ASX Release

ASX Small and Mid Cap Conference
Acrux presentation

Melbourne, Australia; 24 September 2024

Acrux Limited (ASX:ACR, "**Acrux**" or the "**Company**"), is pleased to publish the presentation that will be given by CEO and Managing Director, Michael Kotsanis on Wednesday 25 September at 11.27am at the ASX Small and Mid Cap Conference in Sydney, Australia.

A copy of the presentation follows this announcement.

Register by clicking on this link: ASX Small and Mid-Cap Conference September 2024

Approved for release by the Acrux Board of Directors.

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About Acrux

Acrux is a specialty pharma company with a successful track record of developing and commercialising a pipeline of topically applied pharmaceutical products. Drawing on 25 years of experience, Acrux has successfully marketed through licensees a number of products worldwide with emphasis on the United States.

Acrux is formulating and developing a range of topical generic products by leveraging its highly skilled workforce, on-site laboratories, GMP manufacturing suite, technical, clinical and commercial experience to bring affordable products to market. Acrux encourages collaboration and is well positioned to discuss commercial partnering and product development opportunities.

For further information on Acrux, visit www.acrux.com.au

ACRUX

Acrux is a specialty pharmaceutical company focussed on development and commercialisation

Topically applied prescription pharmaceutical products are our expertise

ASX Small and Mid Cap Conference

25 September 2024

Disclaimer

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 a leader in the development of topically applied prescription pharma products

An Australian based leader in the development of topically applied prescription pharmaceutical products

Founded in 1998 with a 25+ year track record with US NDA, US ANDA and EMA product approvals

Skills and competence to meet complex US FDA Product Specific Guidances for ANDA development of topically applied products

Network of Contract Development and Manufacturing Organisations (CDMO) to provide development, scale up and commercial manufacturing

Network of commercial licensees which have commercialised Acrux products in the United States and over 40 countries

Acrux is well on the pathway to commercial sustainability

2014

Single product focus

2017

Development of initial products in topical generic portfolio

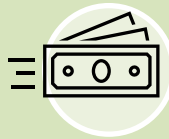
2021

First FDA ANDA approval

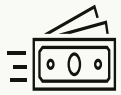
2024

3 product launches
5 FDA approved products
2 products pending approval

Future



Increasing operating cash flows as products are approved and launched

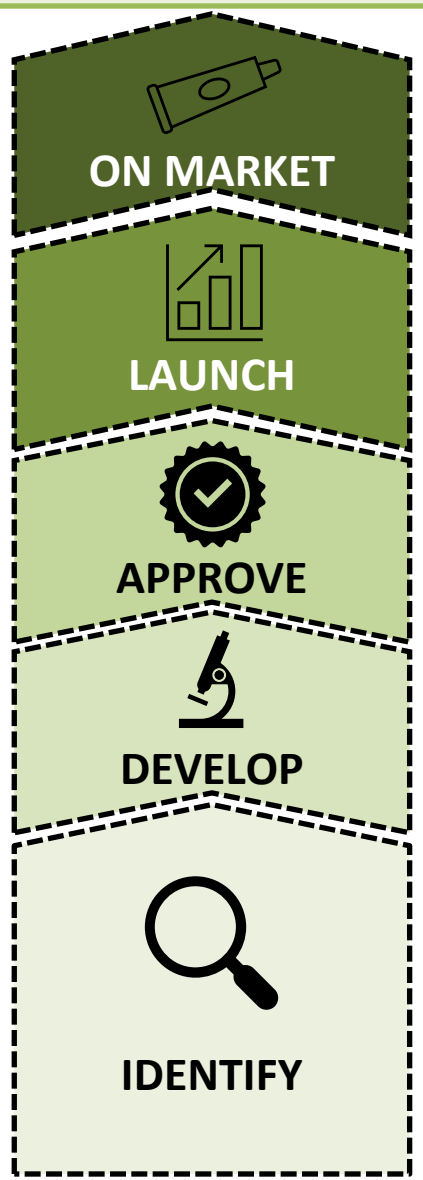


Revenue generation from commercialised products

Strong pipeline of products under development

Acrux growth platform

Through investment in our pipeline, Acrux has proven its capability to develop, receive approval and monetise topical drugs



