

ACRUX

Acrux is a specialty pharmaceutical company focussed on development and commercialisation

Topically applied prescription pharmaceutical products are our expertise

Bioshares, 18th Biotech Summit
July 2024



For personal use only



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 is a leader in the development of topically applied prescription pharma products

For personal use only




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 Guidance for ANDA development



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 focussed on an underserved market segment in the United States

	Total market	Oral drugs	AcruX focus: Topical drugs
Definition of market	Total US prescription pharma market	Drugs that are ingested orally (capsules, tablets)	Drugs that are applied topically (including directly to the skin, eyes, ears)
Market size¹	>US\$460bn	~US\$200bn	~US\$16bn ²
Generic market share	~90% ³	~91% ³	47% ⁴
Typical generic development complexity	Variable	Low	Higher complexity than oral generic drug development
Generic competition	High	Competition from many drug manufacturers	<i>Limited generic competition given niche market and development complexity</i>

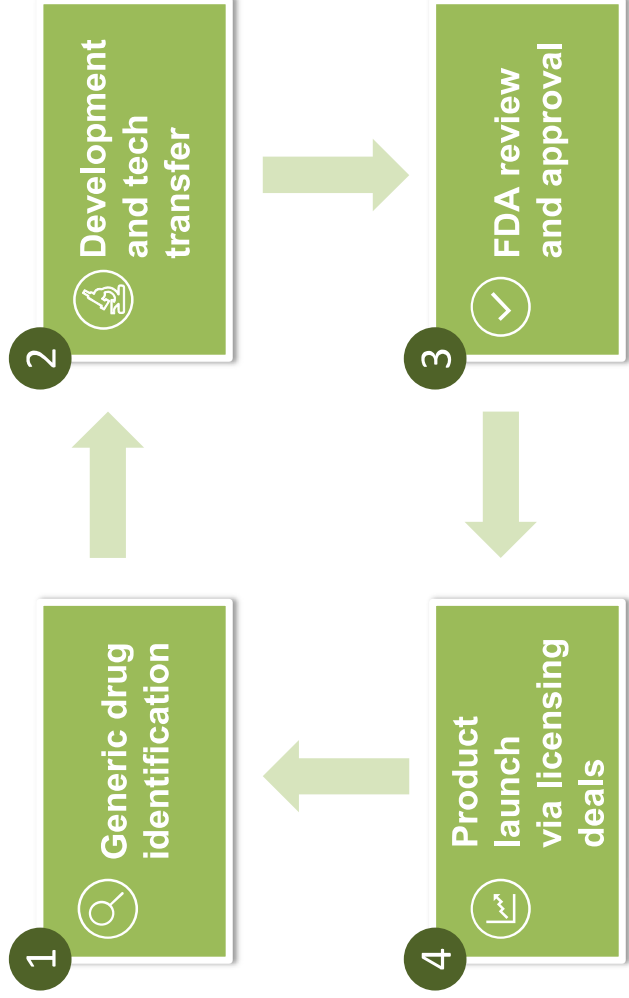
Source:

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

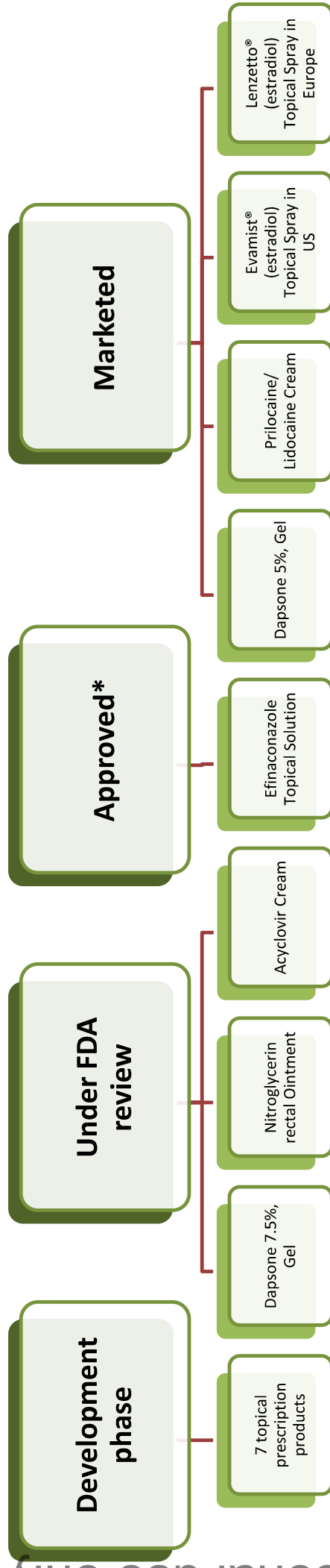


Long Term Growth Model

- 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



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 is no longer commercialised

