



## ASX Release

### Investor Presentation Share Purchase Plan closes Wednesday 18 December 5pm (AEDT)

Melbourne, Australia; 17 December 2024

Acrux Limited (ASX:ACR, “Acrux” or the “Company”), is pleased to update its investor presentation.

The investor presentation has been updated following the **commencement of launch activities for Nitroglycerin 0.4%, Ointment**. The FDA recently notified Acrux that the submission has been approved, product has been manufactured and Acrux’s licensee, TruPharma has commenced its commercial launch activities for the of the product in the US market.

The Company is currently offering a **Share Purchase Plan (SPP)** to eligible shareholders with a target to raise up to \$2 million (before costs). Shareholders as of 5:00pm (AEDT) on Wednesday 4 December 2024 with a registered address in Australia and New Zealand are eligible to participate in the SPP, which **closes on Wednesday 18 December at 5.00pm (AEDT)**. Further information regarding the SPP (including terms and conditions of the SPP) have been provided to eligible shareholders in an SPP Offer Booklet with a link to a personalised application form.

A copy of the presentation follows this announcement.

Approved for release by the Managing Director.

#### For more information, please contact:

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**Acrux Limited**  
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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](http://www.acrux.com.au)



# Investor Presentation

December 2024

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





# 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.



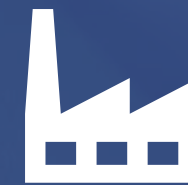
# Acrux is a leader in the development of topically applied prescription pharma products



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 in the next 3 months.

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](http://www.acrux.com.au)



