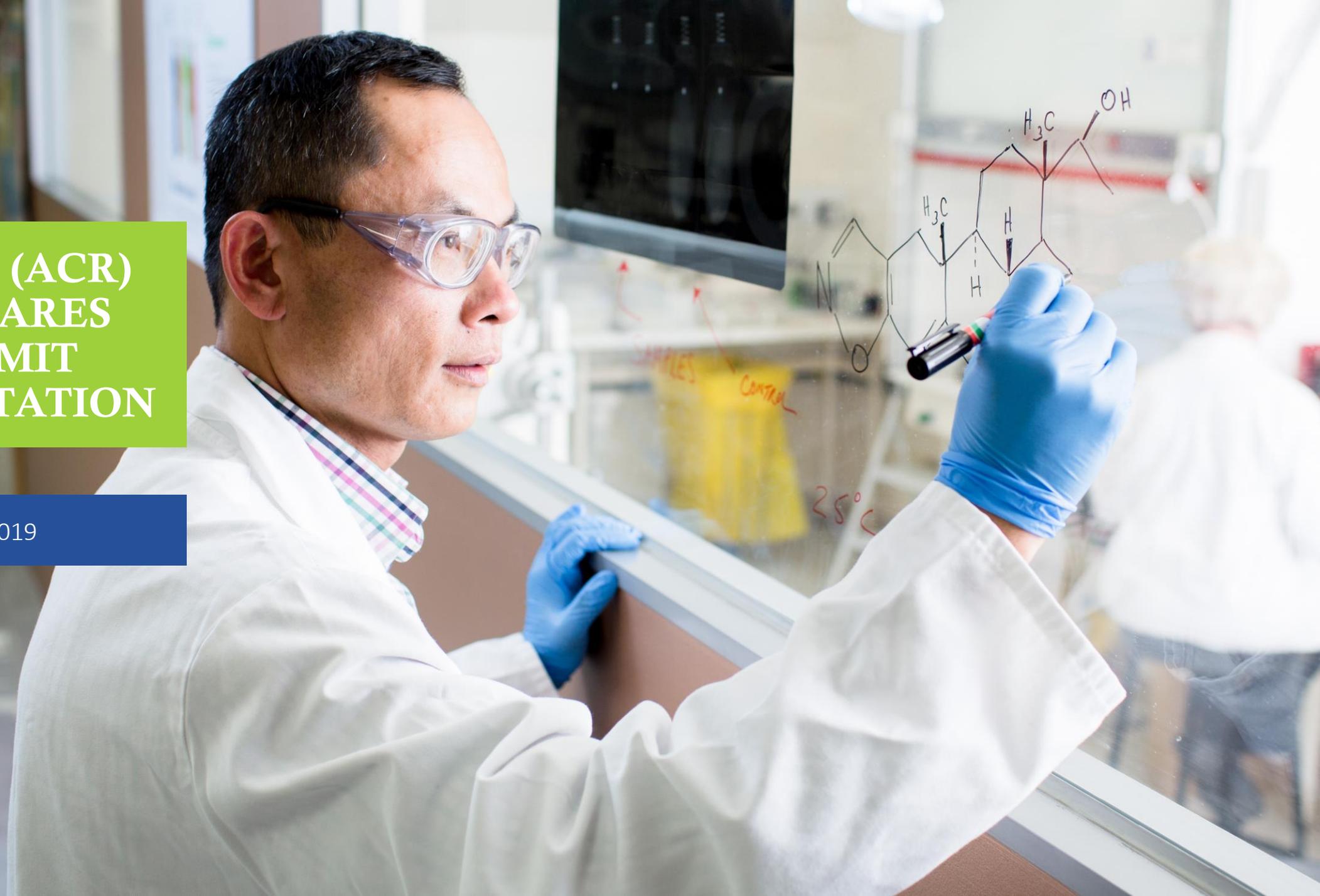
Acrux (ASX: ACR) is a pharmaceutical company dedicated to developing and commercialising topical pharmaceuticals. Incorporated in 1998 and using in house facilities and capabilities, Acrux has successfully developed and commercialised through licensees a number of topically applied pharmaceutical products in the US and Europe. Acrux is developing of 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 (ACR) BIOSHARES SUMMIT PRESENTATION

July 2019



# FORWARD LOOKING STATEMENTS

This presentation contains forward-looking statements which are identified by words such as 'may', 'could', 'believes', 'estimates', 'expects', or 'intends' and other similar words that involve risks and uncertainties.