Development Processes

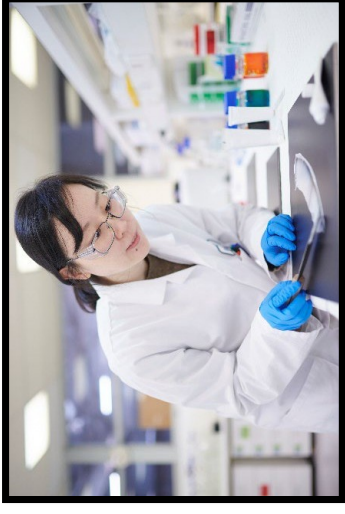
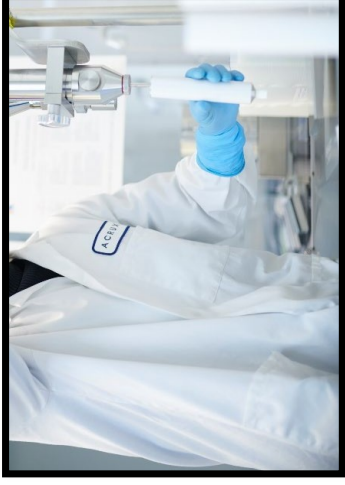
Activities may include development and testing in Acrux's GMP facility and laboratory

- Acrux has a current TGA license for manufacture of transdermal/topical and transmucosal products for clinical trials
- FDA Remote Regulatory Assessment in 2023 for *in-vitro* bioequivalence testing which found no objectionable conditions



Mid to later stage development activities

- Analytical method development
- Container closure selection, extractables and leachables testing
- Stability testing
- Manufacturing scale-up and technical transfer to commercial-scale facilities
- Bioequivalence testing to FDA standards



Facilities and Capabilities

R&D focus - onsite laboratories and GMP licensed facility
Inspected by TGA and FDA

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



Acrux recent product launches and future planned launches

For personal use only

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*

Planned launches pending FDA approval**

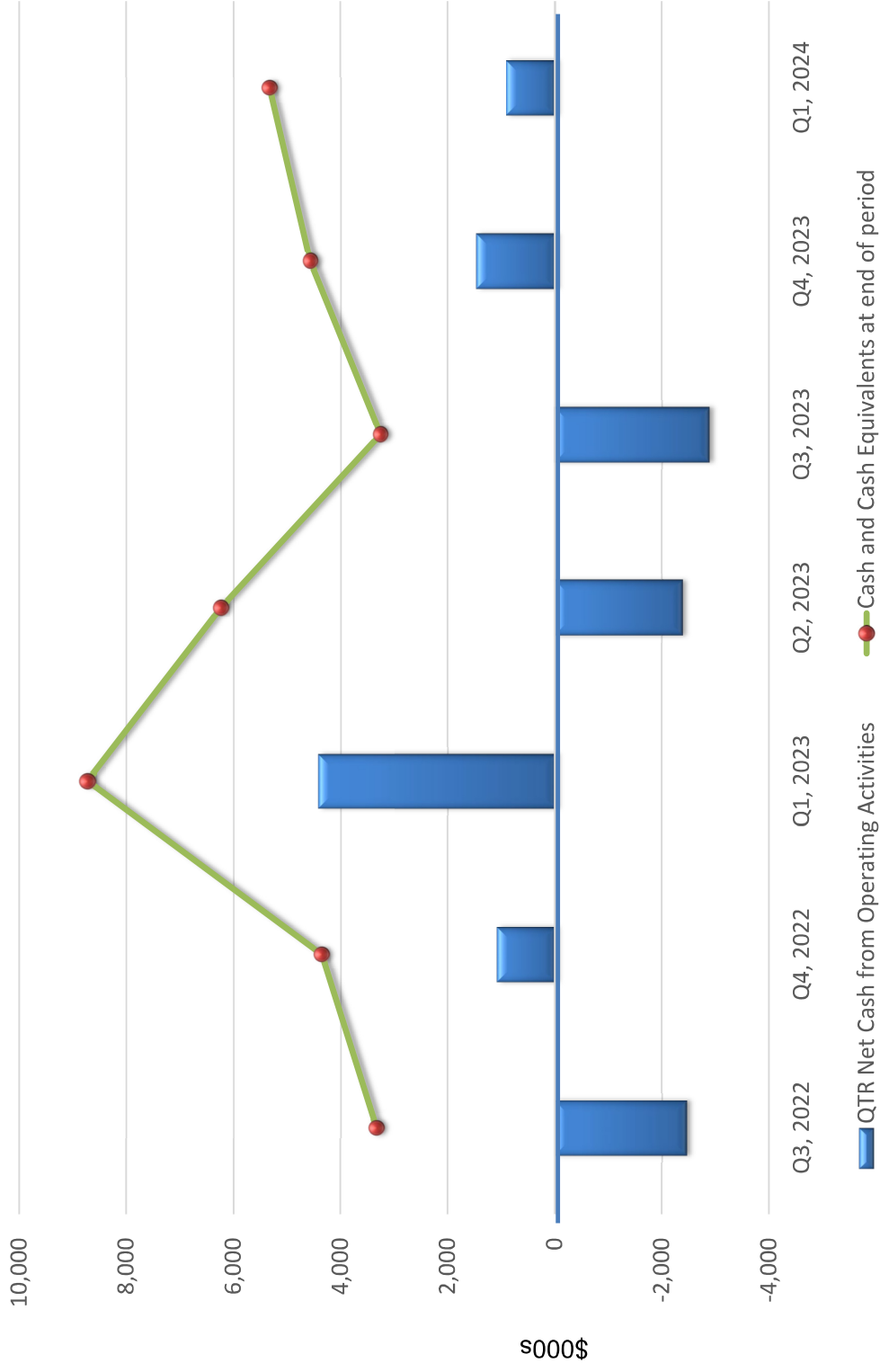
1. **Dapsone 7.5% Gel** for acne
2. **Nitroglycerine 0.4% Ointment** for pain from anal fissure
3. **Acyclovir 5% Cream** for cold sores