# 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 (IAD) 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

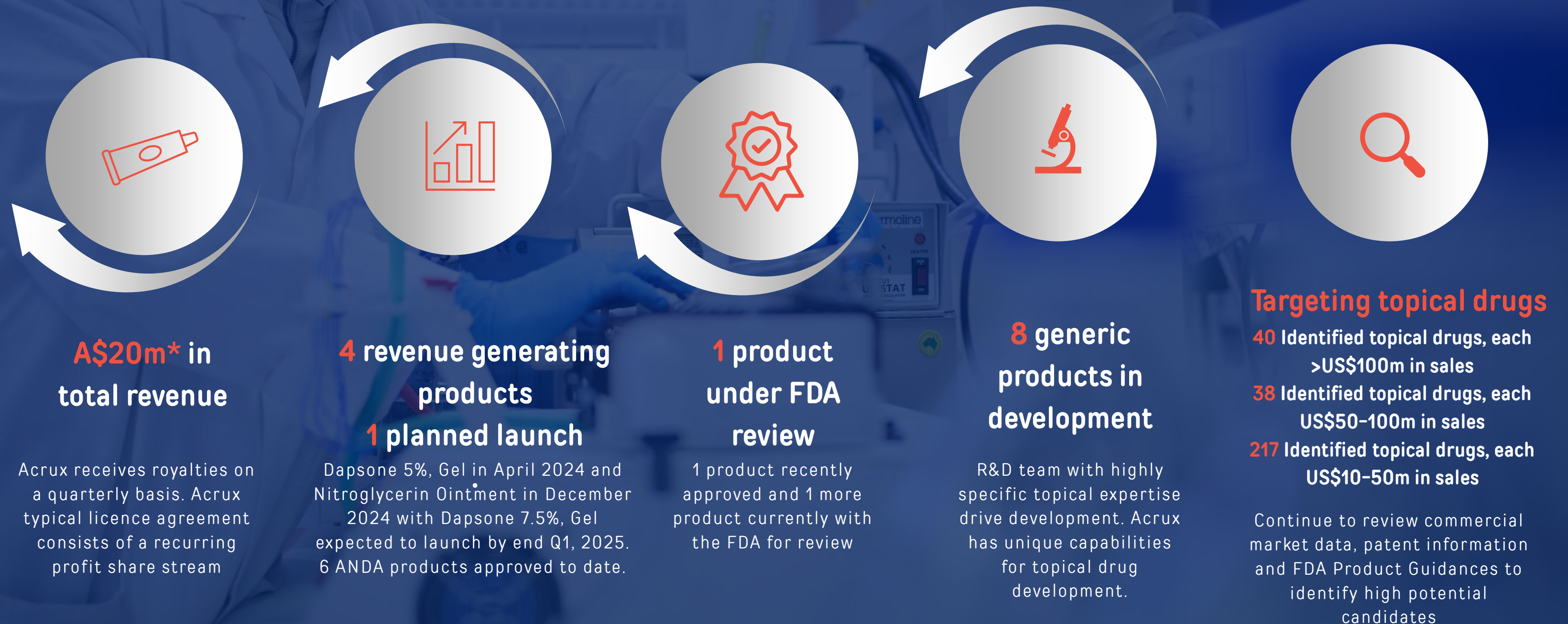


**Highly skilled and experienced  
Board and Management Team  
with decades of industry  
specific experience**



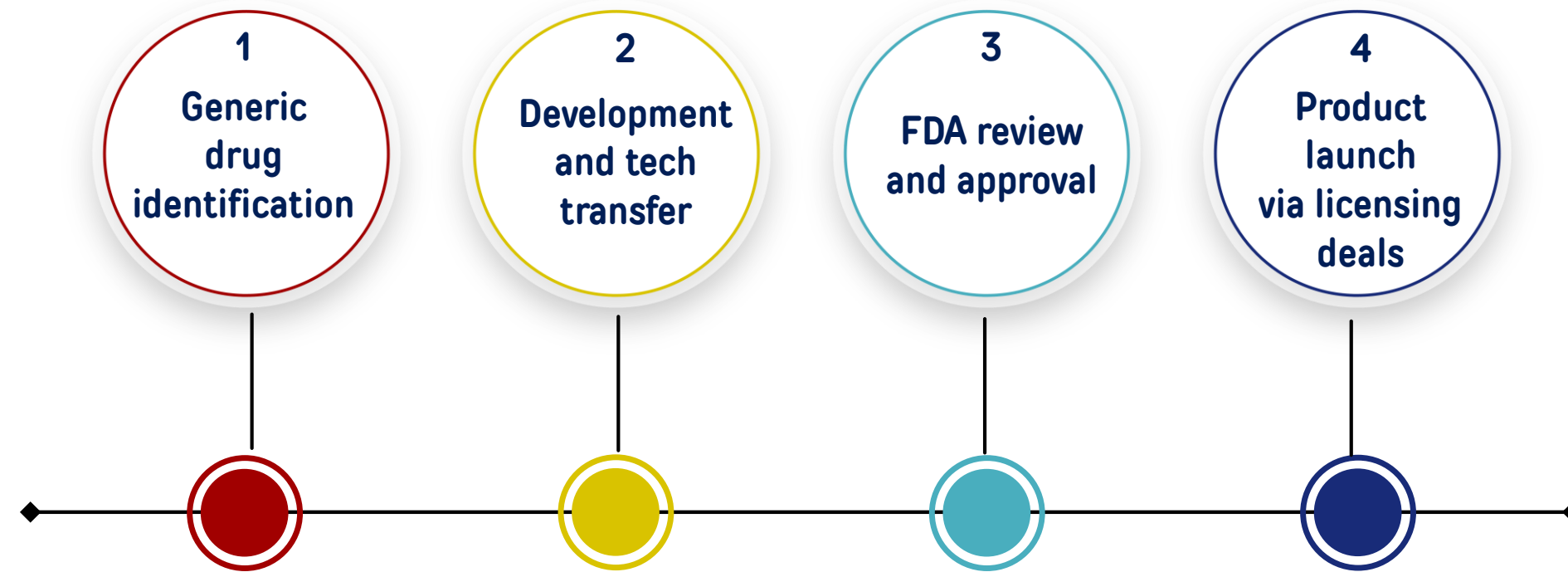
# Acrux growth platform

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



\* 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

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

\* Lenzetto® is marketed in ex-US and the Acrux royalty stream was monetised in FY23