These statements are based on an assessment of present economic and operating conditions, and on a number of assumptions regarding future events and actions that, as at the date of this presentation, are expected to take place.

Actual results could differ materially depending on factors such as the availability of resources, the results of non-clinical and clinical studies, the timing and effects of regulatory actions, the strength of competition, the outcome of legal proceedings and the effectiveness of patent protection.

Such forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions and other important factors, many of which are beyond the control of our Company, the Directors and our management.

We cannot and do not give any assurance that the results, performance or achievements expressed or implied by the forward-looking statements contained in this presentation will actually occur and investors are cautioned not to place undue reliance on these forward-looking statements.

We have no intention to update or revise forward-looking statements, or to publish prospective financial information in the future, regardless of whether new information, future events or any other factors affect the information contained in this presentation, except where required by law and under our continuous disclosure obligations.

These forward looking statements are subject to various risk factors that could cause our actual results to differ materially from the results expressed or anticipated in these statements.



# COMPETITION IN GENERIC DRUGS – OVERVIEW AND ACRUX APPROACH

## Key items to be discussed

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- Rationale behind Acrux's strategic focus on the identification and development of topical generic drugs
- Considerations to be weighed when selecting and prioritising product opportunities
- **Product selection criteria** that leverages Acrux's inherent competitive advantages
- **Case study** of successful topical generic drug commercialisation
- Medium term view as **Acrux shifts towards a greater commercial focus**

### Presenting today



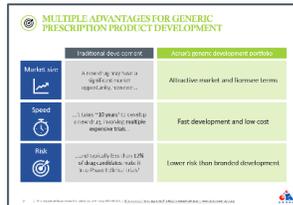
**Michael Kotsanis BSc, MBus**  
*CEO & Managing Director*

- **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 with over EUR250 million in revenue and a **leader in the field of generic medicines**
- Prior to Synthon Michael was President, Europe for Hospira, responsible for delivering over US\$500 million in annual sales. Hospira was the **largest global generic injectable company** prior to its acquisition by Pfizer

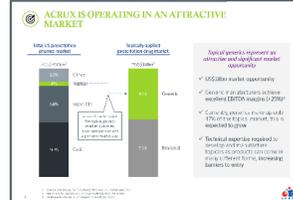
# ACRUX IS FOCUSED ON THE SELECTION AND DEVELOPMENT OF GENERIC DRUGS THAT ARE TOPICALLY ADMINISTERED (TOPICAL GENERICS)



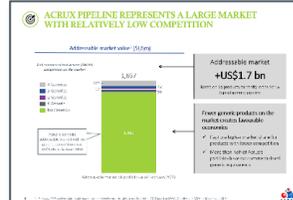
AcruX has deliberately targeted an attractive, accessible and valuable market..



Multiple key advantages for targeting the topical generic market



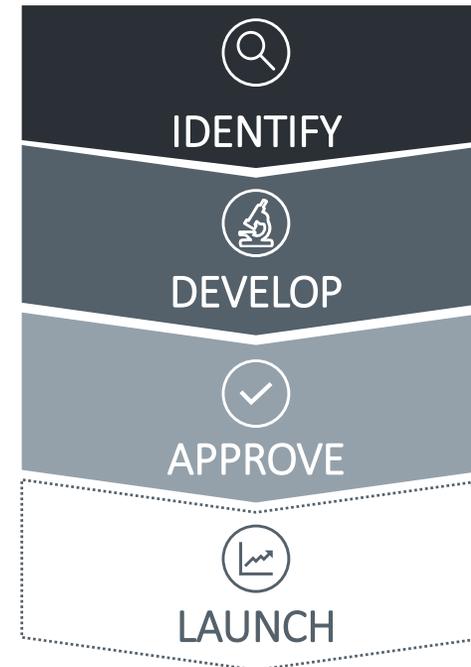
US\$20bn<sup>1</sup>  
Niche targeted within a >US\$450bn market



US\$1.5bn<sup>1</sup>  
The combined addressable market of AcruX's pipeline of 14 drugs



