



### 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.



### **INVESTMENT HIGHLIGHTS**



# Attractive and accessible market

- The topical generic market provides attractive returns with fast, low-risk development for drug developers
- The size of the topical generic market in the US alone worth ~US\$18bn



# Focus on creating value

- Acrux is deliberately focusing on drug selection and development to create maximum value
- Acrux has a clear pathway to capture this value through strategic partnerships



# Delivering on strategy

- Strong execution building the topical generic pipeline since 2015. 14 products now in portfolio, with an addressable market of US\$1.7bn
- First submission to FDA in June 2018, with acceptance for review in August, in line with guidance
- Second submission to FDA in August 2018, with acceptance for review in October, in line with guidance



# Multiple value catalysts

- First revenues expected in calendar year 2019
- Multiple FDA ANDA submissions in FY19 and beyond
- Licensing interest received from several parties

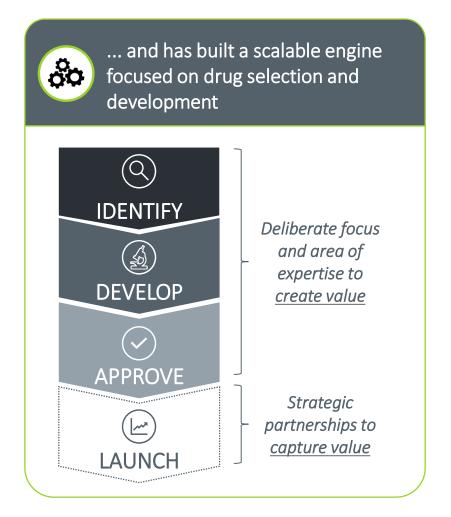


# World class development team

- Experienced management team with a proven history of meeting operational milestones
- Strategic direction led by a board with highly relevant expertise

# ACRUX HAS A CLEAR STRATEGY TO CREATE SHAREHOLDER VALUE









# MULTIPLE KEY ADVANTAGES FOR GENERIC PRESCRIPTION PRODUCT DEVELOPMENT

#### Traditional development

Acrux's generic development portfolio

Market size



A new drug may have a significant market opportunity, however...

Attractive market and licensee terms

Speed



...it takes ~10 years¹ to develop a new drug, involving multiple expensive trials...

Fast development and low cost

Risk



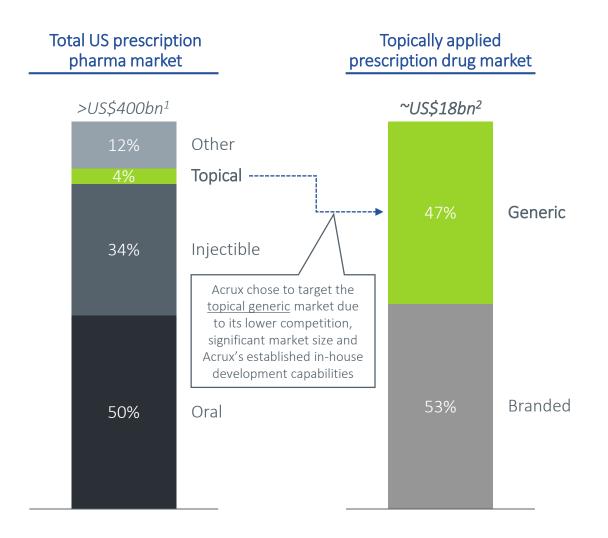
...and typically less than 12% of drug candidates make it into Phase I clinical trials<sup>1</sup>

Lower risk than branded development



# **MARKET**

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



Topical generics represent an attractive and significant market opportunity

- ✓ US\$18bn market opportunity
- ✓ Generic manufacturers achieve excellent EBITDA margins (+25%)<sup>3</sup>
- ✓ Generics make up only 47% of the topical market, this is expected to grow<sup>2</sup>
- ✓ Technical expertise required to develop and manufacture topicals as products can come in many different forms, increasing barriers to entry



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

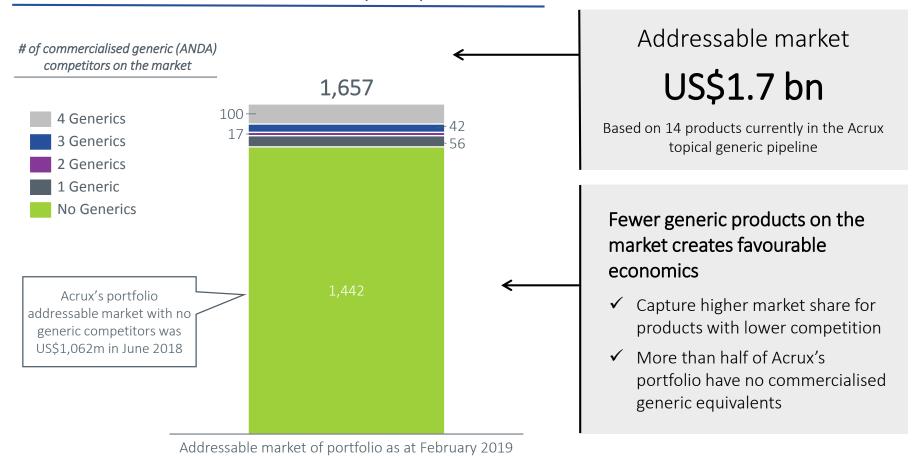
<sup>2.</sup> Market size for topically applied drugs IQVIA Q3, 2017 MAT (US\$)

<sup>3.</sup> Citi Research – Generics Landscape Chart Pack (September 2018)



# ACRUX PIPELINE REPRESENTS A LARGE MARKET WITH RELATIVELY LOW COMPETITION

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







# ACRUX HAS A FOCUSED STRATEGY ON DRUG SELECTION AND DEVELOPMENT

#### An illustrative pathway for generic drug development and commercialisation

#### **Status** Description Identified topical 165 Market screening to identify high potential molecules, each with prescription topical products >US\$10m in sales **IDENTIFY** R&D team with highly specific topical expertise drive development. Typical drug Products in development development time is 3-4 years including engaging CMOs<sup>1</sup> to scale up manufacturing **DEVELOP** The FDA has made a commitment to review Products under FDA review 90% of first round applications within 10 months<sup>2</sup> **APPROVE** Acrux expects a typical license agreement to consist of an Commercial discussions underway annuity revenue stream, with the potential for milestone payments to be included as well **LAUNCH**



<sup>1.</sup> CMO: Contract Manufacturing Organisations;

<sup>2.</sup> Under GDUFA II, the FDA has committed to review 90% of ANDA applications within 10 months. ANDA approval will follow if the FDA is satisfied during the review process.

# 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 inhouse 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 scientists with experience in developing pharma products

*350+* years of combined experience in drug development

common goal: develop highvalue topical generics



## STRATEGIC DIRECTION LED BY A BOARD WITH HIGHLY RELEVANT EXPERTISE



Michael Kotsanis CEO & Managing Director









GBS VENTURE PARTNERS

- 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, EMEA 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





Hośpira

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



## **ACRUX CONTINUES TO MAKE PROGRESS ACROSS ITS KEY COMMERCIAL OBJECTIVES**

#### **FY19**

#### **CY19**

Acrux objectives



Submit 2 dossiers to FDA (in addition to FY18 *submission*)



Scale up 6 projects from Acrux laboratory to CMOs



Add further products to generic portfolio



First revenues from generic portfolio in **CY19** 

Status

- 1 dossier submitted in FY18
- 1 dossier submitted in FY19
- On track to submit an additional dossier in FY19

#### On track

Technical transfer process initiated during FY19 to date for 3 projects

#### On track

14 products in development pipeline including 2 products accepted for FDA review

On track



## HALF YEAR PROFIT AND LOSS

	Half Yea		
		31 December	
	2018	2017	
	\$'000	\$'000	%
Royalty revenue	275	2,420	(88.6%)
Interest & other income	320	323	(0.9%)
R&D tax incentive rebate	2,057	-	-
Total	2,652	2,743	(3.3%)
R&D investment	(4,926)	(5,303)	7.1%
Other operating costs	(1,030)	(1,682)	38.7%
Non operating costs	(210)	(448)	53.1%
Total expenses	(6,166)	(7,433)	17.0%
Operating loss before impairment loss and income tax	(3,514)	(4,690)	25.1%
Impairment loss	-	(5,647)	-
Operating loss before income tax	(3,514)	(10,337)	66.0%
Income tax (expense) / benefit	(22)	1,643	(101.3%)
Net loss for the half-year	(3,536)	(8,694)	59.3%
Loss per share			
Basic loss per share	(2.12) cents	(5.22) cents	
Cash reserves	22,224	32,363	(31.3%)



## HALF YEAR CASHFLOW

	Half Yea		
	31 December	31 December	
	2018	2017	
	\$'000	\$'000	%
Cash flow from operating activities			
Receipts from product agreements	254	6,570	(96.1%)
Payments to suppliers and employees	(6,571)	(7,183)	8.5%
Interest received	328	253	29.6%
Income tax refunded / (paid)	51	(1,069)	104.8%
Net cash used in operating activities	(5,938)	(1,429)	(315.5%)
Cash flow from investing activities	(2.22)	(4.50)	(00 70/)
Payment for property, plant and equipment	(308)	(159)	(93.7%)
Net cash used in investing activities	(308)	(159)	(93.7%)
Net decrease in cash and cash equivalents	(6,246)	(1,588)	(293.3%)
Cash at beginning of half year	28,470	33,974	(16.2%)
Foreign exchange differences on cash holdings	-	(23)	-
Cash and at end of the half year	22,224	32,363	(31.3%)



### **CORPORATE OVERVIEW**

### Trading Information

Share price (as at 21 February 2019)	A\$0.180
Shares outstanding <sup>1</sup>	166.6m
Market capitalisation	A\$30.0m
Cash (as at 31 Dec 2018)	A\$22.2m
Implied enterprise value	A\$7.8m

### Major Shareholders

%
6.14
2.58
1.74
1.56

### Share price performance (last 12 months)





<sup>1.</sup> Excludes 1m options expiring in July 2019 and 6.3m performance rights vesting subject to various vesting conditions



### THANK YOU

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