# Acrux revenue is generated through long term commercial relationships



## **Commercial Partners in the United States:**

Padagis – is the 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

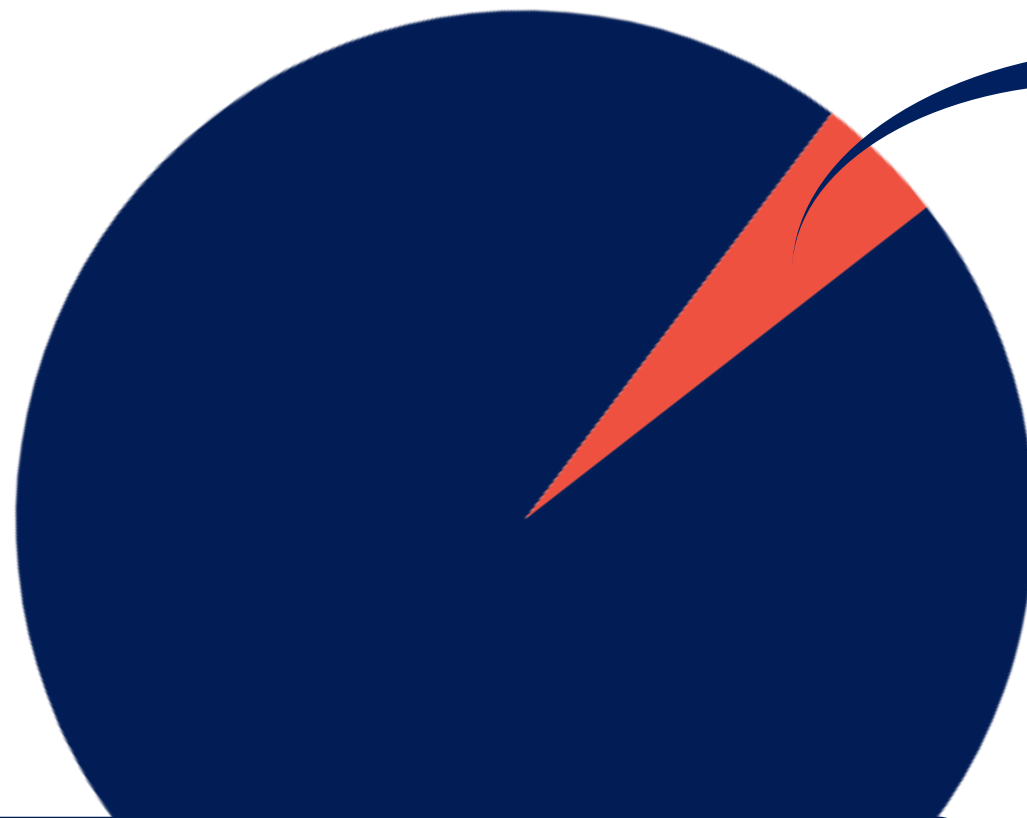
Experienced team to manage development and regulatory process through to commercialisation

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.