* 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 quarterly cashflow (\$'000s)

For personal use only



10 Data – Appendix 4C from Q3, 2022 to Q1, 2024



Outlook based on a track record of developing and commercialising products



Revenue generation from commercialised products



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



FDA approval of 4 products since 2021



2 recent **launches** in the United States

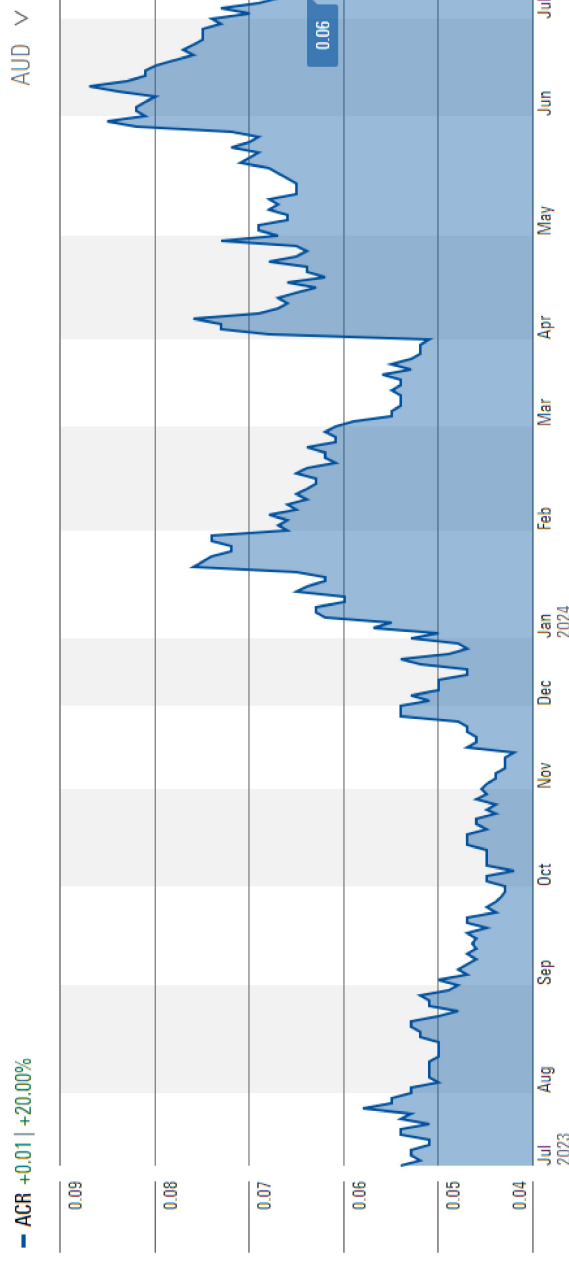


Strong pipeline of products under development

For personal use only

Corporate Overview

Ticker	ASX: ACR
Market capitalisation	\$17.4 million
Share price	\$0.06
Shares on issue	290,716,856
Average daily liquidity (average over 6 months)	553k shares



Source: <https://www.morningstar.com.au/investments/security/ASX/ACR/chart> - 1 year chart

Substantial Shareholder	Holding	%
Phillip Asset Management Ltd (Bioscience Managers Translation Fund I)	31.8 million shares	10.95%
Top 20 shareholders	99.8 million shares	34.32%



Connecting with Acrux

For personal use only



www.acrux.com.au

info@acrux.com.au



ASX: ACR



+61 3 8379 0100



Follow Acrux
on LinkedIn