3	**Revenue generating products**	Acrux receives royalties on a quarterly basis. Acrux expects a typical licence agreement to consist of a **recurring profit share stream**
2+2	**2 products launched, 2 products anticipated for launch in near term**	Dapsone 5%, Gel in April 2024, Dapsone 7.5%, Gel and one additional product expected to launch by end Q1, 2025
7	ANDA products submitted to FDA for review to date	5 approved to date
7	Generic products in development	R&D team with highly specific topical expertise drive development. Acrux has unique capabilities for topical drug development.
40	Identified topical drugs, Each >US$100m in sales	Continue to review commercial market data, patent information, FDA Product Specific Guidances to identify high potential prescription topical product development candidates
38	Identified topical drugs, Each US$50-100m in sales	
217	Identified topical drugs, Each US$10-50m in sales	

Acrux recent product launches and future planned launches

Prilocaine 2.5% Lidocaine 2.5%, Cream

Launched December 2022
US FDA approved indication as a topical anesthetic for local analgesia*

Dapsone 5%, Gel

Launched April 2024
US FDA approved indication for the topical treatment of acne vulgaris*

2 recent **launches** in the United States, 2 more launches planned

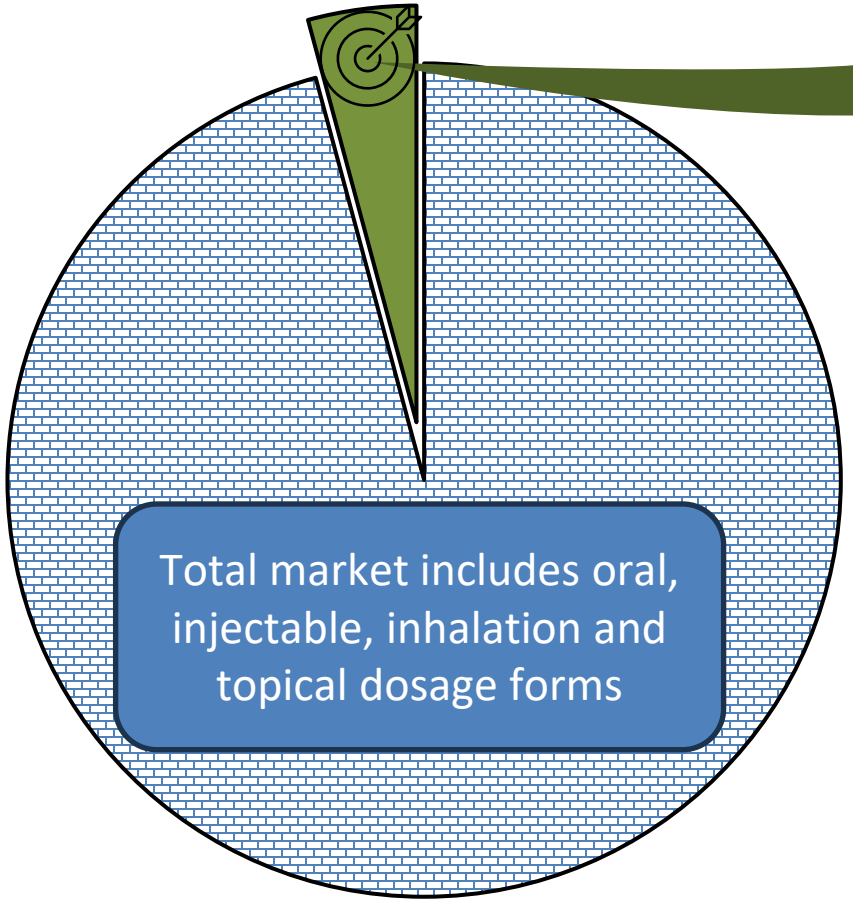
Planned launches and products under FDA review

1. Dapsone 7.5% Gel for acne *
2. Nitroglycerine 0.4% Ointment for pain from anal fissure **
3. Acyclovir 5% Cream for cold sores **

- Additional 7 products under active development

* Not approved outside the United States. Consult full prescribing information before use.
** Submitted and currently under US FDA review. Not yet approved for use.