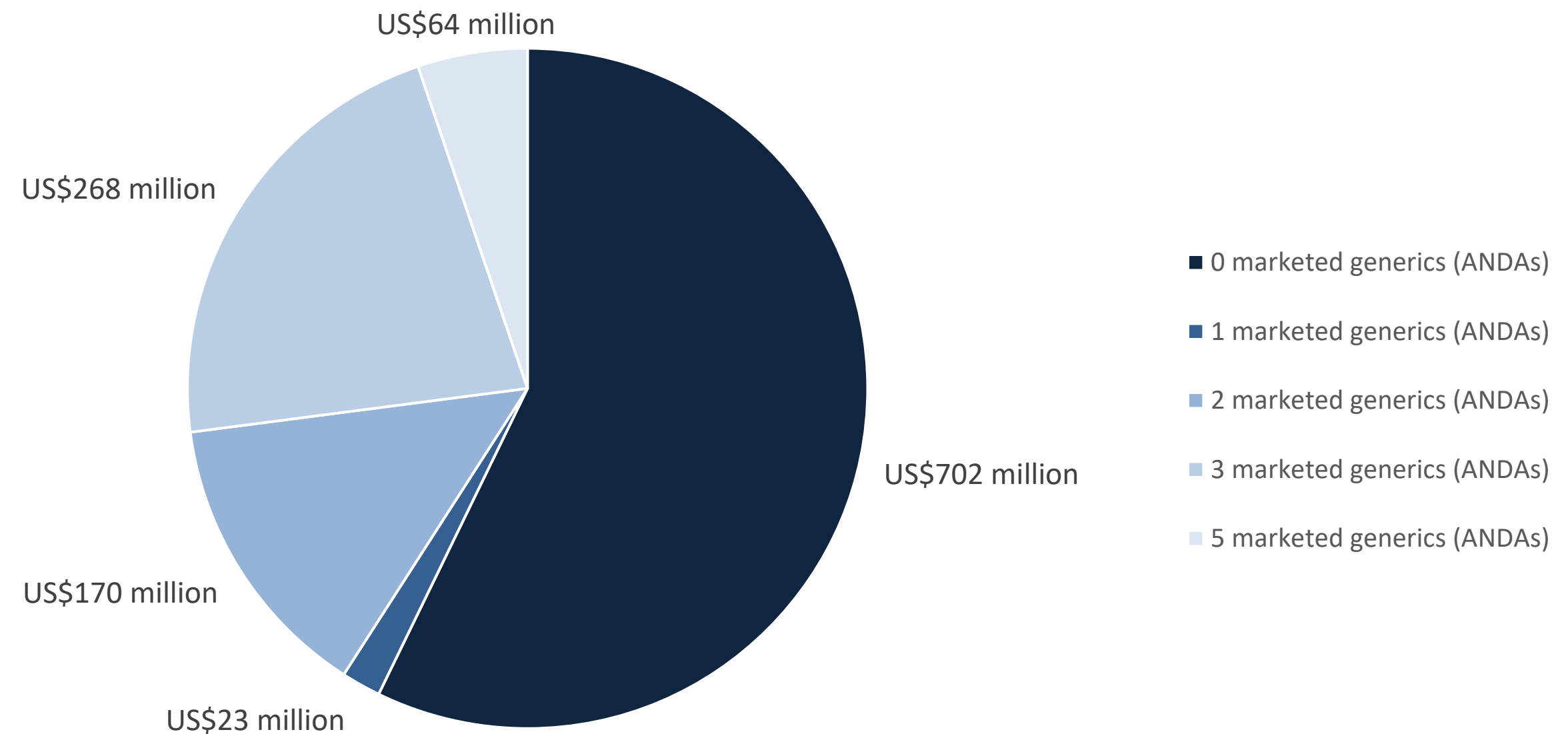
Opportunity to develop products for established but low competition generic products as well as newly genericised.

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
<b>Number of products - Total</b>	<b>40</b>	<b>38</b>	<b>217</b>

