



ASX/Media Release

22 October 2019

Investor Presentation (Australian Microcap Investment Conference)

Melbourne, Australia; 22 October 2019: Acrux Limited (ASX:ACR, “Acrux” or the “Company”) is pleased to provide a copy of the investor presentation from the Australian Microcap Investment Conference today.

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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



ACRUX INVESTOR PRESENTATION (ASX: ACR)

October 2019



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 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	<ul style="list-style-type: none"> Acrux has invested A\$34m in R&D from FY16-19 and now have a drug development pipeline of 14 generic products 	<ul style="list-style-type: none"> 1-3 product licensing deals in CY20 3-5 product licensing deals in CY21
Products commercialised by Acrux	<ul style="list-style-type: none"> Estradiol spray <i>Commercialised as Lenzetto® in 33 countries with royalties and milestones received from FY17 onwards. Commercialised as Evamist® in the United States.</i> Testosterone solution <i>Commercialised in 6 countries with royalties and milestones received from FY10 – FY18</i> 	<ul style="list-style-type: none"> <i>Royalties received on Lenzetto sales grew 77% over prior year</i> <i>Royalties payable to Acrux are expected to further grow and exceed \$800k in FY20</i>

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 specialized 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



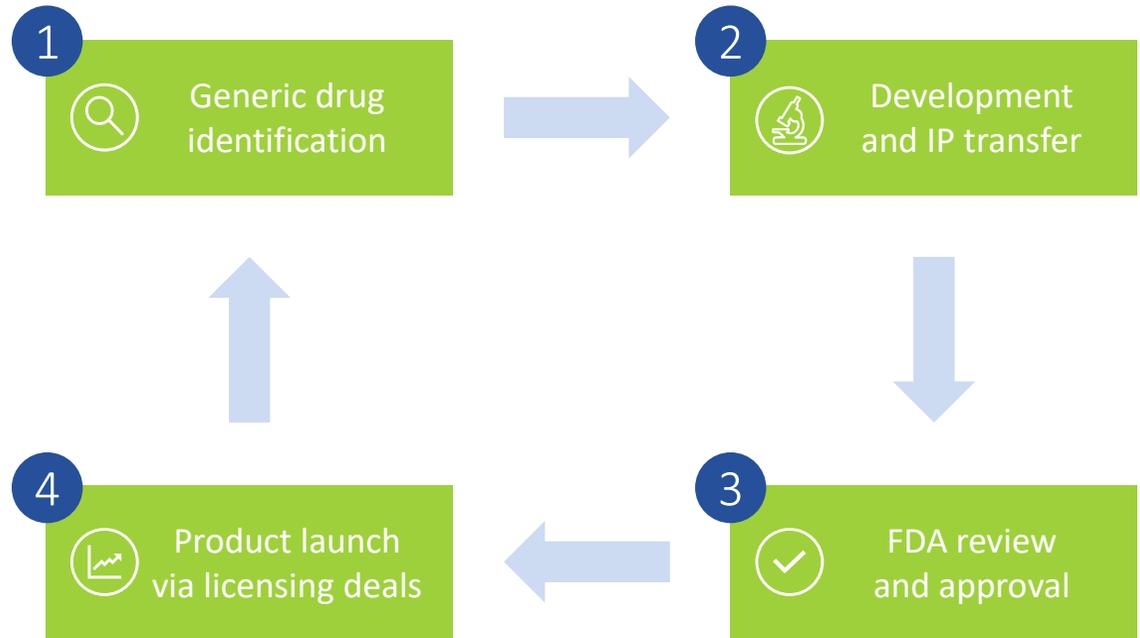
R&D investment in product pipeline nearing commercialisation

- **\$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 have 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	<i>Variable</i>	<i>Competition from many drug manufacturers</i>	<i>Limited generic competition given niche market and development complexity</i>

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



STRONG AND CONSISTENT RETURNS

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

	Acrux's generic portfolio strategy	Novel drug development
Commercial Strategy	<p><u>Portfolio Strategy</u></p> <p>Sophisticated screening of generic drug candidates along with development and commercialisation track record underpin Acrux's de-risked portfolio strategy</p>	<p><u>Single Drug Strategy</u></p> <p>Novel drug development will remain speculative given high costs and risks of development</p>
Development Process	<ul style="list-style-type: none">▪ Acrux rigorously screens market data for drug candidates in attractive markets where Acrux can leverage its drug development and commercialisation track record	<ul style="list-style-type: none">▪ Less than 12% of novel drug candidates make it into Phase I clinical trials¹
Time, Cost and Value	<ul style="list-style-type: none">▪ 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	<ul style="list-style-type: none">▪ Developing a novel drug takes 10+ years¹▪ Drug development involves multiple expensive long-term trials