.. and has built a scalable engine focused on drug selection and development



Deliberate focus and area of expertise to create value

Strategic partnerships to capture value

# THE TOPICAL DRUG MARKET HAS LOWER PENETRATION OF GENERICS

	Total market	Oral drugs	Acrux focus Topical drugs
Definition of market	Total US prescription pharma market	Drugs that are ingested orally	Drugs that are applied topically (including directly to the skin, eyes, ears and nose)
Market size <sup>1</sup>	>US\$450bn	~US\$200bn	~US\$20bn <sup>2</sup>
Generic market share	~90% <sup>3</sup>	~91% <sup>3</sup>	47% <sup>4</sup>
Generic competition	Variable	High levels of generic competition from a significant number of drug manufacturers	Limited generic competition given niche market size and development complexity
Typical generic development complexity		Low	Greater complexity than oral generic drug development

Source:

1 – US market by dosage form, IQVIA Q1, 2019 MAT, US market sales (US\$)

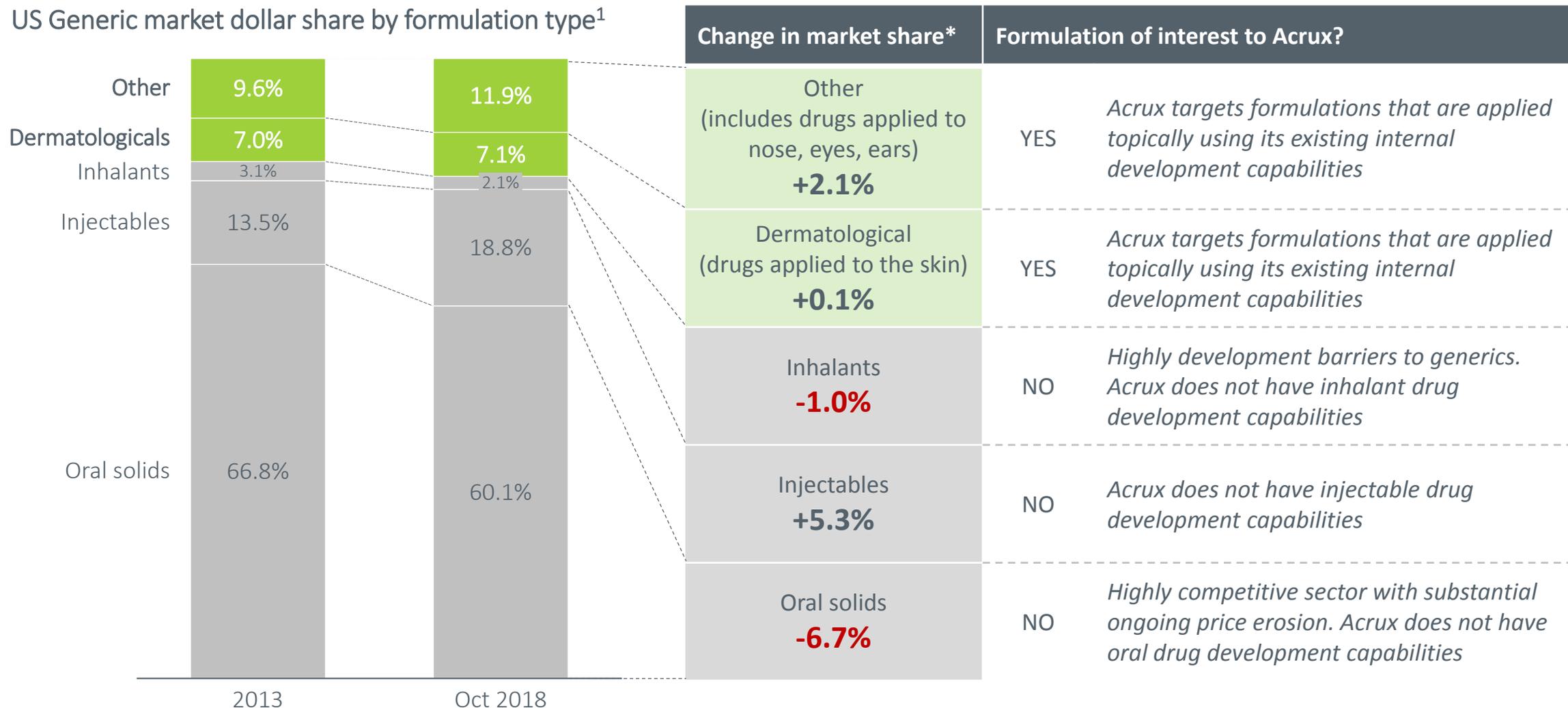
2 – Market size for topically applied drugs IQVIA Q1, 2019 MAT US market sales (US\$)

