



ASX Release

Acrux presentation at Hidden Gems in Life Sciences Forum

Melbourne, Australia; 13 June 2024

Acrux Limited (ASX:ACR, “**Acrux**” or the “**Company**”) is pleased to announce its participation in the *Hidden Gems in Life Sciences Forum* arranged by MST Financial. The Acrux presentation will be on Thursday 13 June at 3.30pm and will be accessible by webinar.

CEO and Managing Director, Michael Kotsanis will present an overview of the Company and its progress in building a marketed range of topically applied pharmaceuticals for the United States market.

The live webinar can be viewed via Zoom with this link: [click here to attend webinar](#)

A copy of the presentation follows this announcement.

Approved for release by the Acrux Board of Directors.

For more information, please contact:

Michael Kotsanis
Acrux Limited
CEO & Managing Director

P: + 61 3 8379 0100
E: michael.kotsanis@acrux.com.au

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

Typically applied prescription pharmaceutical products are our expertise



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



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

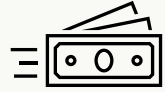


Network of Contract Development and Manufacturing Organisations (CDMO) to provide development, scale up and commercial manufacturing



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

Track record of developing and commercialising products



Revenue generation from commercialised products



Strong pipeline of products under development



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



FDA approval of 4 products since 2021



2 recent **launches** in the United States



Licensees for commercial products: Padagis, Gedeon Richter, TruPharma

AcruX is focussed on an underserved market segment in the United States

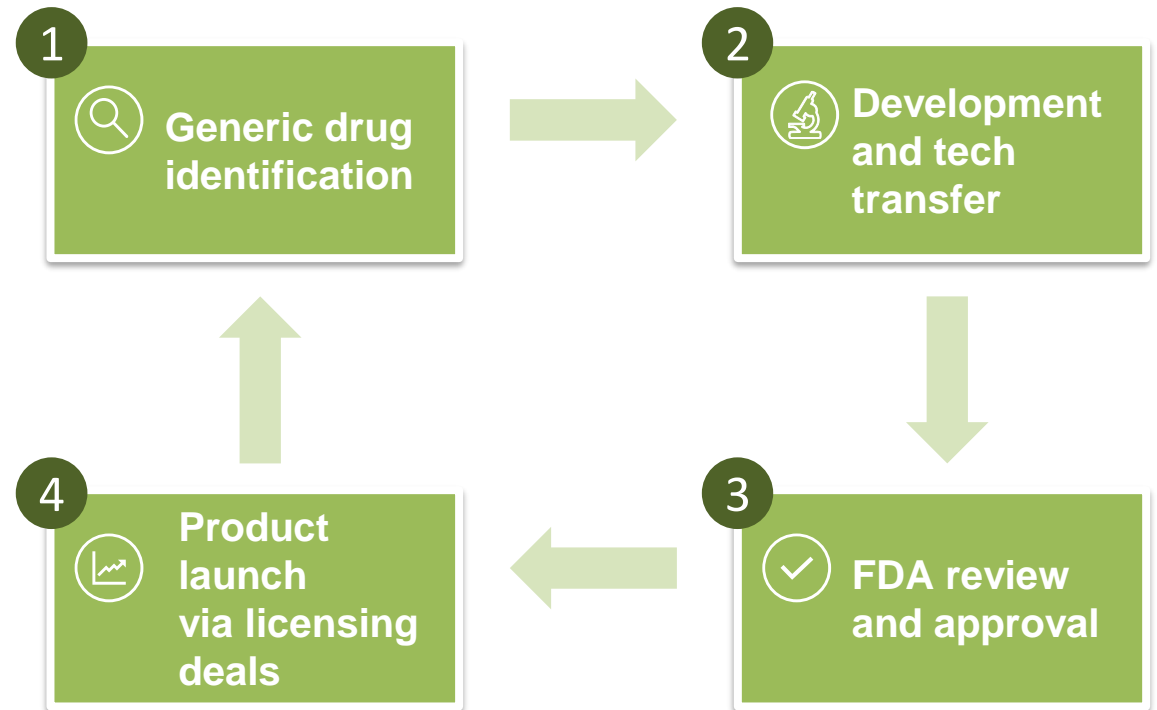
	Total market	Oral drugs	AcruX focus: Topical drugs
Definition of market	Total US prescription pharma market	Drugs that are ingested orally (capsules, tablets)	Drugs that are applied topically (including directly to the skin, eyes, ears)
Market size¹	>US\$460bn	~US\$200bn	~US\$16bn ²
Generic market share	~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:

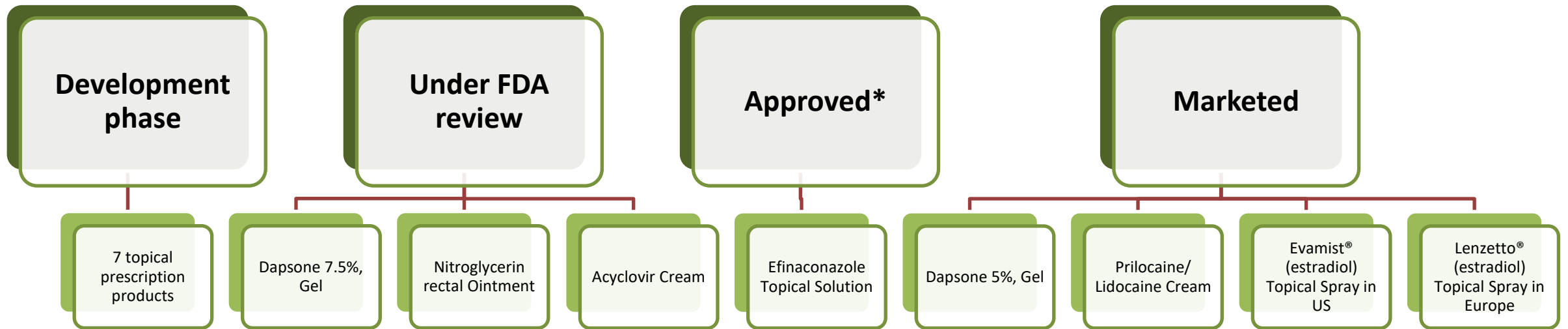
1. US market by dosage form, IQVIA Q3, 2020 MAT, US\$ market sales
2. Market size for topically applied drugs IQVIA Q3, 2020 MAT, US\$ market sales
3. IQVIA Global Generic and Biosimilars Trends and Insights – 2018
4. IQVIA, National Sales Perspectives, January 2019 – Unbranded generic share of dermatology,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



- 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

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 and validation
- Container closure selection, extractables and leachables testing
- Stability testing
- Manufacturing scale-up and technical transfer to commercial-scale facilities
- Performing CMC activities, studies and reports for regulatory submissions
- Bioequivalence testing to FDA standards





Acrux has licensed out product candidates at both early and late stage development phases

Acrux is able to develop topical products through to ANDA or NDA submission

Acrux works closely with corporate partners that are fully capable and committed to further development and marketing of its products

Acrux is open to alternative business models for development and commercialisation activities

Acrux has significant experience in the technical transfer of products to external manufacturing organisations. Acrux has 8 contracted CMOs spanning various dosage forms and scale

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

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.

Ticker	ASX: ACR
Market capitalisation	\$23.3 million
Share price	\$0.083
Shares on issue	290,716,856
Average daily liquidity (average over 3 months)	1.02 million 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%





www.acrux.com.au

info@acrux.com.au



ASX: ACR



+61 3 8379 0100



Follow us on LinkedIn