



Investor Presentation

February 2025

Acruz is a specialty pharmaceutical company focused on the development and commercialization of topically applied pharmaceutical products

ACRUX

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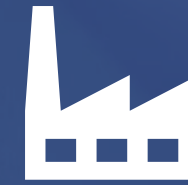
Acrux is a leader in the development of topically applied prescription pharma products



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



Commercial licensees have commercialised Acrux products in the United States and over 40 countries

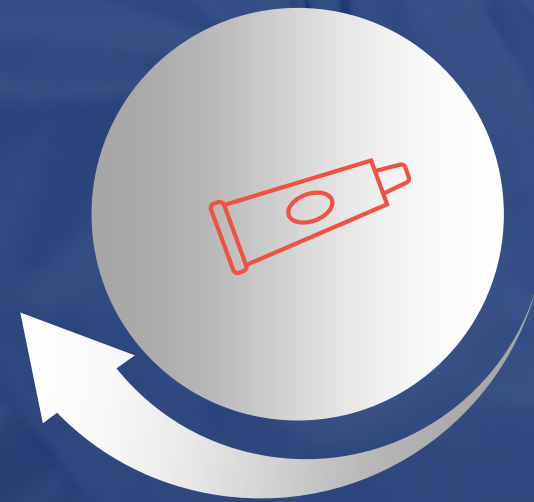
Acrux has **4** marketed products in the US. Acrux is supported by **8** contracted manufacturers for its ANDA (generic) portfolio. Acrux has generated total revenue of **A\$20M** over FY23 and FY24. An additional **new** product will be launched in the US shortly.

Incorporated in 1998, Acrux draws on its highly skilled workforce, on-site laboratories, GMP manufacturing suite, technical and commercial experience to progress its pipeline and bring further affordable products to market.

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

Acrux growth platform

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



A\$20m* in total revenue

Acrux receives royalties on a quarterly basis. Acrux typical licence agreement consists of a recurring profit share stream



4 revenue generating products
1 planned launch

Dapsone 5%, Gel in April 2024 and Nitroglycerin Ointment in December 2024 with Dapsone 7.5%, Gel expected to launch shortly. 6 ANDA products approved to date.



1 product under FDA review

1 product recently approved and 1 more product currently with the FDA for review



8 generic products in development

R&D team with highly specific topical expertise drive development. Acrux has unique capabilities for topical drug development.



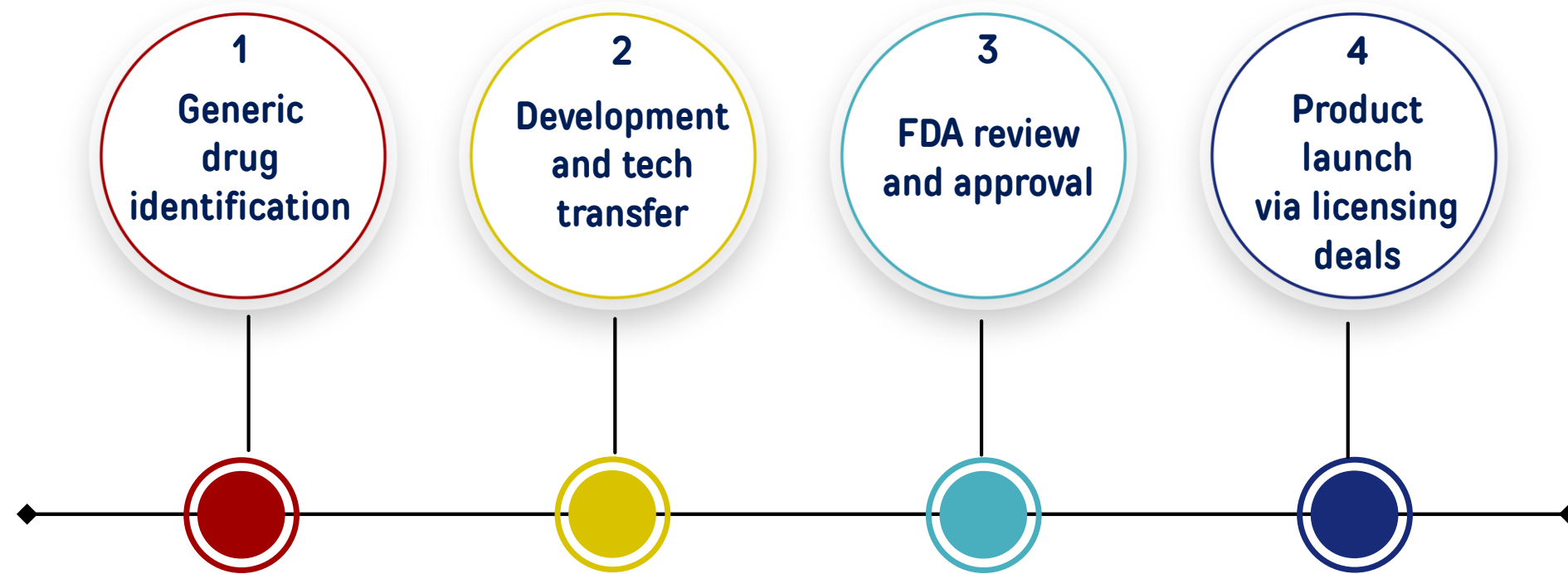
Targeting topical drugs

- 40** Identified topical drugs, each >US\$100m in sales
- 38** Identified topical drugs, each US\$50-100m in sales
- 217** Identified topical drugs, each US\$10-50m in sales