\* 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



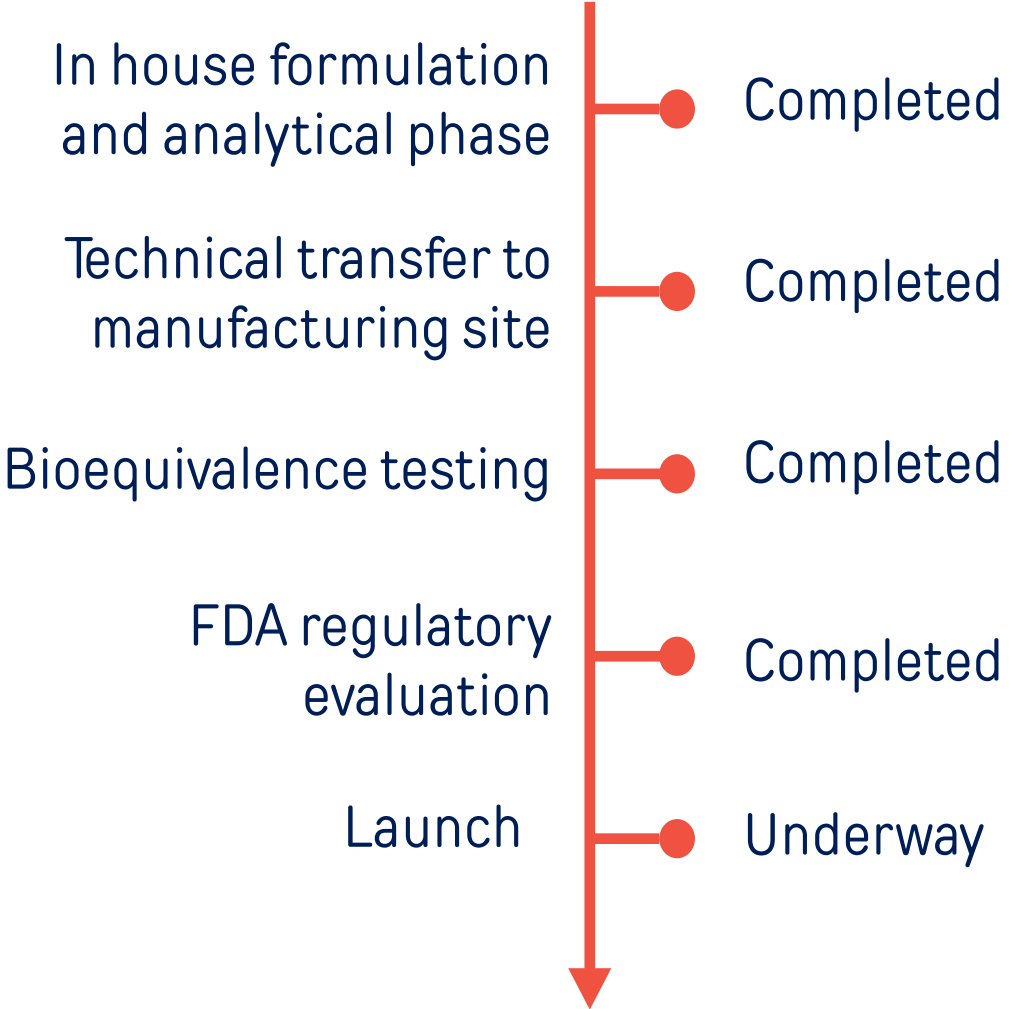
\* IQVIA August 2024, MAT US\$ sales. A marketed ANDA is a marketed generic. The graph excludes branded products Evamist® and Lenzetto® (Estradiol Spray products) which have no generic competitors in Europe or the United States.



