



ACRUX INVESTOR PRESENTATION (ASX: ACR)

February 2021



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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.

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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.



Topical Generics – an attractive market segment

	Total market	Oral drugs 	Acrux focus: Prescription topical drugs 
Definition of market (all drugs including NCEs and generics)	Total US prescription pharma market	Drugs that are ingested orally (eg tablets, capsules)	Drugs that are applied topically to the skin, eyes, ears and nose (eg creams, ointments, gels, solutions)
Market size ¹	>US\$510bn	~US\$200bn	~US\$16bn ²
Generic market share	~90% ³	~91% ³	47% ⁴
Typical generic development complexity	Variable	Low	Greater complexity than oral generic drug development
Generic competition	<i>Variable</i>	<i>High competition from many generic drug manufacturers</i>	<i>Limited generic competition given niche market and development complexity</i>

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Source:

1. US market by dosage form, IQVIA Q3, 2020 MAT, US market sales (US\$); 2. Market size for topically applied drugs IQVIA Q1, 2020 MAT, US market sales (US\$)
3. IQVIA Global Generic and Biosimilars Trends and Insights – 2018; 4. IQVIA, National Sales Perspectives, January 2019 – Unbranded generic share of dermatology, MAT



Key Investment highlights

Acrux is a revenue generating pharmaceutical company with an extensive product pipeline of topical generic pharmaceuticals nearing additional regulatory and commercialisation milestones

 <p>Focus on specialised and lucrative topical generic market</p>	<ul style="list-style-type: none">▪ 2 products on market in over 30 countries. Testosterone solution ANDA approved and pending launch▪ The topical generic market provides attractive returns with low-risk and low development costs for highly specialised drug developers▪ The size of the topical generic market in the US is ~US\$16bn*▪ 13 topical generic products with an addressable market of ~US\$1.1bn*▪ Licensing deals executed with recurring revenue and milestone payments for selected products
 <p>Highly skilled development team</p>	<ul style="list-style-type: none">▪ Proven commercialisation strategy to bring a portfolio of products to market▪ Led by an experienced management team, Acrux possesses unique development and commercialisation know-how and capabilities▪ TGA approved, Good Manufacturing Practice (GMP) facility with 25 specialised scientists creates a substantial competitive advantage in generic product selection, development and commercialisation
 <p>R&D investment in product pipeline entering commercialisation</p>	<ul style="list-style-type: none">▪ Two products currently sold through licensees in Europe, the United States and other countries▪ Additional products nearing FDA approval in addition to Testosterone Solution approved in January 2021▪ 4 product licensing deals executed with 4 different pharma companies for 9 products in CY 2020▪ Objective to be cash flow positive by end of 2022

* US market by dosage form, IQVIA Q3, 2020 MAT, US market sales (US\$)



Platform for growth established

Through investment in the platform over the past 5 years Acrux has a competitive advantage in the identification, development, registration and launch of generic topical drugs

	Acrux Product Status	Description
R_x ON MARKET	2 2 products sold in over 30 countries	Acrux receives royalties on a quarterly basis. Revenue from estradiol licensees grew by 48% in FY20 v FY19
 LAUNCH	9 4 product licensing deals executed in CY2020 for 9 products	Acrux expects a typical licence agreement to consist of a recurring profit share stream and on selected products, milestones pre and post commercialisation
 APPROVE	3 Products accepted for FDA review in CY18, 19	Testosterone solution approved. Following initial review there may be additional FDA questions to be answered prior to approval ¹ . Products can be launched following Final Approval.
 DEVELOP	10 Generic products in development	R&D team with highly specific topical expertise drive development. Acrux has unique capabilities for topical drug development.
 IDENTIFY	53 Identified topical drugs, Each >US\$100m in sales 94 Identified topical drugs, Each \$10-100m in sales	Continue to screen market to identify high potential prescription topical products

1. 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





Business overview


1. Acrux is a specialty topical and transdermal drug development and commercialisation company
2. Acrux is revenue generating with an extensive product pipeline of topical generic pharmaceuticals creating additional regulatory and commercialisation milestone payments.

