ACRUX ANNUAL GENERAL MEETING
(ASX: ACR)

28 November 2019

ACRUX

ROSS DOBINSON

CHAIRMAN

MICHAEL KOTSANIS

CEO

IMPORTANT NOTICE AND DISCLAIMERS

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.

ACRUX

ACRUX IS AN EXPERIENCED AND PROVEN DEVELOPER OF HIGH VALUE TOPICAL DRUGS

Acrux is a revenue generating pharmaceutical company with an advancing product pipeline of topical generic products nearing additional commercialisation and revenue milestones

	Acrux products	Acrux outcomes and expectation
Acrux Pipeline	▪ Acrux has invested A$34m in R&D from FY16-19 and now has a drug development pipeline of 14 generic products	▪ 1-3 product licensing deals in CY20 ▪ 3-5 product licensing deals in CY21
Products commercialised by Acrux	▪ *Estradiol spray* *Commercialised as Lenzetto® in 33 countries with royalties and milestones received from FY17 onwards. Commercialised as Evamist® in the United States.* ▪ *Testosterone solution* *Commercialised in 6 countries with royalties and milestones received from FY10 – FY18*	▪ *Royalties received on Lenzetto sales grew 77% over prior year* ▪ *Royalties payable to Acrux are expected to further grow and exceed $800k in FY20*

INVESTMENT HIGHLIGHTS

Acrux is a revenue generating pharmaceutical company with an advancing product pipeline of topical generic products nearing additional commercialisation and revenue milestones

Focus on specialised and lucrative topical generic 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 is **~US$20bn**
- **14 products** now in the pipeline of generic products, with an addressable market of **~US$1.5bn**
- Multiple licensing deals with recurring revenue and potential milestones under negotiation

Highly skilled development team

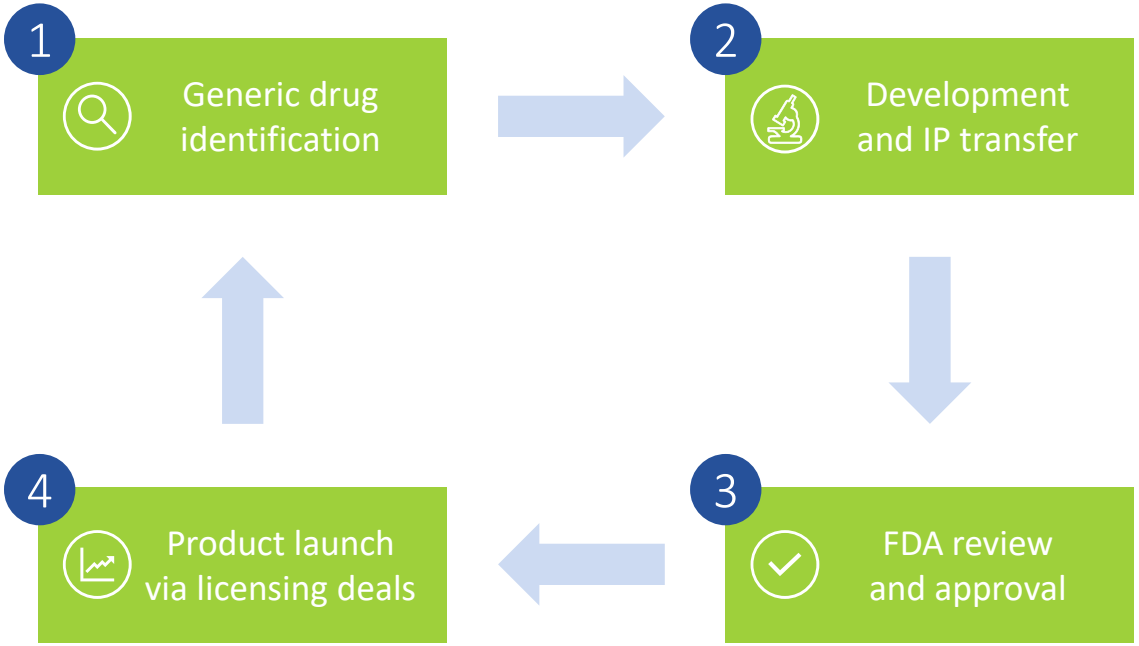
- Defined commercialisation strategy to repeatably **bring products to market**
- Led by managing director Michael Kotsanis the Acrux team possesses **unique development and commercialisation know-how and capabilities**
- State of the art GMP facility and 25 specialised scientists create a substantial competitive advantage in generic product selection, development and commercialisation