# 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

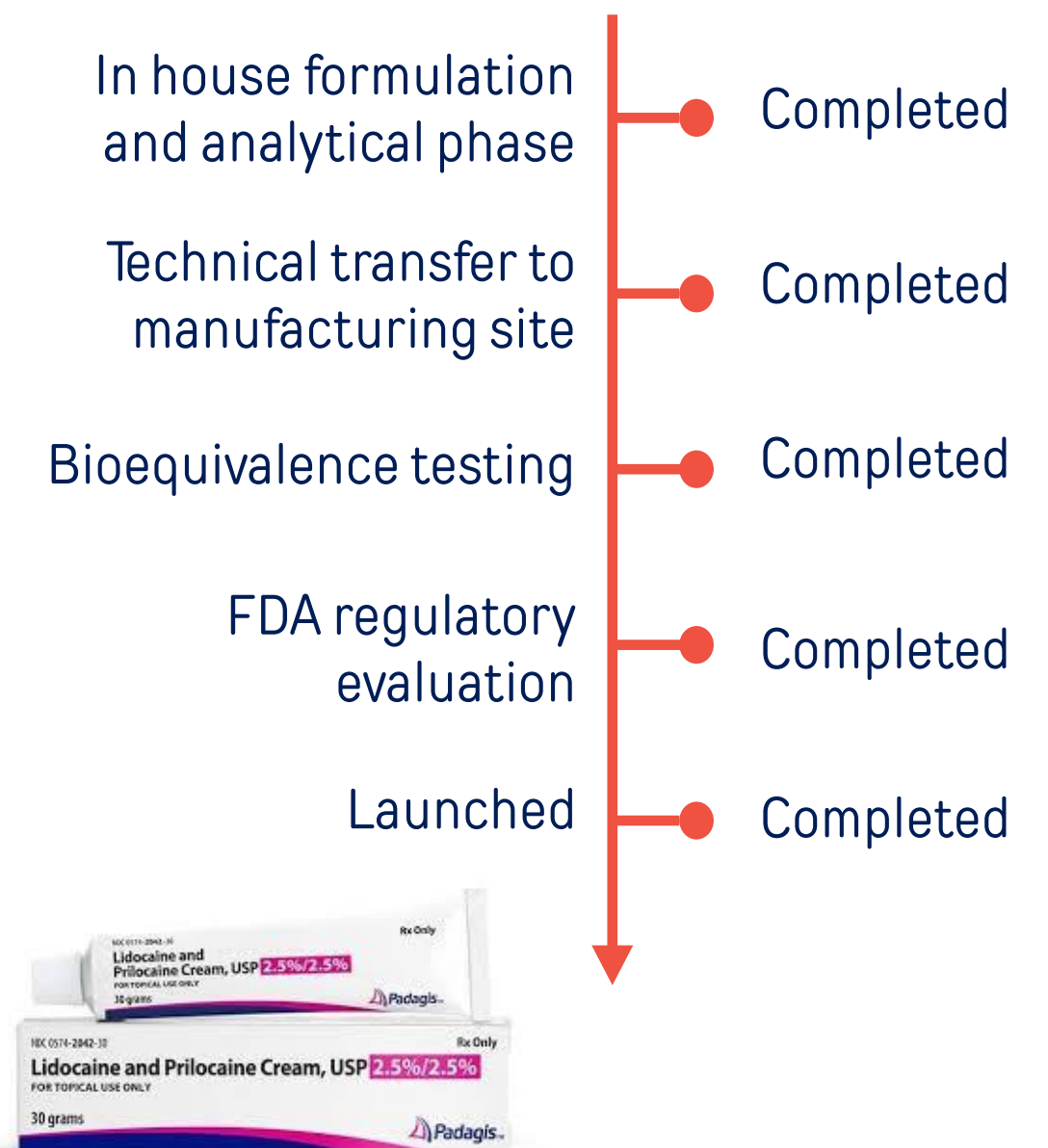


\* Not approved outside the United States. Consult full prescribing information before use.