	Acrux products	Recent Acrux outcomes
Products commercialised by Acrux	<ul style="list-style-type: none">▪ Estradiol spray Sold as Lenzetto® in 37 countries with royalties and milestones received by Acrux from FY17 onwards. Sold as Evamist® in the United States.▪ Testosterone solution Sold in 6 countries with royalties and milestones received by Acrux from FY10 – FY18. Peak annual sales were US\$179 million in 2013.	<ul style="list-style-type: none">▪ Acrux revenue from its Estradiol licensees grew 48% in FY20 over prior financial year▪ Royalties payable to Acrux are expected to further grow and exceed \$1 million in FY21▪ Testosterone Solution ANDA recently approved by the FDA and pending launch
Acrux Pipeline	<ul style="list-style-type: none">▪ Acrux has a development pipeline of 13 topical generic pharmaceuticals with 3 of these products submitted already to the FDA	<ul style="list-style-type: none">▪ 4 licensing deals executed in FY20▪ Profit share payable to Acrux following product launches with milestones on selected products pre and post commercialisation






Future catalysts


 **ACRUX STRATEGY**

The success of Acrux's strategy and management's execution will be driven and measured by:

- Commercial launch and cash flow generation from new topical generic drugs
- Licensing and profit share agreements with generic pharmaceutical companies
- FDA approvals for new products
- Ongoing screening and initiation of new products in development

 **CY 2021 OBJECTIVES**

- Continued royalty growth of existing on market products
- 4 additional products submitted for FDA review
- 2 product launches with profit share and other payments to Acrux