R&D investment in product pipeline nears commercialisation

- **$34m invested in R&D since August 2015** with R&D costs largely invested for near term products
- **3 products** nearing FDA approval
- **1 – 3 product licensing deals to be executed in CY 2020**
- **3 – 5 additional product licensing deals to be executed in CY 2021**
- **Objective to be cash flow positive by end of 2021**

REVENUE GENERATING BUSINESS MODEL SUPPORTING LONG-TERM GROWTH

- With a State of the art GMP facility and 25 specialised scientists, Acrux possesses the capabilities for the development, regulatory submission and approval of generic topical and transdermal drugs
- Expertise extends to negotiating and dealing with commercial partners for the licensing and commercial launch of products on a global scale
- The core business model of drug development is supported by ongoing licensing opportunities for manufacturing and distribution



Acrux has invested A$34m in R&D from FY16-19 and now has a drug development pipeline of 14 generic products

TOPICAL GENERICS: AN ATTRACTIVE US$20B 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	Variable	Low	Greater complexity than oral generic drug development
Generic competition	*Variable*	*Competition from many drug manufacturers*	***Limited generic competition given niche market 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

GENERIC DRUG DEVELOPMENT IS FASTER AND LESS RISKY THAN NOVEL DRUG DEVELOPMENT

Acrux's drug development strategy provides more certainty than novel drug development

	Acrux's portfolio strategy for topical generics	Novel drug development
Commercial Strategy	**Portfolio Strategy** Sophisticated screening of generic drug candidates underpins Acrux's de-risked portfolio strategy	Single Drug Strategy Novel drug development will remain speculative given high costs and risks of development
Development Process	▪ Acrux rigorously screens market data for drug candidates in attractive markets where Acrux can leverage its drug development and commercialisation track record	▪ Less than **12% of novel drug candidates** make it into Phase I clinical trials[1]
Time, Cost and Value	▪ Acrux is able to develop and commercialise a generic drug for ~AUD$3-4m within ~4 years ▪ Once a licensing deal is executed and a product launched royalty/profit share revenue is expected to grow strongly	▪ Developing a novel drug takes 10+ years[1] ▪ Drug development involves multiple expensive long-term trials

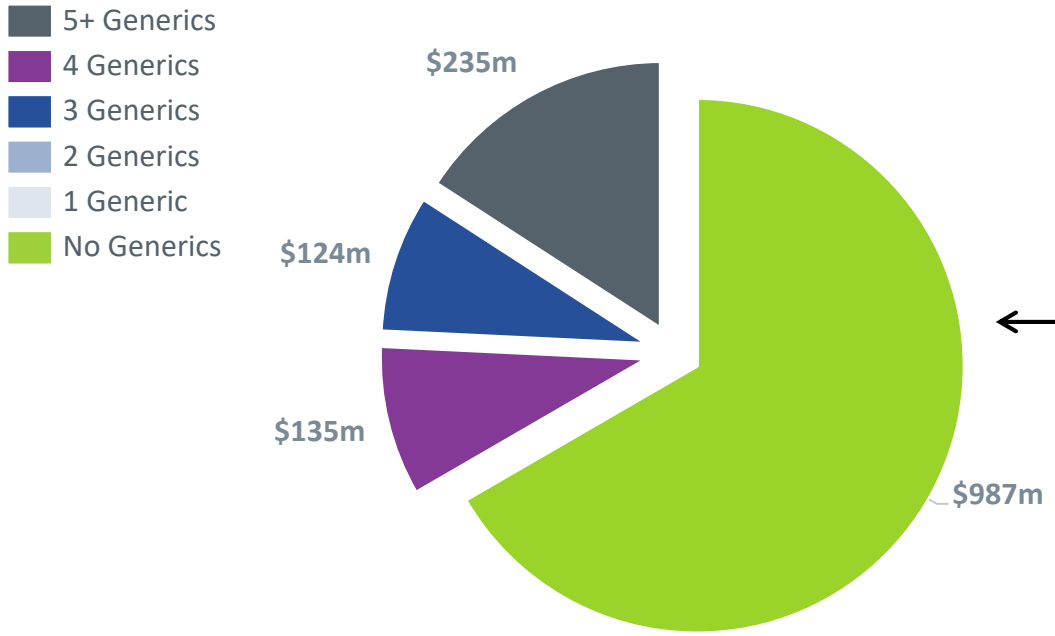
1. Pharmaceutical Research and Manufacturers of America (PhRMA 2015): https://www.phrma.org/graphic/the-biopharmaceutical-research-and-development-process