Continue to review commercial market data, patent information and FDA Product Guidances to identify high potential candidates

* Combined FY23 and FY24

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 in the United States and other markets
- 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

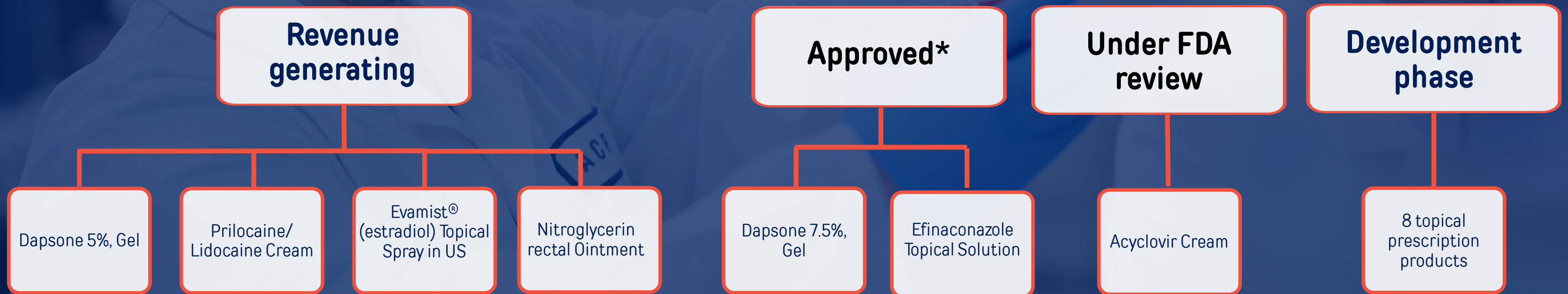
Early development process conducted at Acrux laboratory in Melbourne, Australia

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

Acrux topical product portfolio – United States

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 dependent on Paragraph IV IP settlement

Acrux revenue is generated through long term commercial relationships



Commercial Partners in the United States:

Padagis – is a generic pharmaceutical leader in topicals in the United States

TruPharma – is a US focused partner for the sale, marketing, and distribution of prescription pharmaceutical products

Commercial Partners ex-United States:

Gedeon Richter – is a European multinational pharmaceutical and biotechnology company

Active commercial discussions in multiple countries for commercial licensing of Acrux products

Leveraging development expertise:

Expertise to leverage US portfolio into new territories and expertise to bring other partner's products to market

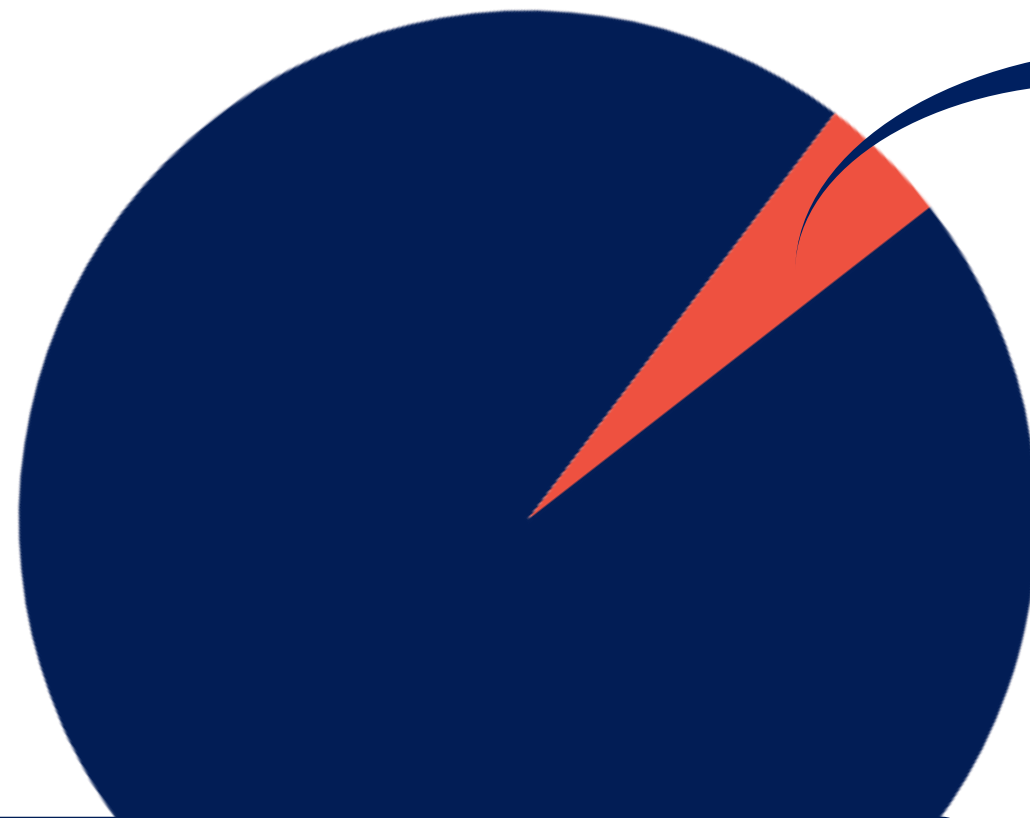
Experienced team to manage development and regulatory process through to commercialisation

