ACRUX

Acrux is a specialty pharmaceutical company focussed on development and commercialisation

Topically applied prescription pharmaceutical products are our expertise

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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.

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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 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

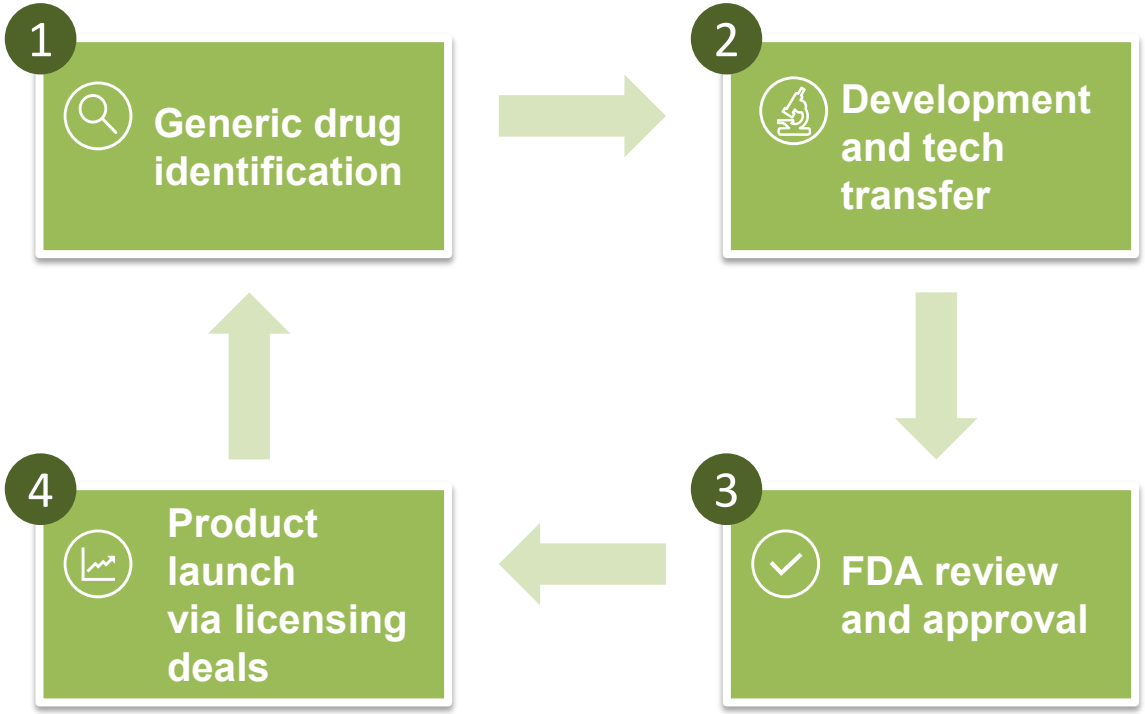
	Total market	Oral drugs	Acrux focus: Topical drugs
Definition of market	Total US prescription pharma market	Drugs that are ingested orally (capsules, tablets)	Drugs that are applied topically (including directly to the skin, eyes, ears)
Market size[1]	>US$460bn	~US$200bn	~US$16bn[2]
Generic market share	~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	***Limited generic competition given niche market and development complexity***

Source:

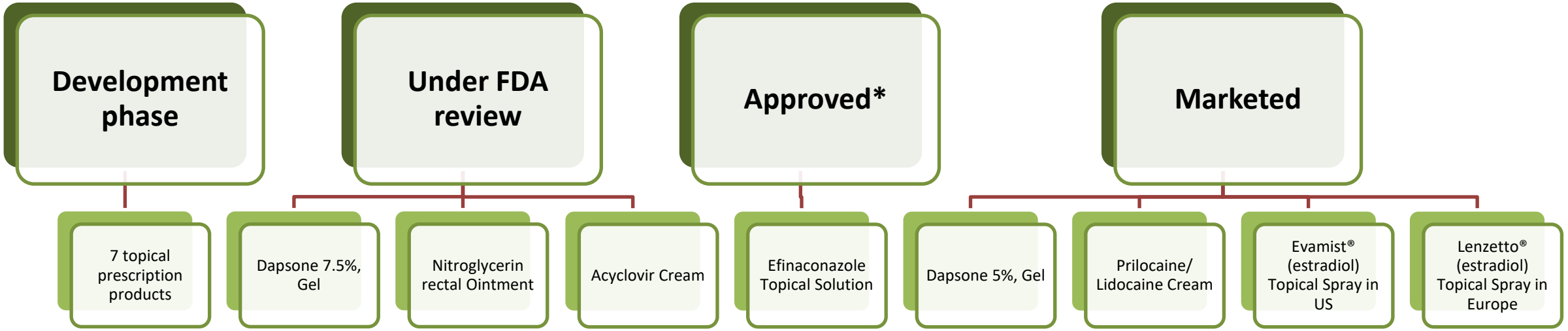
1. US market by dosage form, IQVIA Q3, 2020 MAT, US$ market sales
2. Market size for topically applied drugs IQVIA Q3, 2020 MAT, USS market sales
3. IQVIA Global Generic and Biosimilars Trends and Insights – 2018
4. IQVIA, National Sales Perspectives, January 2019 – Unbranded generic share of dermatology,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

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.

Corporate Overview

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%

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