Acrux focusses on topically applied pharmaceutical products



Total US pharmaceutical market estimated US$500 billion in sales[2]

The market size for topically applied pharmaceutical products is US$21 billion[1]

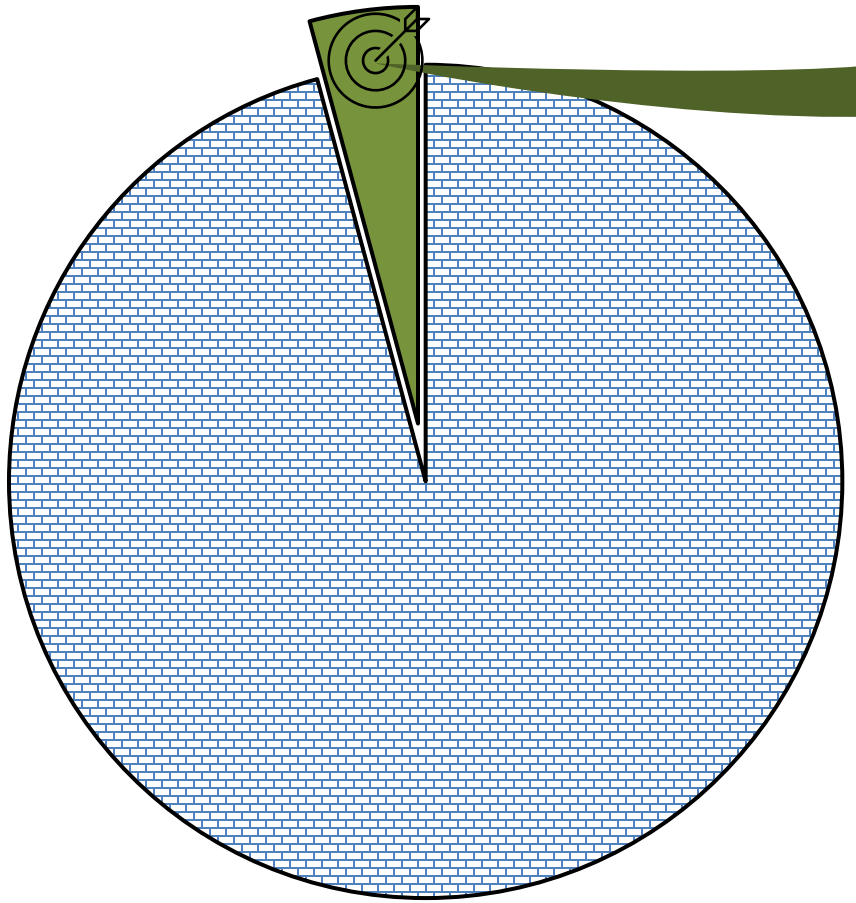
Dosage forms include creams gels, ointments, suspensions, solutions, patches

Sterile and non-sterile dosage forms

Development of topical generics is characterized by higher complexity than other dosage forms, especially oral drugs

1. Market size for topically applied drugs IQVIA June 2024 MAT, US$ sales. IQVIA data does not capture all distribution channels in the United States for topical products.
2. Total US pharma market size market based on Acrux estimates

There is a significant range of topically applied pharmaceuticals that Acrux can target