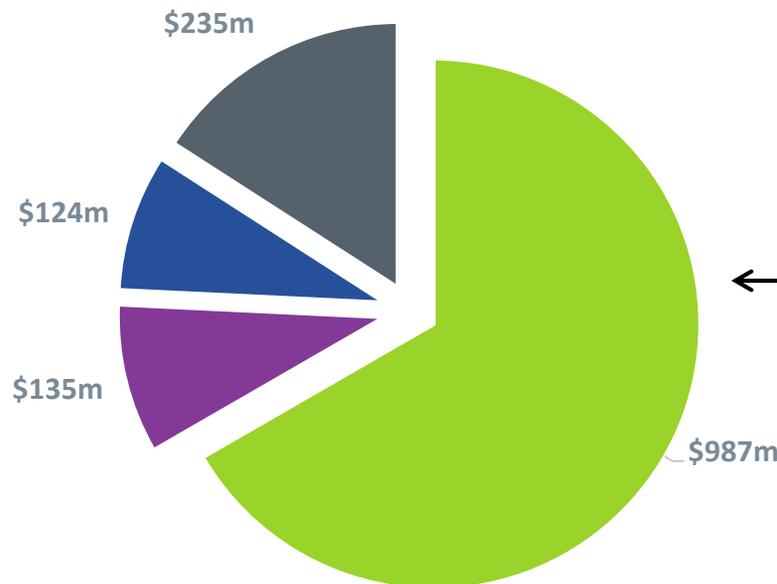
ACRUX PRODUCT PIPELINE'S \$1.5 BILLION ADDRESSABLE MARKET

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

Addressable market value of pipeline¹ (\$USm)

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

- 5+ Generics
- 4 Generics
- 3 Generics
- 2 Generics
- 1 Generic
- No Generics



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. 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 Jublia® 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

Synthon



maynepharma



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
 LAUNCH	1-3 Product licensing deals targetted for CY 2020	Acrux expects a typical license agreement to consist of an <u>annuity-style revenue stream</u> , with the potential for milestone payments to be included as well
 APPROVE	3 Products accepted for FDA review in CY 18/19	The FDA has made a commitment to review 90% of ANDAs within 10 months ² . Following initial review there may be additional FDA questions to be answered prior to approval
 DEVELOP	14 Generic products in development	<u>R&D team</u> with highly specific topical expertise drive development. Acrux has unique capabilities for topical drug development.
 IDENTIFY	176 Identified topical drugs, each with >US\$10m in sales	Market screening to <u>identify</u> 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