# 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

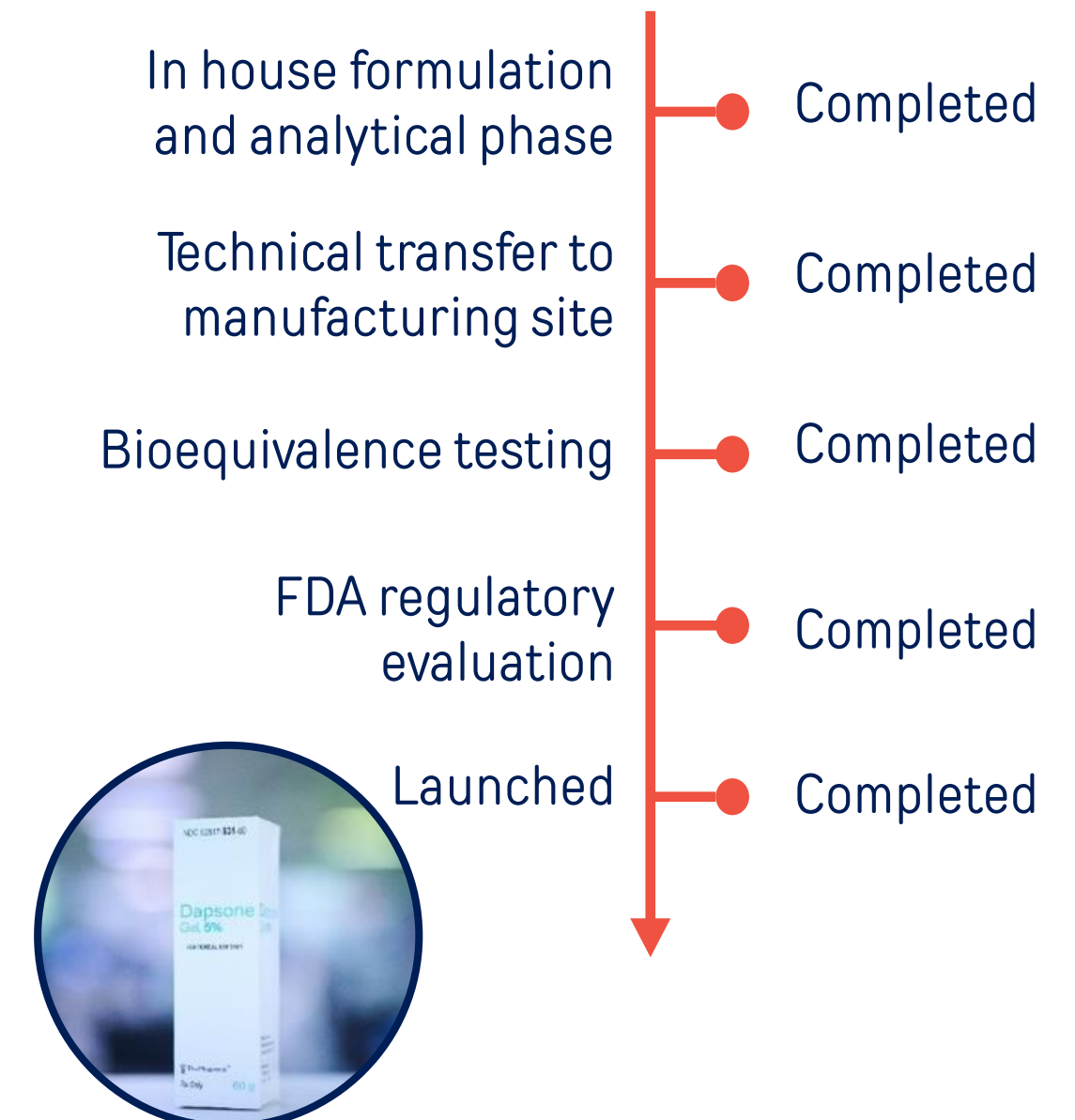




# Marketed Product – Dapsone 5%, Gel

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 pending
US commercially licensee	TruPharma
Ex-US commercial rights	Discussions underway