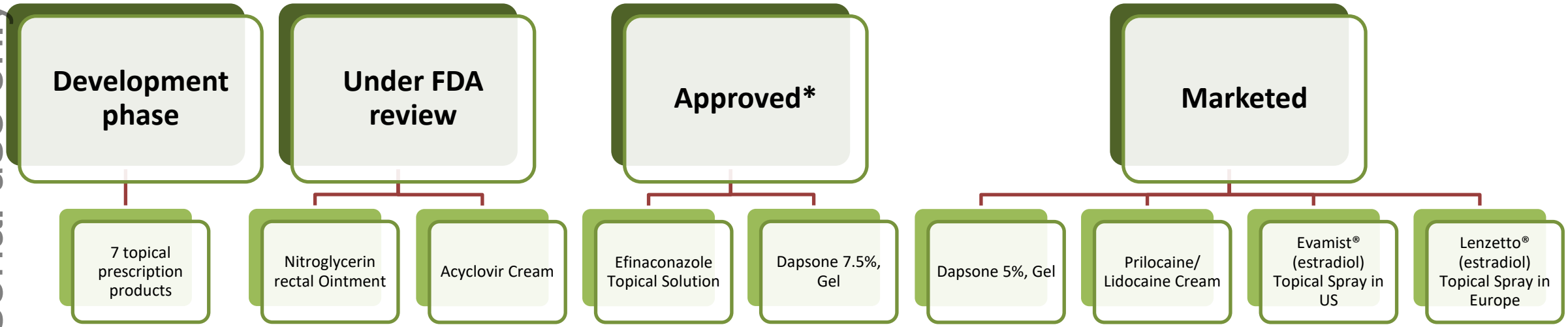
US$21 billion* market has a broad range of development targets for topically applied pharmaceuticals

Application site	>US$100m	US$50m-100m	US$10m-50m
TOPICAL DERMATOLOGICALS	13	11	81
TOPICAL OPHTHALMIC	14	11	48
TRANSDERMAL PATCHES	4	8	32
TOPICAL EXTERNAL		3	8
TOPICAL NASAL	2	1	11
MOUTH/THROAT TOPICAL			9
TOPICAL RECTAL			8
TOPICAL VAGINAL	6	3	11
TOPICAL OTIC	1	1	5
TOPICAL UROLOGICAL			3
TOPICAL ALL OTHERS			1
Grand Total	**40**	**38**	**217**

Acrux is focussed on the specialty sector of topically applied pharmaceuticals

* Market size for topically applied products. One product is one drug substance and one strength. IQVIA June 2024 MAT, US$ sales