Clear track record in achieving regulatory approvals in multiple jurisdictions

Established licensee and CMO infrastructure and relationships

Market for topically applied pharmaceuticals

Topical pharmaceuticals represents a US\$21 billion market in the United States.



Total US pharmaceutical market estimated US\$500 billion in sales*

Total market includes oral, injectable, inhalation, topical and other dosage forms

The market size for topically applied pharmaceutical products is US\$21 billion*

Different competitive dynamics to other market segments as fewer developers and manufacturers have the necessary competency

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

* 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 – market volume is likely underestimated

* Total US pharma market size market based on IQVIA MAT sales data and Acrux estimates

AcruX can target a significant number of topically applied pharmaceuticals

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

AcruX is focussed on the specialty sector of topically applied pharmaceuticals

Why topicals? Generally smaller market size (volume and total market value) but generally fewer generic competitors and therefore lower price discounting.

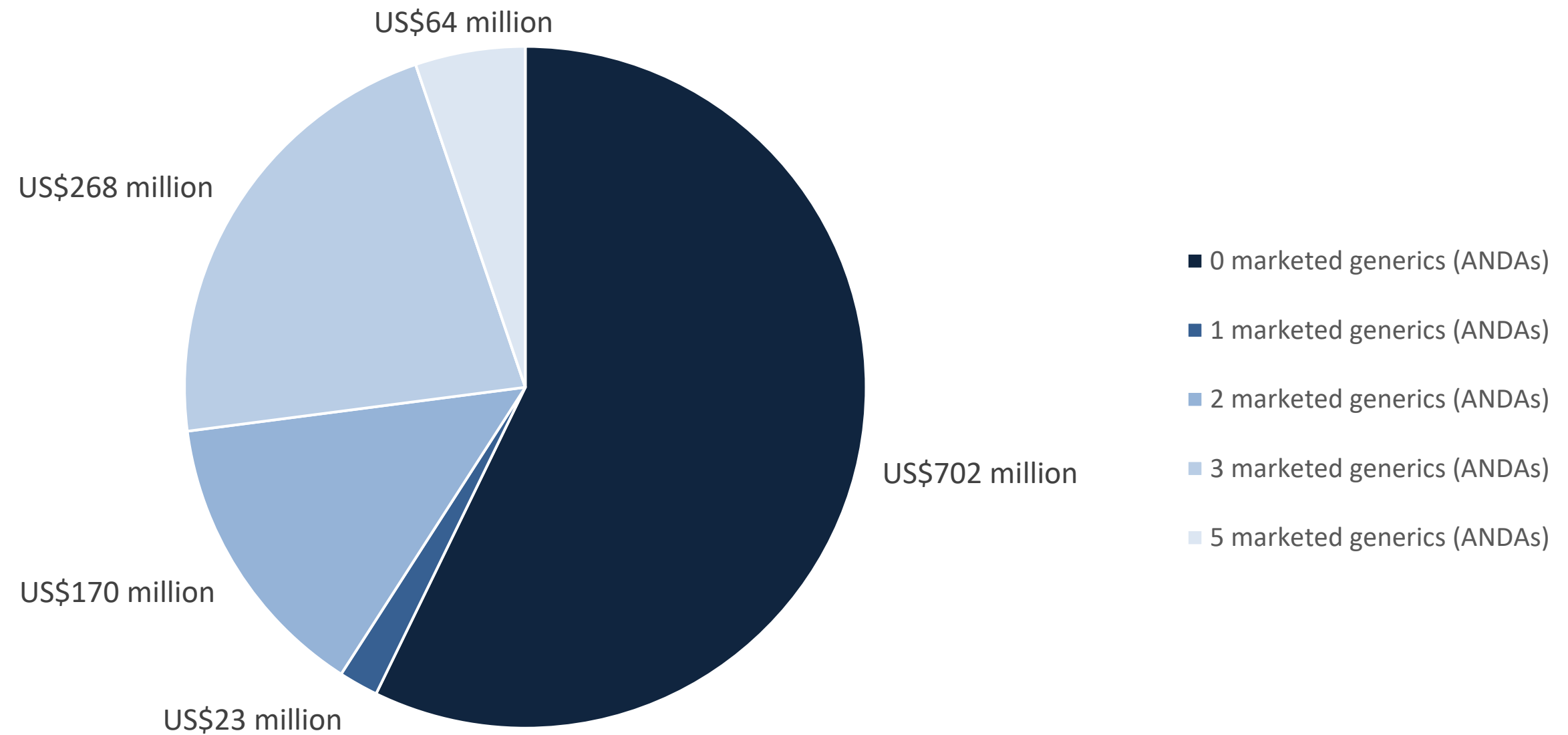
Opportunity to develop products for established but low competition generic products as well as newly genericised.