ACRUX PRODUCT PIPELINE'S $1.5 BILLION ADDRESSABLE MARKET

Acrux's $34m investment in R&D unlocks a $1.5bn market in topical drugs with limited generic competition

Addressable market value of pipeline[1] ($USm)

# of commercialised generic (ANDA) competitors approved and on the market[2]



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. Addressable market for Acrux pipeline is based on twelve months sales to end March 2019 based on IQVIA (Quintiles and IMS Health) sales data
2. March 2019 based on IQVIA (Quintiles and IMS Health) sales data. As at August 2019 there are currently 10+ dossiers submitted to the FDA for a generic version of Julbia® with none commercialised

EXPERIENCED MANAGEMENT TEAM WITH A PROVEN HISTORY OF COMMERCIALISING GENERIC DRUGS

CEO & MD Michael Kotsanis leads a team of highly credentialed experts in generic drugs

Michael Kotsanis
CEO & Managing Director

- **Experienced leader** in the pharmaceuticals industry with demonstrated success **commercialising generic products**
- Formally CCO 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,** before its acquisition by Pfizer
- Michael holds a BSc and a MBus

Felicia Colagrande, BSc(Hons), MBA
Product Development and Technical Affairs Director

Significant pharmaceutical operations, dermal drug development, analytical development and production experience. Leads 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. Experience in senior management roles ASX listed PDFs

PLATFORM FOR GROWTH ESTABLISHED

With $34m invested in the platform over the past 4 years Acrux has a competitive advantage in the identification, development, registration and launch of generic topical drugs

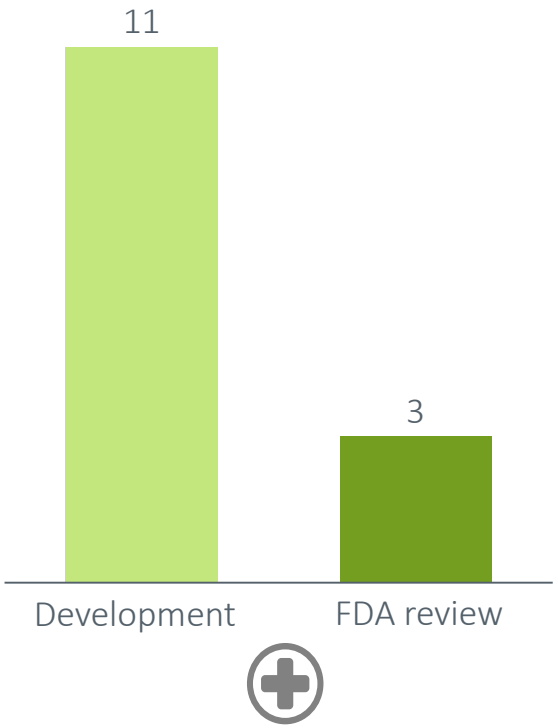
Acrux Pipeline Status		Description
1-3	Product licensing deals targetted for CY 2020	Acrux expects a typical license agreement to consist of an annuity-style revenue stream, with the potential for milestone payments to be included as well
3	Products accepted for FDA review in CY 18/19	The FDA has made a commitment to review 90% of ANDAs within 10 months[1]. Following initial review there may be additional FDA questions to be answered prior to approval
14	Generic products in development	R&D team with highly specific topical expertise drive development. Acrux has unique capabilities for topical drug development
176	Identified topical drugs, each with >US$10m in sales	Market screening 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