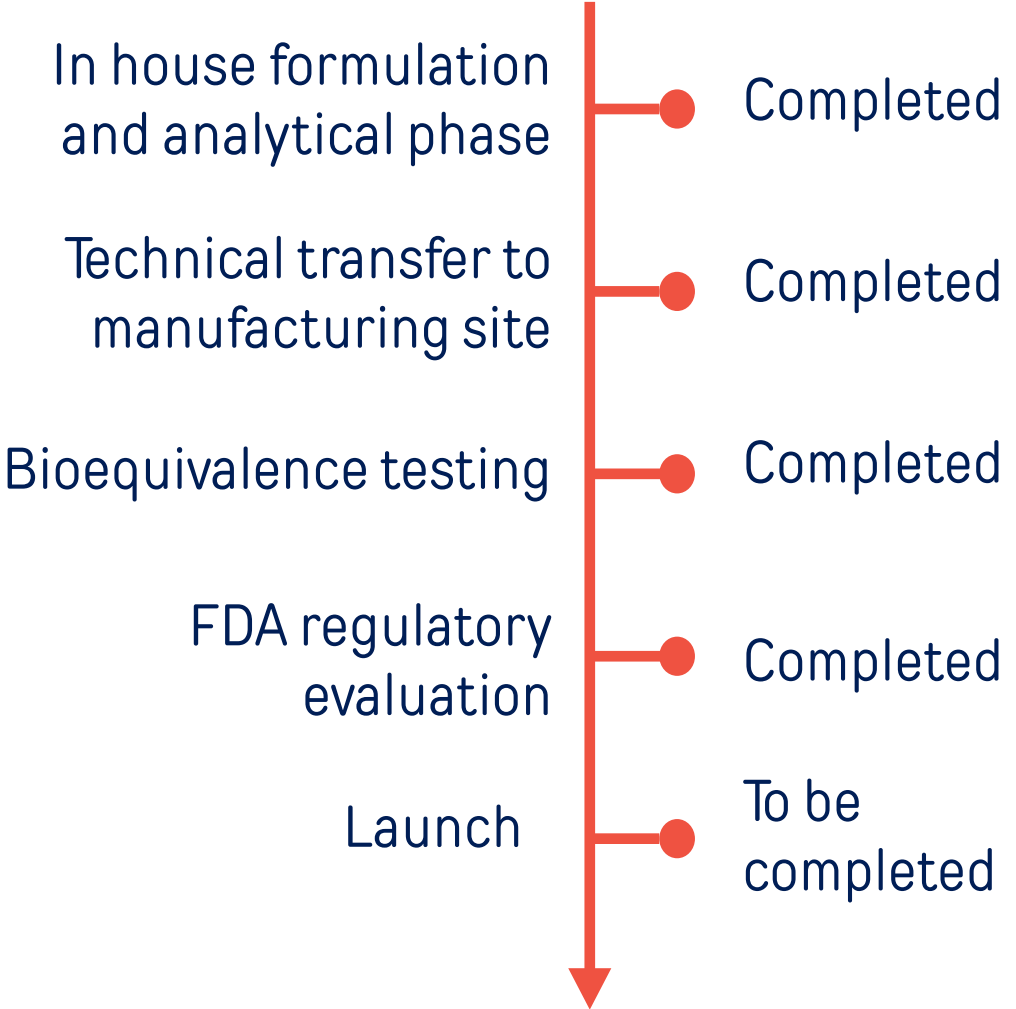
## Key Milestones



# 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 Q1, 2025
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 – 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

In house formulation and analytical phase

Completed

Technical transfer to manufacturing site

Completed

Bioequivalence testing

Completed

FDA regulatory evaluation

Completed

Launched

Completed



\* 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 track record of developing and commercialising products



3 recent **launches** in the United States, 1 more 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

# Capital Raise Plan

Trading Halt	3 December 2024
Placement bids due	4 December 2024
ASX announcement on placement & resume trading	5 December 2024
Placement settlement date	Week commencing 9 December 2024
Record Date for SPP	4 December 2024
Announcement of SPP offer	5 December 2024

Dispatch of SPP offer booklet and opening date of SPP offer	6 December 2024
Closing date of SPP offer	18 December 2024
Announcement of results of SPP	23 December 2024
SPP shares commence trading on ASX and dispatch of holding statements	24 December 2024
Prospectus for Attaching Options	January 2025
Notice of Meeting for Extraordinary General Meeting (EGM) to approve Director Placement subscriptions and Attaching Options for Placement and SPP subscriptions	January 2025



# Capital Raise Offer – to raise \$4.65 million via a \$2.65m Placement and \$2m SPP

Placement	<ul style="list-style-type: none"> <li>A Placement to sophisticated and professional investors of \$2.65 million comprising: <ul style="list-style-type: none"> <li>The issue of approximately 71,428,571 new ordinary fully paid Acrux shares (New Shares) utilizing the Company’s capacity under 7.1 and 7.1A to raise approximately \$2.5 million</li> <li>The issue of approximately 4,285,714 new ordinary fully paid Acrux shares (New Shares) to Acrux Directors for a combined Placement of \$150,000. The Director Placement is on the same financial terms as the Placement to sophisticated and professional investors and is subject to shareholder approval at an extraordinary general meeting (EGM) to be held in February 2025</li> </ul> </li> </ul>
Offer Price	<ul style="list-style-type: none"> <li>Offer Price of 3.5 cents per New Share represents a 19.35% discount to the 5-day VWAP to 3 December 2024</li> </ul>
Share Purchase Plan (SPP)	<ul style="list-style-type: none"> <li>The Company will offer eligible shareholders the opportunity to participate in a SPP and apply for up to A\$30,000 of New Shares to raise up to an additional A\$2 million. The SPP will be offered at the same financial terms as the Placement.</li> <li>Record Date for determining eligibility for the SPP is 5.00pm (AEDT) on Wednesday 4 December 2024.</li> <li>Further details in relation to the SPP, including the scale back policy, will be provided to eligible shareholders in an SPP booklet and will be published on the ASX announcements page for Acrux and the Acrux website</li> </ul>
Attaching Options	<ul style="list-style-type: none"> <li>Shares will be offered under the Placement and SPP with one free Attaching Option for every New Share issued</li> <li>The Attaching Options are intended to be listed on the ASX with an exercise price of 5.25 cents and will expire 2 years after issue</li> <li>The Attaching Options will be offered under a transaction-specific prospectus and the issue of Attaching Options will be conditional on shareholder approval at an EGM. The Attaching Options offer is also conditional on the Attaching Options meeting the ASX’s quotations conditions</li> </ul>
Ranking	<ul style="list-style-type: none"> <li>Shares issued under the Offer will rank equally with existing Shares on issue (save for the entitlement to subscribe for Attaching Options)</li> </ul>
Joint Lead Managers	<ul style="list-style-type: none"> <li>Evolution Capital Pty Ltd and Peak Asset Management</li> </ul>

## Connecting with Acrux



[www.acrux.com.au](http://www.acrux.com.au)

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