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
Number of products - Total	40	38	217

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

Acrux portfolio – addressable market is over \$1.2 billion*

Acrux products are targeting topical markets with limited competition

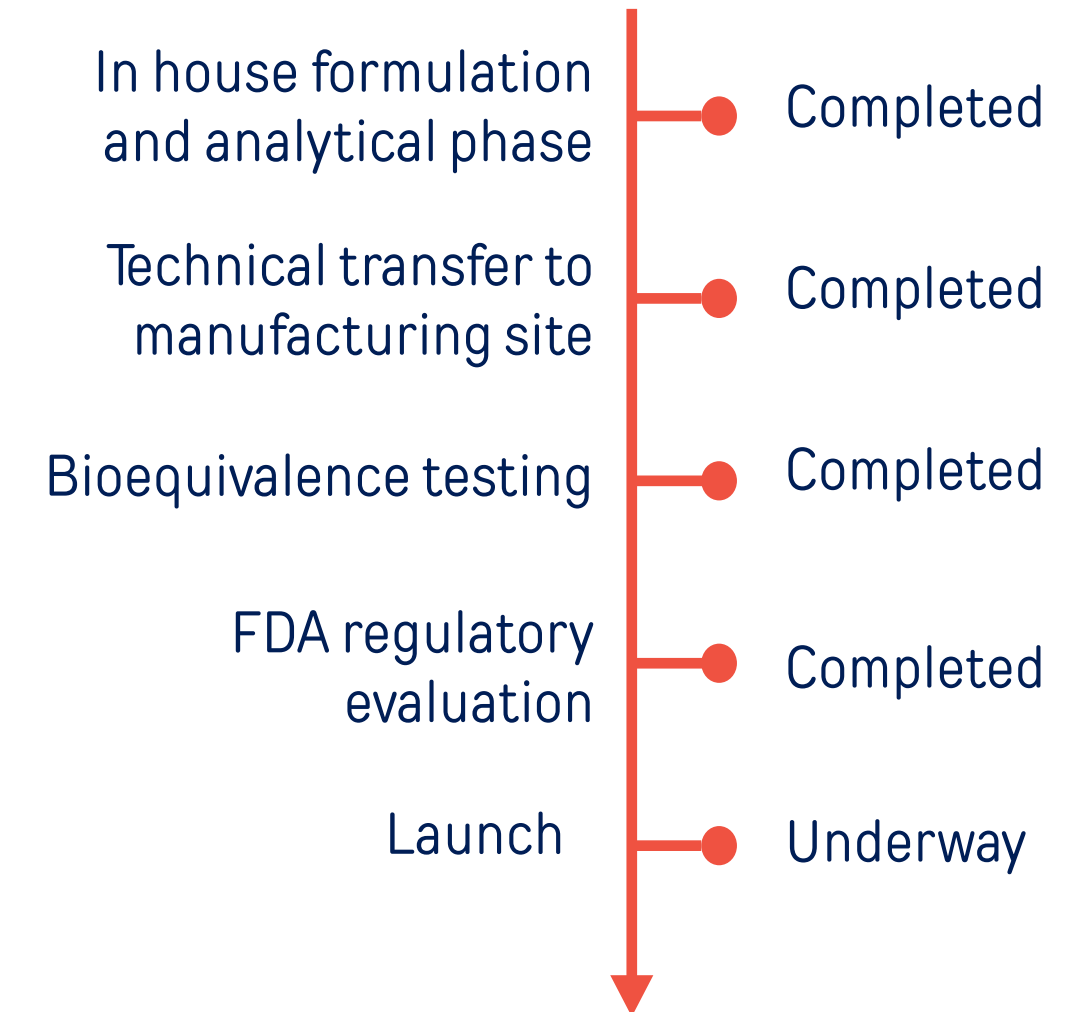


* IQVIA August 2024, MAT US\$ sales. A marketed ANDA is a marketed generic. The graph excludes branded products Evamist® and Lenzetto® (Estradiol Spray products) which have no generic competitors in Europe or the United States.