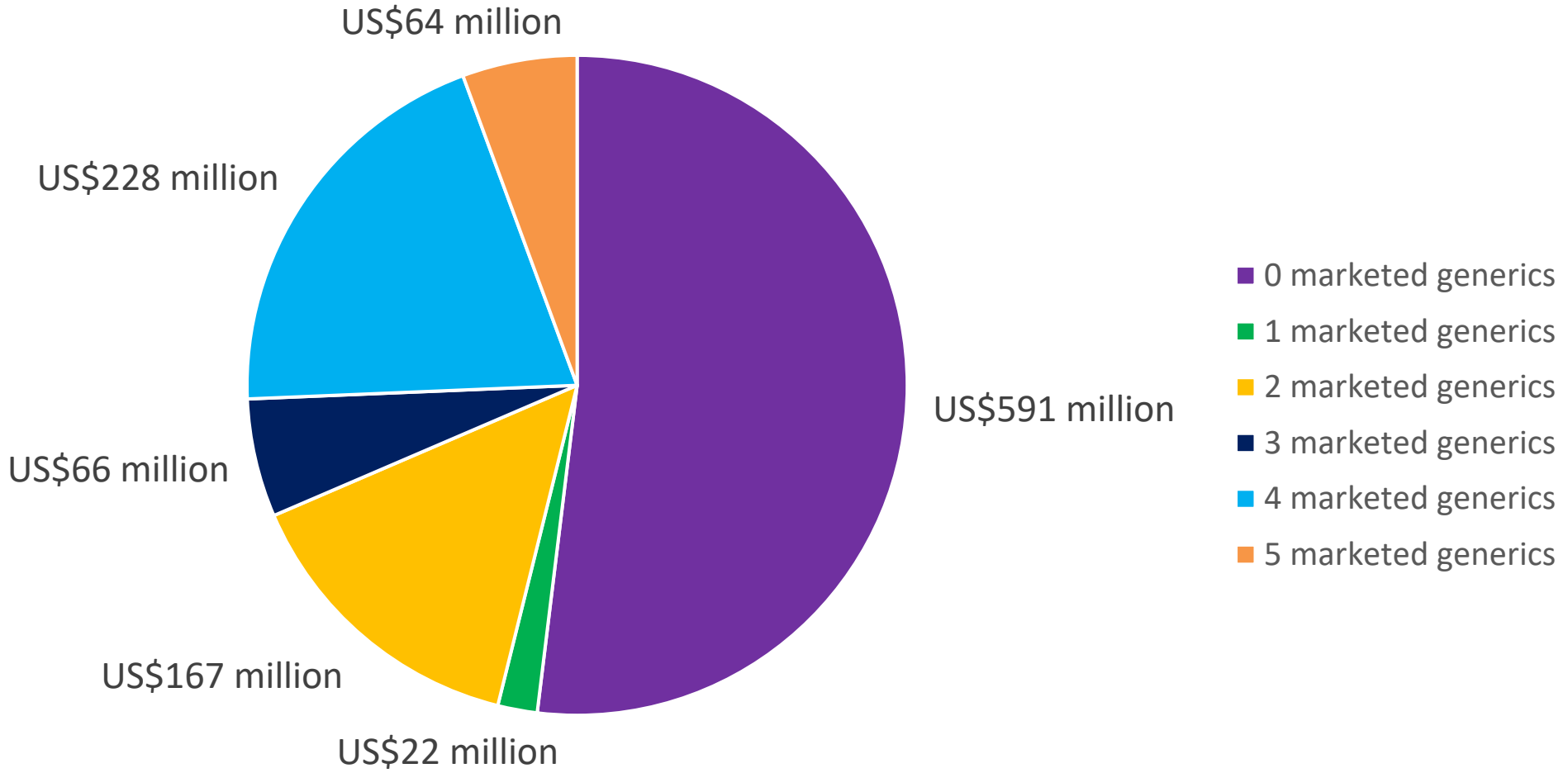
Acrux topical product portfolio



Acrux's objective is to develop a diversified, on-market portfolio of products generating a sustainable revenue stream

* Efinaconazole Topical Solution US launch date is based on Paragraph IV IP settlement
* Excludes Testosterone Topical Solution which was formerly approved and has been divested