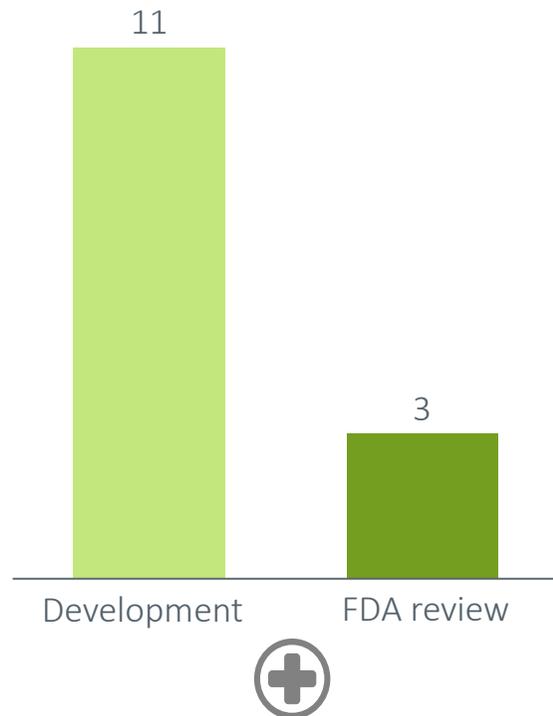




MILESTONES & 2020-21 STRATEGIC OBJECTIVES

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

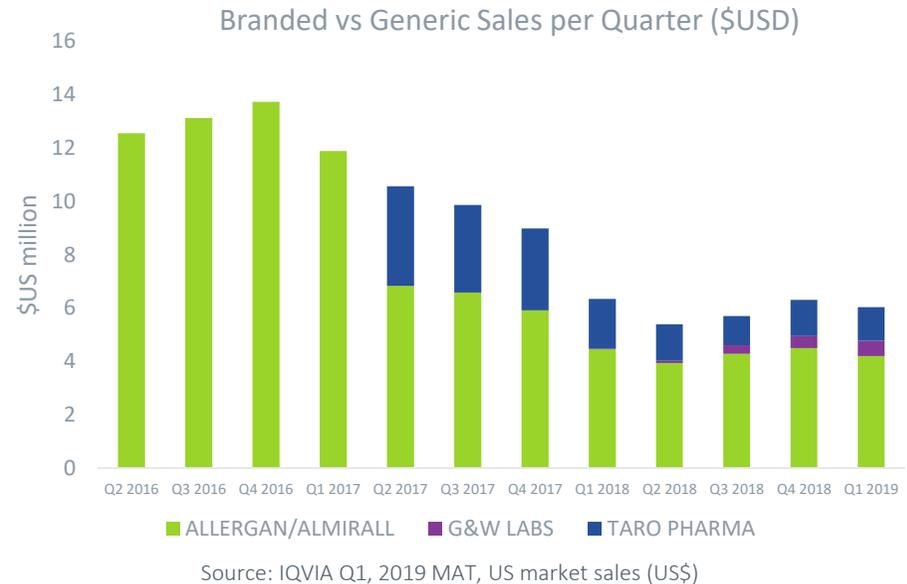
	CY20	CY21
 Pipeline objectives	<ul style="list-style-type: none">4 products submitted to the FDA for reviewmaintain 11 products in development	<ul style="list-style-type: none">4 products submitted to the FDA for reviewmaintain 11 products in development
 Commercial objectives	<ul style="list-style-type: none">1-3 product licensing deals executed	<ul style="list-style-type: none">3-5 product licensing deals executedCash 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
- On 4 April 2017, Taro Pharmaceuticals first generic version of Tazarotene was approved
- 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



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

CASE STUDY: SOL-GEL'S SHARE PRICE IS UP >30% SINCE ANNOUNCING APPROVAL OF ITS FIRST GENERIC PRODUCT



- 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

Share price (\$US)



Sol-Gel revenue (\$USD)	0.04	0.00	6.4	7.8
	30-Sep-18	31-Dec-18	31-Mar-19	30-Jun-19
# Products commercialised	0	0	1	1
# Products in pipeline	5	5	4	4
Market cap (\$USD)	142	114	128	168

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**
- Formally CCO for Synthon Holding BV and President, Europe for Hospira
- Holds a BSc and a MBus



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 and Co-founder of Medvest Inc, a VC group partnered with Johnson & Johnson



Tim Oldham
Non-Executive Director

- Former CEO of Cell Therapies
- Former President, Asia Pacific for Hospira Inc and previously various senior positions with Mayne Pharma

CORPORATE OVERVIEW

Acrux has a proven track record of commercialising products, and is entering a new phase of value creation for shareholders following 4 years of R&D

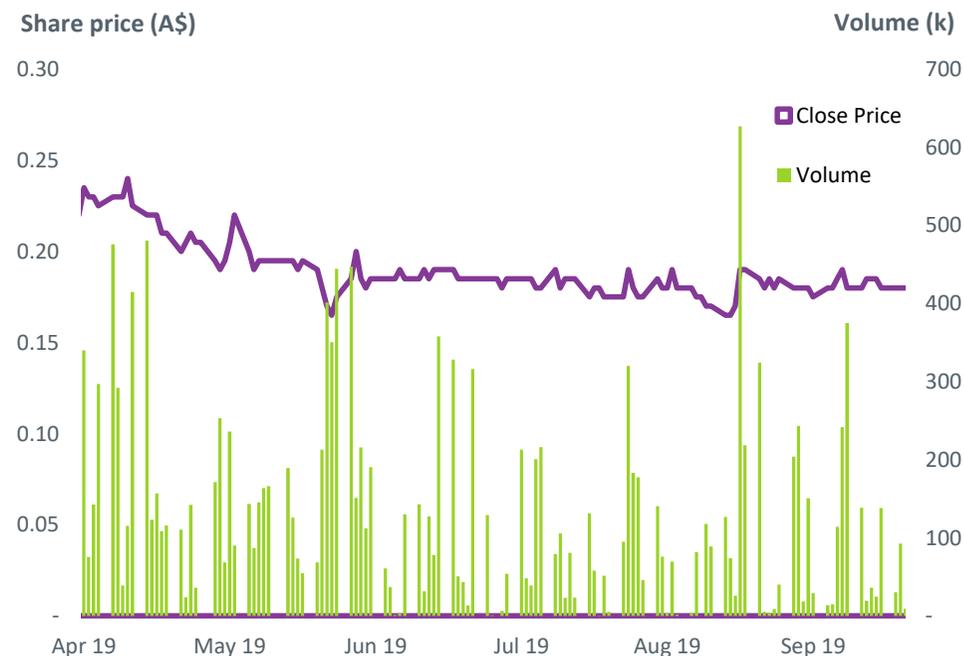
Trading information

Share price (as at 18 October 2019)	A\$0.18
Shares outstanding	166.7m
Market capitalisation	A\$30m
Cash (as at 30 June 2019)	A\$18.2m
Enterprise value	A\$11.8m

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)





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
- **Licensing and profit share agreements with generic pharmaceutical companies**
- FDA approvals for new products
- 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 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 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

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