Product launch – Nitroglycerin 0.4%, Ointment

Indication	For the treatment of moderate to severe pain associated with chronic anal fissure
Addressable market	US\$23.2 million
Approved and marketed generics (ANDAs)	1
Development pathway for United States market	Compare Acrux product to reference drug with Q1 (same ingredients), Q2 (same concentration of ingredients), Q3 (same physical and chemical properties. Bioequivalence study with IVRT endpoint (in vitro drug testing).
Regulatory status in United States	Approved by FDA
Commercial status in United States	Launch activities underway
US commercially licensee	TruPharma
Ex-US commercial rights	Discussions underway

Key Milestones

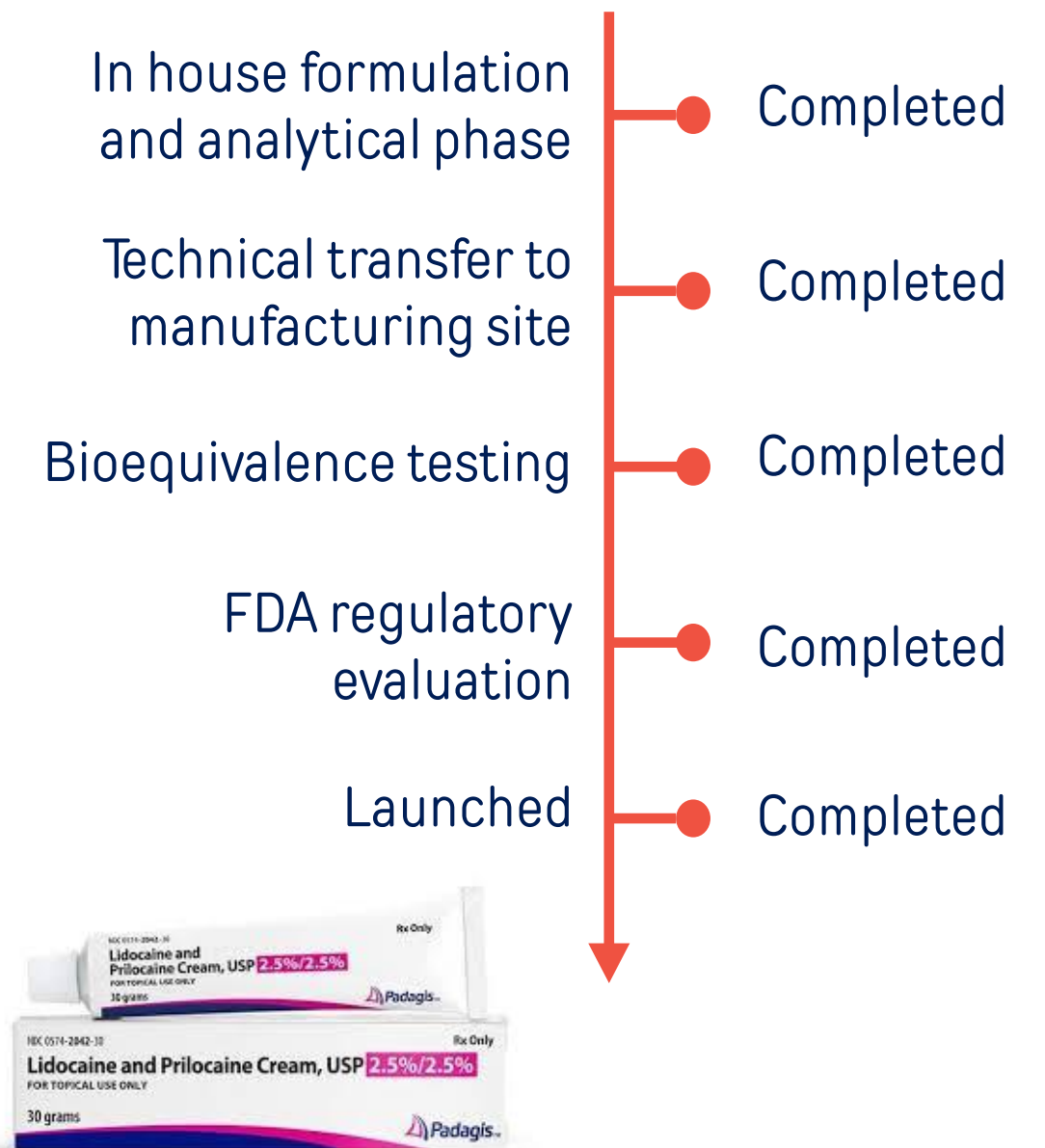


* Not approved outside the United States. Consult full prescribing information before use.

Marketed Product – Prilocaine 2.5%, Lidocaine 2.5%, Cream

Indication	Topical anesthetic for use on normal intact skin for local analgesia, or, genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia.
Addressable market	US\$24.4 million
Approved and marketed generics (ANDAs)	3
Development pathway for United States market	Bioequivalence study to demonstrate equivalent drug levels in plasma compared to reference product. Comparability of local skin reactions for the Acrux product and reference product.
Regulatory status in United States	Approved by US FDA
Commercial status in United States	Launched on 12/22
US commercially licensee	Padagis
Ex-US commercial rights	Discussions underway