3 – IQVIA Global / US Generics and Biosimilars: Trends, Issues and Outlook – February 2019

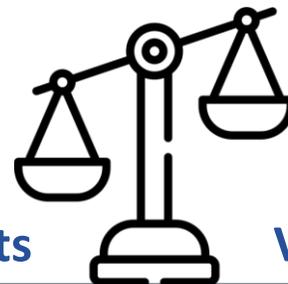
4 – IQVIA, National Sales Perspectives, January 2019 – Unbranded generic share of dermatology, MAT

# ACRUX FOCUSES ON DERMATOLOGICAL AND OTHER TOPICAL FORMULATIONS

US Generic market dollar share by formulation type<sup>1</sup>



# ACRUX PORTFOLIO SELECTION IS BASED ON A ROBUST ASSESSMENT OF KEY FACTORS



**Costs**

**Value**

## Key factors in assessing the development viability of each drug

	<b>Costs</b>	<b>Value</b>
Market size	Smaller markets by sales value may appear to be not as interesting to drug developers...	...however many attractive niche markets exist that currently have no or limited generic competition
Competitive landscape	Smaller market segments that do not have a large generic share of sales may represent an entry and take-up risk...	...yet these markets also display strong upside for generic products to quickly capture market share and the FDA incentivises generic drug developers for low competition products
Time and cost of development	Projects with lower development and time hurdles offer greater near-term earnings potential...	...and a greater chance of increased competition from other generic drug developers and manufacturers
Complexity of development	Increased development complexity will result in higher barriers to entry...	...providing Acrux with an opportunity to leverage its unique capabilities and highly skilled team
Intellectual property	Launching a generic version of a drug with IP protection may require legal proceedings...	...however generic companies able to challenge patents successfully are rewarded with FDA incentives

# ACRUX HAS DEVELOPED HIGHLY SOPHISTICATED DRUG DEVELOPMENT CAPABILITIES

An illustrative pathway for generic drug development



- Ongoing monitoring of topical drug markets, the competitive landscape and FDA guidance documents
- Changes to the FDA Product Specific Guidelines (PSG) presents both opportunities and risks
- Focus on Competitive Generic Therapies (CGT) products which have no generic competition and receive priority review from the FDA

## AcruX's unique expertise and competitive advantages

- AcruX has unique capabilities for in-vitro drug development including IVRT (in-vitro release testing) and IVPT (in-vitro permeation testing)
  - For some products, the FDA has recently included in vitro testing as an alternative development approach to expensive clinical endpoint studies to demonstrate bioequivalence for topical generics
  - AcruX is in a position to utilise its capabilities to develop eligible drugs more efficiently than the competition

# CASE STUDY: SOL-GEL'S SHARE PRICE IS UP >50% SINCE ANNOUNCING APPROVAL OF ITS FIRST GENERIC PRODUCT ON FEBRUARY 6 2019



- A small\* clinical-stage dermatology company focused on **identifying, developing and commercialising branded and generic topical drug products for the treatment of skin disease**
- Sol-Gel announced FDA approval for its first generic product in February 2019, in a partnership with Perrigo in which the two companies will share gross profits generated from sales of the product

Share price (\$US)



	30-Sep-18	31-Dec-18	31-Mar-19	30-Jun-19
Sol-Gel revenue (US\$m)	0.04	0.00	6.36	TBC
# Products in Commercialisation	0	0	1	TBC
# Products in Pipeline	5	5	4	TBC
Market cap (US\$m)	142	114	128	173

# ACRUX: A GREATER COMMERCIAL FOCUS AS PRODUCT DEVELOPMENT PIPELINE MATURES

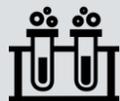
Within three years, Acrux is on track to:



Have 10+ products in the current development pipeline submitted to the FDA



Be receiving a regular royalty or profit share payment on the sale of approved products



Aim to keep a stable number of active projects in development

# THANK YOU

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