Acrux topical generic portfolio – addressable market is over $1.1 billion*

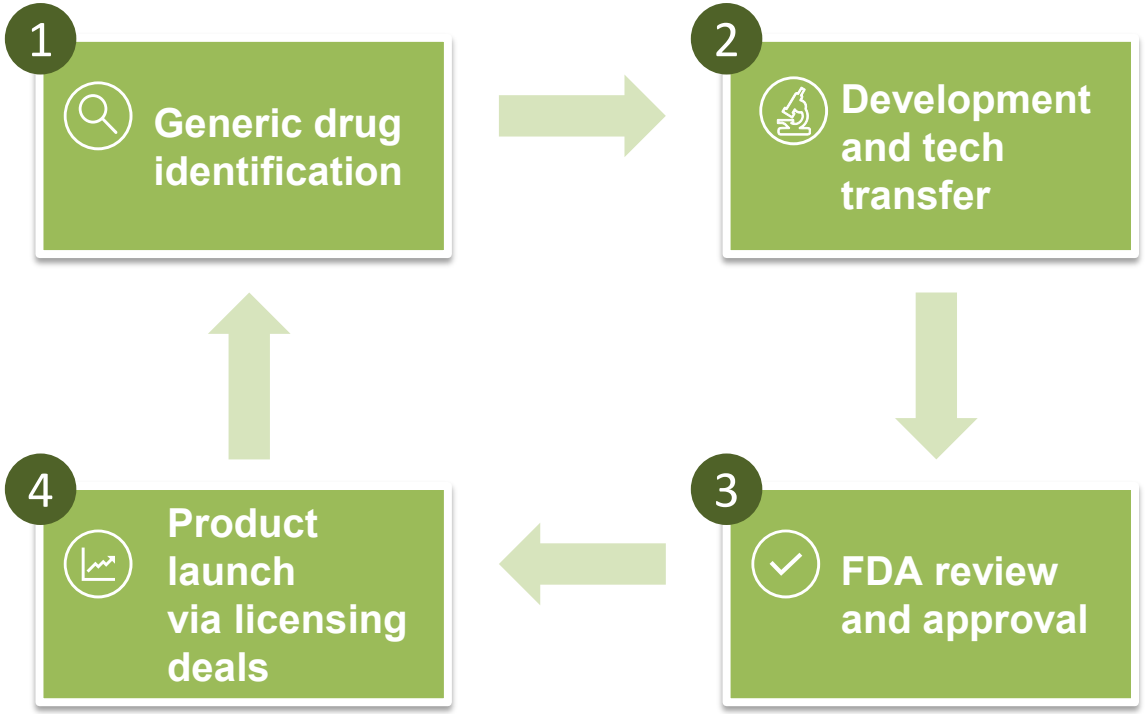


Strong pipeline of products under development

* IQVIA June 2024, MAT US$ sales. A marketed ANDA is a marketed generic.
* Excludes Acrux branded products Evamist® and Lenzetto®
* IQVIA data does not capture all distribution channels in the United States for topical products.

Long Term Growth Model

- With a TGA approved 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 drives product regulatory submissions and commercial product launches



Facilities and Capabilities

R&D focus - onsite laboratories and GMP licensed facility FDA remote regulatory assessment and inspected by TGA

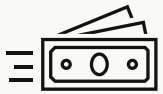
Early development process conducted at Acrux laboratory in Melbourne, Australia

Bioequivalence testing conducted to meet FDA Product Specific Guidances including *in-vitro* tests (IVRT, IVPT), pharmacokinetic (PK) testing and other specific FDA requirements

FDA approval of products based on *in vitro* and *in-vivo* testing

Growth outlook based on a track record of developing and commercialising products

2 recent **launches** in the United States, 2 more launches planned



Revenue generation from commercialised products

2 products currently **under evaluation** by the FDA

FDA approval of 5 products since 2021

Strong pipeline of products under development

Appendix

What is a generic drug?

Therapeutic Goods Administration (TGA) – Australia

"A generic medicine is an additional brand of an existing medicine. It contains the same active ingredient (the chemical that makes the medicine work) as the existing medicine.
Apart from containing the same active ingredient, generic brands also have to be 'bioequivalent'. That is, if you take the same dose of a generic medicine as an existing medicine, the same amount of active ingredient is absorbed by your body over the same period of time."

Food and Drug Administration (FDA) – United States

"A generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that a generic medicine works in the same way and provides the same clinical benefit as the brand-name medicine. In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart."

Corporate Overview and share price

Key Data	
Ticker	ASX: ACR
Market capitalisation	$15.7 million
52 week range	$0.035 - $0.099
Share price	$0.054
Shares on issue	290.7 million
30 June cash balance	$2.9 million
Average daily liquidity*	358k shares

Key Shareholders	
Phillip Asset Management Ltd (Bioscience Managers)	10.95%
Top 20 shareholders	34.60%

Acrux over 12 months

Data – 19 September 2024. *Average daily liquidity over 90 days

Connecting with Acrux

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