Key Milestones

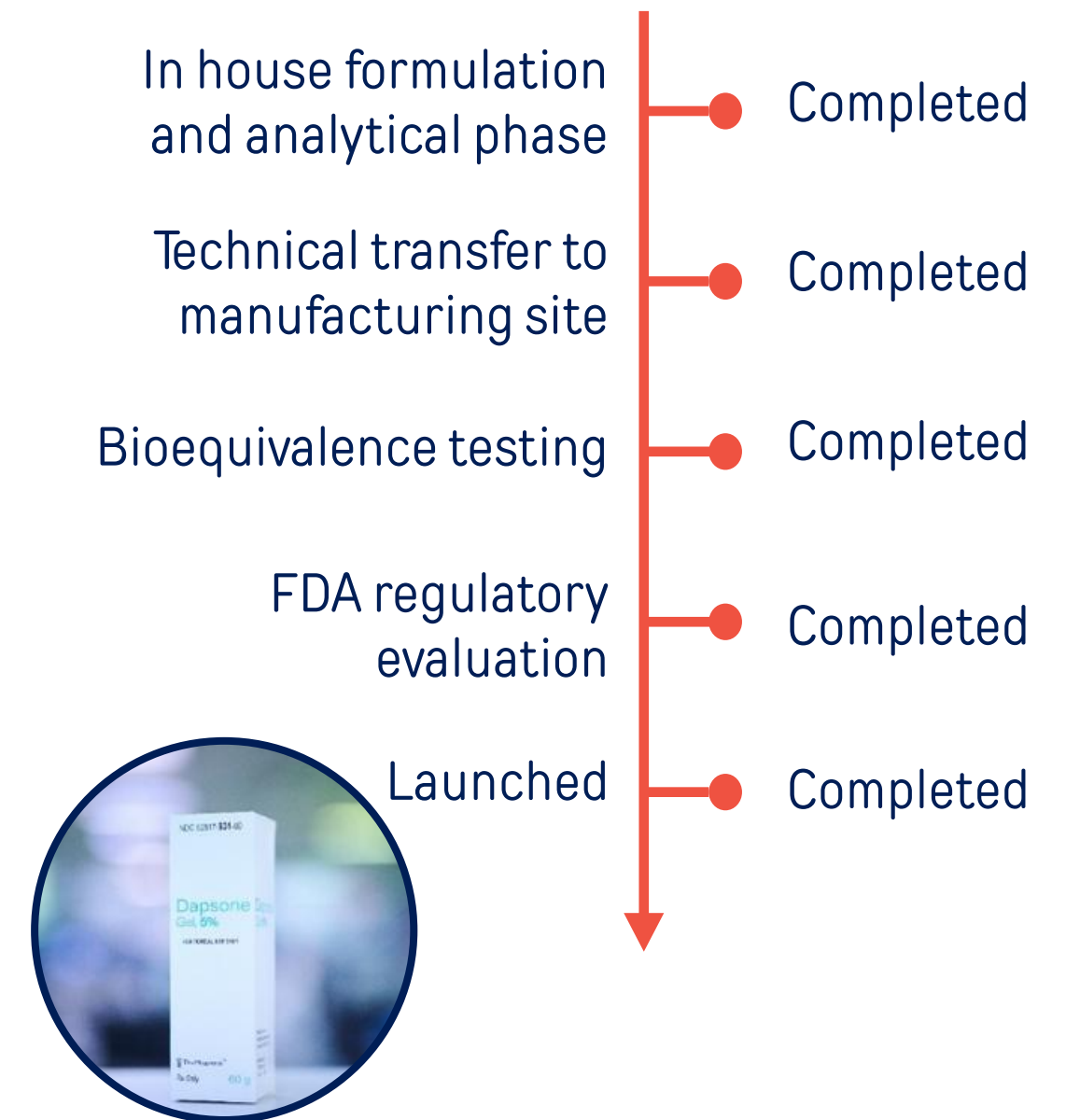


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Marketed Product – Dapsone 5%, Gel

Indication	The topical treatment of acne vulgaris
Addressable market	US\$15.8 million
Approved and marketed generics (ANDAs)	5
Development pathway for United States market	Compare Acrux product to reference drug with Q1 (same ingredients), Q2 (same concentration of ingredients), Q3 (same physical and chemical properties). Bioequivalence studies with IVRT, IVPT endpoints (in vitro drug testing).
Regulatory status in United States	Approved by US FDA
Commercial status in United States	Launched 04/24, range extension launch 12/24
US commercially licensee	TruPharma
Ex-US commercial rights	Discussions underway