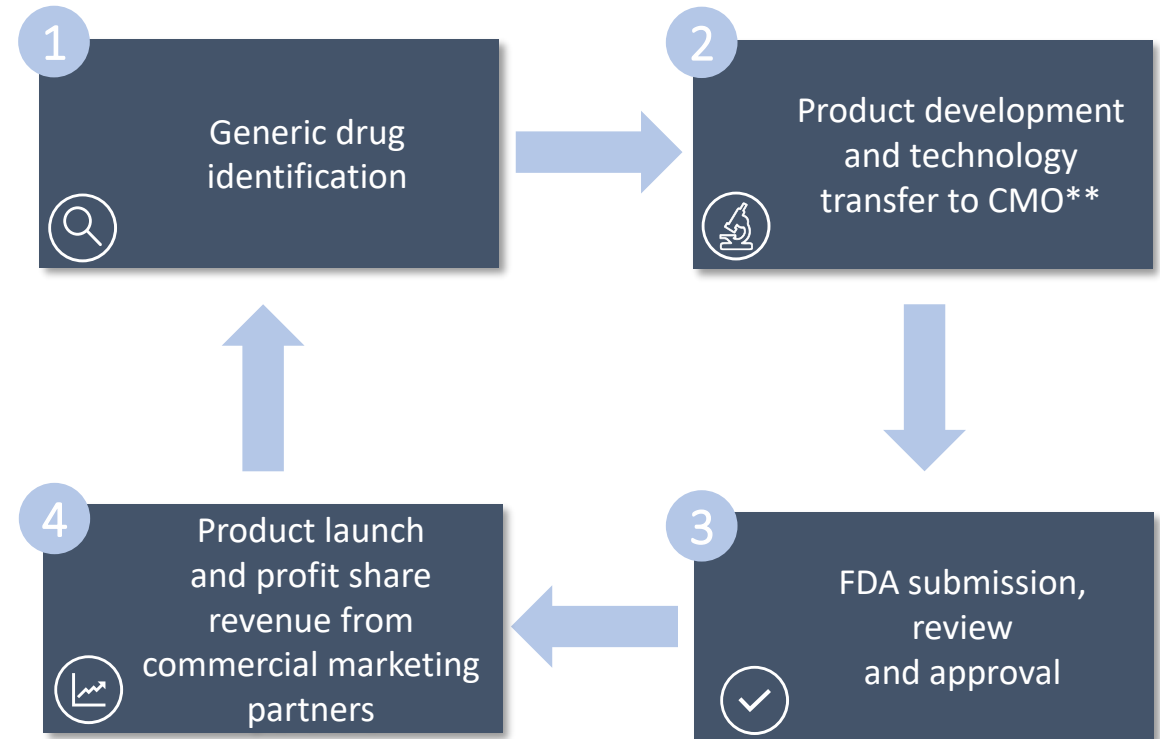
 **CY 2022 OBJECTIVES**

- Continued royalty growth of existing on market products
- Objective to be cash flow positive by end of 2022
- Ongoing screening and initiation of new products in development
- 2 additional products submitted for FDA review



Revenue generating business model supporting long-term growth

- On market products are generating growing royalty revenues for Acrux
- Through the Acrux GMP* facility with 25 specialised scientists, Acrux possesses the capabilities to develop and commercialise generic topical and transdermal pharmaceutical products
- Acrux has 6 licensees with products commercialised in 38 countries
- The core business model of generic drug development is supported by ongoing licensing opportunities for commercial marketing and distribution



* Good Manufacturing Practice

** Contract Manufacturing Organisation

1H FY21 Profit and Loss

Profit and loss for the year ended 31 December 2020			
	31 December	31 December	
	2020	2019	Mvt
	\$'000	\$'000	
Revenue and Other Income			
Revenue from licensing agreements	788	436	80.7%
COVID relief payments	364	0	
Other income	12	140	-91.4%
	1,164	576	102.1%
Less: Expenses			
R&D investment	(7,418)	(5,144)	44.2%
Other operating costs	(1,117)	(1,045)	6.9%
Non Operating Costs	(191)	(279)	-31.5%
	(8,726)	(6,468)	34.9%
Loss before income tax	(7,562)	(5,892)	28.3%
Income tax benefit/(expense)	(224)	(543)	-58.7%
Net loss for the year	(7,786)	(6,435)	21.0%
Basic loss per share	(4.46)	(3.86)	
Cash reserves	11,461	14,336	

¹ A Share Purchase Plan was offered to shareholders in January 2021 at the same price as the Placement and a further \$9.9 million dollars was raised. A total of \$17.7 million dollars was raised from the SPP and the two tranche placement between December 2020 and February 2021.

1H FY21 Cashflow

Cashflow for the year ended 31 December 2020			
	31 December 2020 \$'000	31 December 2019 \$'000	Mvt
Operating Activities			
Receipts from product agreements	700	416	68.3%
Payments to suppliers and employees	(7,630)	(6,075)	25.6%
Interest received	27	163	-83.4%
COVID Relied payments	364	0	
Finance costs	(94)	(97)	-3.1%
Grant income	2,328	2,015	15.5%
Net cash used in operating activities	(4,305)	(3,578)	20.3%
Net cash used - property, plant and equipment	(52)	(177)	-70.6%
Financing Activities			
Lease liability principal repayments	(82)	(61)	34.4%
Proceeds from share issue	6,694	0	
Net cash used in financing activities	6,612	(61)	
Net decrease in cash and cash equivalents	2,255	(3,816)	-159.1%
Cash at beginning of year	9,206	18,152	-49.3%
Cash at end of year	11,461	14,336	-20.1%

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BENEFITS OF A POOLED DEVELOPMENT FUND

1

Companies with PDF status are taxed at 15% on their income and capital gains received from their investments

2

Australian resident shareholders are exempt from capital gains tax after selling their shares

3

Unfranked dividends received by an Australian resident shareholder from the Company will be exempt from tax in the hands of the shareholder

4

Franked dividends will also be exempt from tax unless the shareholder elects to treat the franked dividend as taxable

Shareholders should seek professional advice from their tax advisor regarding Pooled Development Funds and the benefits specifically available to their situation

Thank you

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