



ACRUX INVESTOR PRESENTATION AND FULL YEAR RESULTS (ASX: ACR)

August 2019



INVESTMENT HIGHLIGHTS



Attractive and accessible market

- The topical generic market provides attractive returns with fast, low-risk development costs for highly specialised drug developers
- The size of the topical generic market in the US alone worth **~US\$20bn**



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 monetising strategic partnerships



Delivering on strategy

- **Strong execution building the topical generic pipeline since mid 2015, submitting first product in 2018**
- **14 products** now in portfolio, with an addressable market of **~US\$1.5bn**
- 3 generic products now submitted and accepted for review by the FDA, **in line with guidance**



Multiple value catalysts

- **First revenues expected in calendar year 2019**
- **4 additional drugs to be accepted for review by the FDA in CY20**
- 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 ACHIEVED KEY MILESTONES IN FY19, PERFORMING STRONGLY AGAINST SET OBJECTIVES

Acrux objectives

FY19		
 <p>Submit 2 dossiers to FDA <i>(in addition to FY18 submission)</i></p>	 <p>Scale up 6 projects from Acrux laboratory to CMOs</p>	 <p>Add further products to generic portfolio</p>





Status

- *1 dossier submitted in FY18*
- *2 dossiers submitted in FY19*

*5 projects scaled to CMO**




Product portfolio increased from 13 to 14

ACRUX HAS CLEAR OBJECTIVES IN THE NEAR TERM AS THE COMPANY SEEKS TO CONTINUE ITS PROGRESS

	CY19	CY20		
Acrux objectives	 First revenues from generic portfolio in CY19	 Add further products to generic portfolio	 Execute licensing deals for products in pipeline	 Have 4 additional dossiers accepted for review by the FDA
Status	<i>On track</i>	<i>On track</i>	<i>On track</i>	<i>On track</i>



MULTIPLE 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 ¹	Lower risk than branded development



TOPICAL GENERICS: AN ATTRACTIVE US\$20bn MARKET

	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 ¹	>US\$460bn	~US\$200bn	~US\$20bn ²
Generic market share	~90% ³	~91% ³	47% ⁴
Typical generic development complexity		Low	Greater complexity than oral generic drug development
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

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\$)
3. IQVIA Global Generic and Biosimilars Trends and Insights – 2018
4. IQVIA, National Sales Perspectives, January 2019 – Unbranded generic share of dermatology, MAT



ACRUX HAS A FOCUSED STRATEGY ON DRUG SELECTION AND DEVELOPMENT

An illustrative pathway for generic drug development and commercialisation

	Status	Description
 LAUNCH	CY19 <i>Commercial discussions underway</i>	<i>Acrux expects a typical license agreement to consist of an annuity-style revenue stream, with the potential for milestone payments to be included as well</i>
 APPROVE	3 <i>Products accepted for FDA review</i>	<i>The FDA has made a commitment to review 90% of ANDAs within 10 months². Following initial review there may be additional FDA questions to be answered prior to approval</i>
 DEVELOP	14 <i>Products in development</i>	R&D team with highly specific topical expertise drive development. Typical drug development time is 3-4 years including engaging a CMO ¹ to scale up manufacturing
 IDENTIFY	176 <i>Identified topical drugs, each with >US\$10m in sales</i>	Market screening to identify high potential prescription topical products

1. CMO: Contract Manufacturing Organisations;

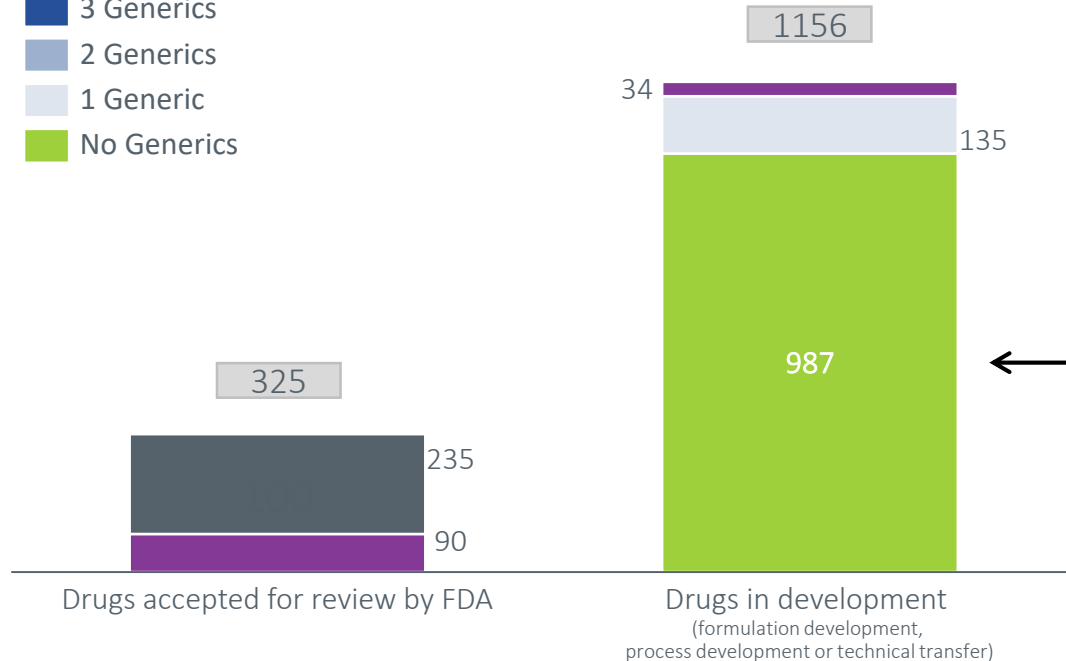
2. Under GDUFA II, the FDA has committed to review 90% of Abbreviated New Drug Applications (ANDA) applications within 10 months. ANDA approval will follow if the FDA is satisfied during the review process