Key Milestones

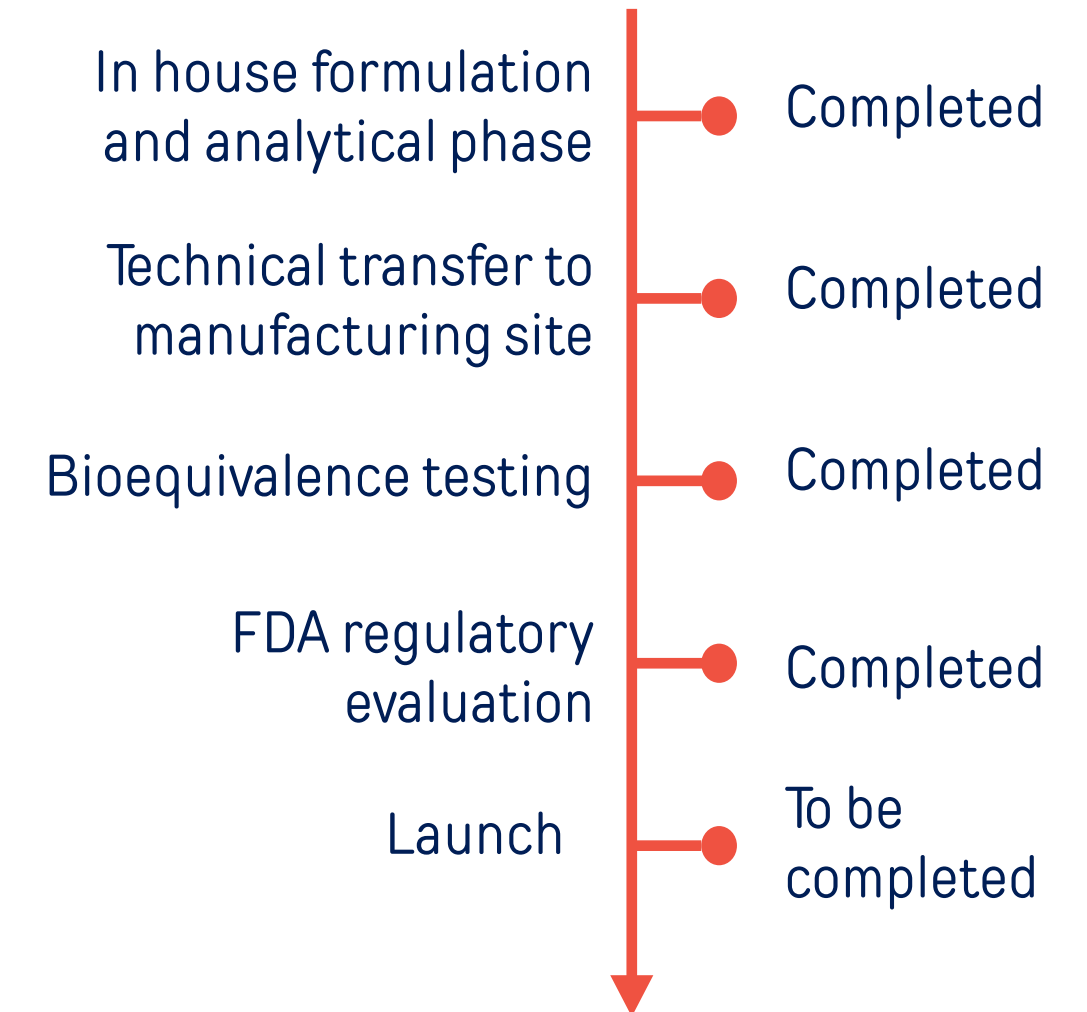


* Not approved outside the United States. Consult full prescribing information before use.

Product pending launch – Dapsone 7.5%, Gel

Indication	For the topical treatment of acne vulgaris in patients 9 years of age and older
Addressable market	US\$37.4 million
Approved and marketed generics (ANDAs)	5
Development pathway for United States market	Compare Acrux product to reference drug with Q1 (same ingredients), Q2 (same concentration of ingredients), Q3 (same physical and chemical properties). Bioequivalence studies with IVRT, IVPT endpoints (in vitro drug testing).
Regulatory status in United States	Approved by US FDA
Commercial status in United States	Launch planned FY25
US commercially licensee	TruPharma
Ex-US commercial rights	Discussions underway