MILESTONES & 2020-21 STRATEGIC OBJECTIVES

Significant value expected over the next 24 months with multiple FDA approvals and licensing deals anticipated across the portfolio

Pipeline composition – CY19



Key upcoming milestones

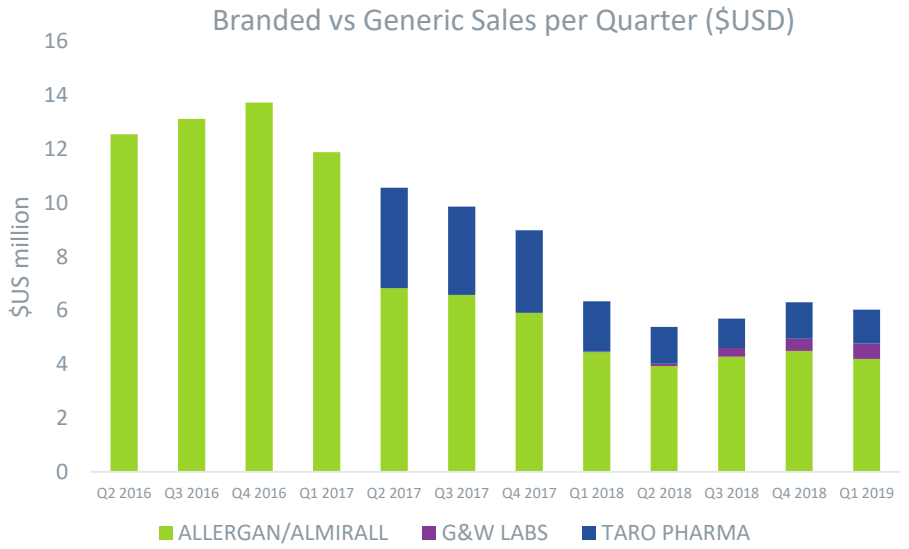
	CY20	CY21
Pipeline objectives	▪ 4 products submitted to the FDA for review ▪ maintain 11 products in development	▪ 4 products submitted to the FDA for review ▪ maintain 11 products in development
Commercial objectives	▪ 1-3 product licensing deals executed	▪ 3-5 product licensing deals executed ▪ Cash flow positive

Typical generic pharma licensing deals include an annuity style profit share or royalty arrangement and may also include milestone payments associated with deal execution, FDA approval and/or commercial launch

CASE STUDY: TOPICAL GENERIC DRUG MARKET ENTRY

With modest development costs generic drugs represent a de-risked approach to drug development

- In September 2000 Allergan received FDA approval for its topical cream Tazarotene which is used for the treatment of psoriasis and acne
- On 4 April 2017, Taro Pharmaceuticals first generic version of Tazarotene was approved
- Sales as measured by IQVIA (Q1, 2017 MAT) were US$51 million
- Allergan's sales of the branded drug fell from USD$12m in Q1 2017 to USD$7m in Q2 2017
- Taro Pharma's generic drug achieved aggregate sales of USD$14.4m in its first 6 quarters of sales
- In Q3 2018 a second generic version of Tazarotene from G&W Labs entered the market



Source: IQVIA Q1, 2019 MAT, US market sales (US$)