ACRUX IS DEVELOPING ITS PRODUCT PIPELINE TOWARDS COMMERCIALISATION

Addressable market value of portfolio¹ (\$USm)

of commercialised generic (ANDA) competitors approved and on the market²



Addressable market

US\$1.5 bn

Based on 14 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 of Acrux's portfolio have no commercialised generic equivalents

1. August 2019 pipeline addressable market based on twelve months sales to end March 2019 based on IQVIA (Quintiles and IMS Health) sales data

2. As at August 2019. Note that there are currently 10+ dossiers submitted to the FDA and neither approved nor commercialised for a generic version of Jublia® and 4 commercialised generics of EMLA® cream



SUMMARY OF PRODUCT PIPELINE

3 dossiers accepted for review

	Generic of Jublia® topical solution	Testosterone topical solution	Generic of EMLA® cream
Date accepted for review:	August 2018	October 2018	August 2019
Market size per annum ¹ :	US\$235m	US\$55m	US\$35m
Number of approved generic competitors ² :	0	4	4
Next steps:	Pending FDA review	Pending FDA review	Pending FDA review

11 drugs in development

Market opportunity: US\$1156m¹
(for products in development phase pre regulatory submission)

4 additional dossiers to be accepted for review by the FDA by 31 December 2020

Number of products in Acrux's development pipeline are targeting markets that currently have no generic competition

1. US market IQVIA Q1, 2019 MAT. US market sales (US\$)

2. As at August 2019. Note that there are currently 10+ dossiers submitted to the FDA which are neither approved nor commercialised for a generic version of Jublia®.

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)



Deborah Ambrosini, CA
CFO & Company Secretary



Over 20 years' experience in accounting and business development spanning the biotechnology, mining, IT communications and financial services sectors. Experience in senior management roles in Pooled Development Funds that are ASX listed

World class topical R&D team

*"We have made **significant progress** over the last 12 months in developing our topical pipeline, and are well positioned to utilise our unique in-house skill set to **deliver products through 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

FULL YEAR PROFIT AND LOSS

	Full Year Ending		%
	30 June 2019	30 June 2018	
	\$'000	\$'000	
Royalty revenue	631	2,687	(76.5)%
Interest & other income	579	671	(13.8)%
Grant revenue	4,072	0	-
Other income	4	74	(94.6)%
Total	5,286	3,432	54.0%
R&D investment	(10,917)	(10,624)	2.8%
Other operating costs	(2,189)	(2,705)	(19.1)%
Non operating costs	(515)	(581)	(11.4)%
Total expenses	(13,621)	(13,910)	(2.1)%
Operating loss before impairment loss and income tax	(8,335)	(10,478)	(20.5)%
Impairment loss	-	(5,647)	
Operating loss before income tax	(8,335)	(16,125)	(48.3)%
Income tax (expense) / benefit	10	1,943	(99.5)%
Net loss for the year	(8,325)	(14,182)	(41.3)%
Loss per share			
Basic loss per share	(5.00) cents	(8.52) cents	
Cash reserves	18,152	28,470	(36.2)%

FULL YEAR CASHFLOW

	Full Year Ending		%
	30 June 2019	30 June 2018	
	\$'000	\$'000	
Cash flow from operating activities			
Receipts from product agreements	576	7,872	(92.7)%
Payments to suppliers and employees	(13,233)	(12,731)	3.9%
Interest received	611	610	0.2%
Income tax refunded / (paid)	51	(1,033)	(104.9)%
Grant income	2,057	-	
Net cash used in operating activities	(9,938)	(5,282)	88.1%
Cash flow from investing activities			
Payment for property, plant and equipment	(380)	(296)	28.4%
Net cash used in investing activities	(380)	(296)	28.4%
Net decrease in cash and cash equivalents	(10,318)	(5,578)	85.0%
Cash at beginning of year	28,470	33,974	(16.2)%
Foreign exchange differences on cash holdings	-	74	-
Cash and cash equivalents at end of the year	18,152	28,470	(36.2)%

CORPORATE OVERVIEW

Trading Information

Share price (as at 23 August 2019)	A\$0.175
Shares outstanding ¹	166.7m
Market capitalisation	A\$29.1m
Cash (as at 30 June 2019)	A\$18.2m
Implied enterprise value	A\$10.9m

Major Shareholders

Shareholder	%
Samuel Terry Asset Management	6.14
DDH Graham Ltd	5.86
Mr Paul Cozzi	2.10
MNM Capital Pty Ltd	1.66

Share price performance (last 12 months)





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.

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THANK YOU

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