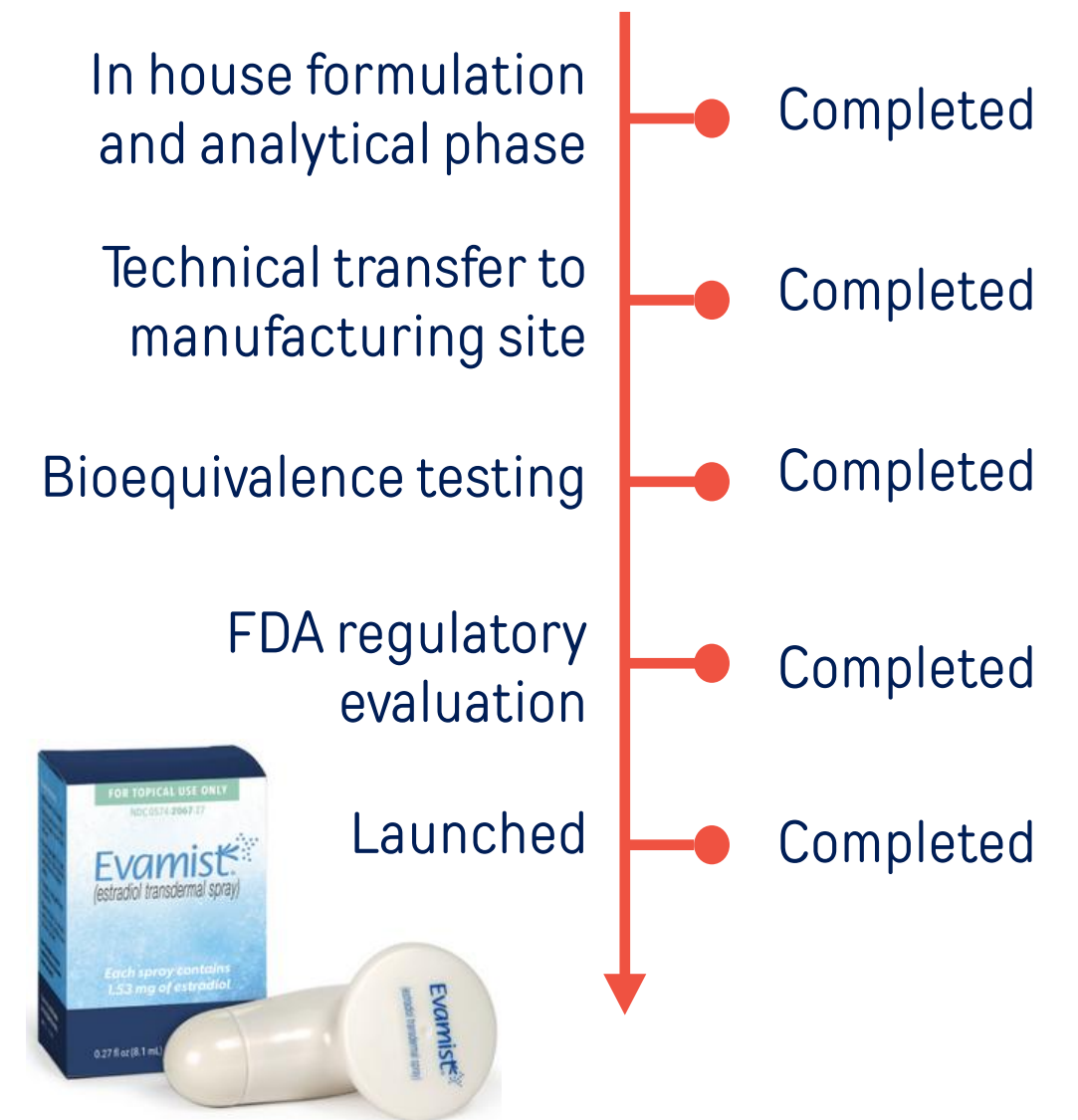
Key Milestones



Marketed Product – Evamist® Estradiol Spray

Indication	Treatment of Moderate to Severe Vasomotor Symptoms due to Menopause
Addressable market (transdermal products)	US\$437 million
Approved and marketed generics (ANDAs)	0
Development pathway for United States market	New Drug Application (NDA) pathway
Regulatory status in United States	Approved by FDA
Commercial status in United States	Launched in 2008
US Commercially licensee	Padagis
Ex-US commercial rights	Not available for partnering

Key Milestones



* Not approved outside the United States. Consult full prescribing information before use.

Pipeline Investment

Building upon a current US market size in excess of A\$150M across the 5 commercialised products and soon to be launched products in FY25*

Currently investing in 8 pipeline products

Pipeline products drive revenue growth in FY25 and beyond

Add new projects as pipeline products are approved and launched, aim to add 2/year

Acrux leadership



Ross Dobinson
Chairman

- 30+ years of experience in investment banking and stockbroking
- Formerly a Director of Reliance (RWC), Starpharma (SPL)



Michael Kotsanis
Chief Executive Officer

- 30+ years of experience in the global pharma markets
- Formerly CCO, Synthon; President, Hospira EMEA



Joanna Johnson
CFO / Company Secretary

- Chartered Accountant with 25+ years of experience in senior finance roles in Hospira, Lupin and IDT



Geoff Brooke
Non-executive Director

- 30+ years experience in the healthcare investment industry
- Founder and MD of Medvest Inc and GBS Venture Partners



Don Brumley
Non-executive Director

- 30+ years of experience as senior partner of Ernst and Young, Oceania
- Formerly Chairman of Bi-Gene (BGT)



Felicia Colagrande
R&D Director

- 25+ years of experience in pharma/biotech industry
- Previous roles at Faulding Pharmaceuticals and Austin Hospital



Tim Oldham
Non-executive Director

- 20+ years of experience in life sciences.
- Currently CEO AdAlta (1AD) and formerly President, Hospira APAC



Mark Hyman
Project Director

- 35 years of experience in pharmaceutical manufacturing, development and project management
- Local and international roles with Sandoz, Novartis and Hospira


Highly skilled and experienced Board and Management Team with decades of industry specific experience

Acrux track record of developing and commercialising products



3 recent **launches** in the United States, 1 near term launch planned



Total revenue generated **A\$20M***



1 product currently **under evaluation** by the FDA and 1 recently approved



FDA approval of 6 products since 2021



Strong pipeline of products under development

* FY23 and FY24

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