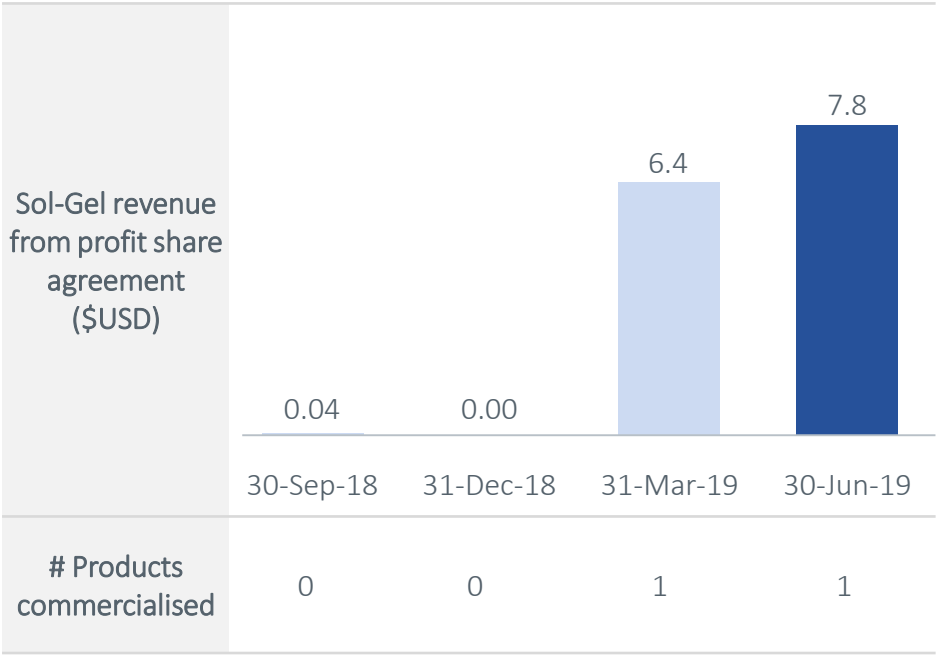
Since launch the generic version of Tazarotene has generated sales of USD$17m

CASE STUDY: SOL-GEL'S PROFIT SHARE FROM THE DEVELOPMENT OF ACYCLOVIR CREAM

Sol-Gel
Advanced Topical Therapy

- A small clinical-stage dermatology company focused on **identifying, developing and commercialising branded and generic topical drug products**
- **Announced FDA approval for first generic product in February 2019**, in a profit sharing partnership with Perrigo

- Acyclovir cream is used for herpes labialis (cold sores)
- The FDA Orange Book formulation patent expired in 2007
- Sol-Gel's licensee launched mid Q1, 2019 following FDA approval
- Sales as measured by IQVIA (Q1, 2019 MAT) were US$89 million



In the first 2 quarters since launch the generic version of acyclovir cream has generated revenue for Sol-Gel of USD$14.2m

ACRUX

ACRUX

DEBORAH AMBROSINI

CFO

FULL YEAR PROFIT AND LOSS

	Full Year Ending 30 June 2019 $'000	30 June 2018 $'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)%**

ACRUX

FULL YEAR CASHFLOW

	Full Year Ending 30 June 2019 $'000	30 June 2018 $'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)%**

ACRUX

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 generic drugs
- FDA approvals for new products
- **Licensing and profit share agreements with generic pharmaceutical companies**
- FDA acceptances for review of new topical generic drugs

CY 2020 OBJECTIVES

- Continued revenue growth of existing on market products
- 4 additional products under FDA review
- 11 products in development
- 1 – 3 product licensing deals executed

CY 2021 OBJECTIVES

- Continued revenue growth of existing on market products
- Cash flow positive by the end of 2021
- 11 products in development
- 3 – 7 products under FDA review
- 3 – 5 additional product licensing deals executed

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

Michael Kotsanis

Acrux Limited

CEO & Managing Director

P: + 61 3 8379 0100

E: michael.kotsanis@acrux.com.au

Visit our website: http://www.acrux.com.au/

Follow us on LinkedIn: