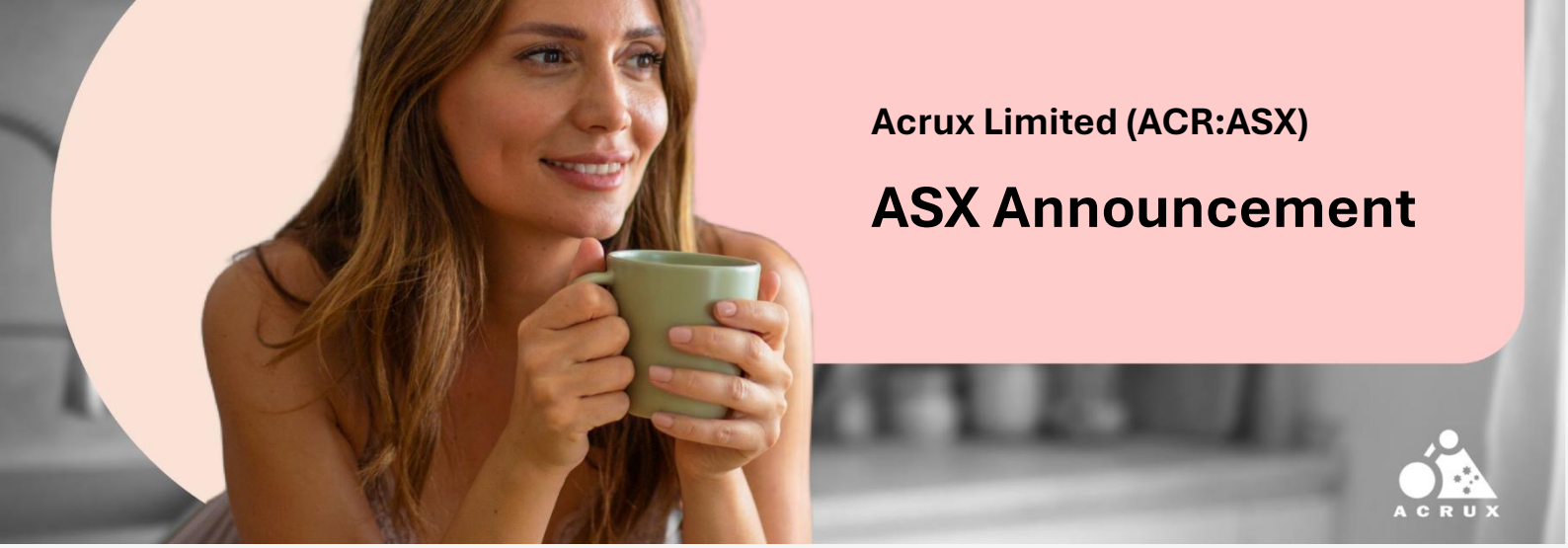

Acrux Limited (ACR:ASX)

ASX Announcement

24 November 2026

Presentation to Annual General Meeting

Melbourne, Australia; Acrux Limited (ASX:ACR): Acrux is pleased to announce the presentation which will be made to the 2026 Annual General Meeting.

ENDS

Approved for release by the Board of Acrux Ltd.

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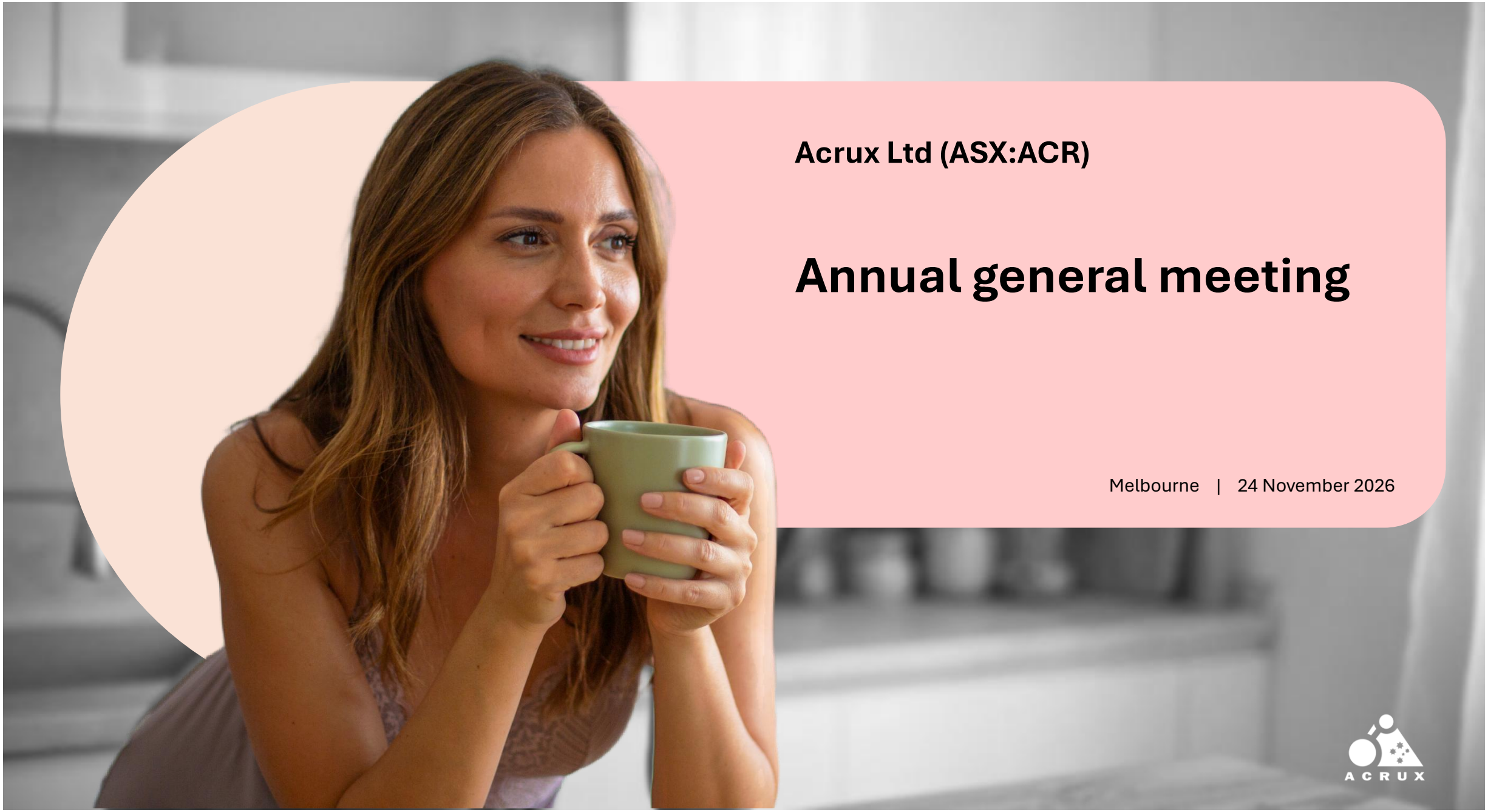
About Acrux:
Acrux Limited (ASX:ACR) is a specialty pharma company with a successful track record of developing and commercialising a pipeline of topically applied pharmaceutical products. Drawing on 25 years of experience, Acrux has successfully marketed through licensees a number of products worldwide with emphasis on the United States.

Click here to sign up to our InvestorHub and keep up to date with company news and latest developments or for further information on Acrux Limited visit www.acrux.com.au

END.



Acrux Ltd (ASX:ACR)

Annual general meeting

Melbourne | 24 November 2026

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, operating conditions, and on a number of assumptions regarding future events and actions that, as at the date of this presentation, are reasonably 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.

Female Testosterone MDTS catalyses Acrux's investment proposition



Helping millions of women with Hypoactive Sexual Desire Disorder (HSDD)

Phase III stage asset.

Significant, fast-growing market.

Early mover advantage.

Favourable FDA position.

Co-development pathway.

What is Hypoactive Sexual Desire Disorder (HSDD)?

Commonly expressed as low or absent sexual desire and/or response to stimulation

Other symptoms include:

- Low self-esteem
- Reduced energy
- Social conflict
- Depression
- Anxiety



~4.9m
menopausal women in the US affected

~10%
of all adult women impacted

References:

- *Islam, RM, Bell, RJ, Green, S, Page, MJ, Davis, SR, (2019). Safety and efficacy of testosterone for women: a systematic review and meta-analysis of randomised controlled trial data. The Lancet Diabetes & Endocrinology. Vol. 7(10), 754–766.*
- *Ronghe V, Pannase K, Gomase KP, Mahakalkar MG, (2023) Understanding Hypoactive Sexual Desire Disorder (HSDD) in Women: Etiology, Diagnosis, nd Treatment. Cureus. Vol. 15(11)*
- *Parish, SJ, Kling, JM, (2023). Testosterone use for hypoactive sexual desire disorder in postmenopausal women. Menopause. Vol. 30(7) 781-783*
- *Shifren, JL, Monz, BU, Russo, PA, Segreti, A, & Johannes, CB. (2008). Sexual problems and distress in United States women: prevalence and correlates. Obstetrics and gynecology, 112(5), 970–978*

HSDD impacts more than desire

It touches every part of a women's well being



SEXUAL HEALTH
Desire – Intimacy - Satisfaction

RELATIONSHIP HEALTH
Connection – Communication - Closeness

EMMOTIONAL WELL-BEING
Mood – Stress – Mental wellness

QUALITY OF LIFE
Fulfilment – Happiness – Life satisfaction

SELF CONFIDENCE
Body image – Self esteem – Feeling like yourself

Addressing HSDD can help women reclaim their well-being - inside and out



Professor Susan R Davis

AO, MBBS FRACP PhD FAHMS

- Head of the Monash Women's Health Research program.
- Fellow and council member of the Australian Academy of Health and Medical Sciences.
- Advisor to the NHS Menopause Improvement Program Steering Committee.
- Author of the 2019 Global Consensus Position Statement on the Use of Testosterone Therapy for Women. ^

Testosterone is not simply a male hormone but is also **an important hormone in women**. Low sexual desire is the most prevalent sexual concern amongst women. When sufficient to cause personal distress women are considered as having hypoactive sexual desire dysfunction or HSDD.

There is irrefutable evidence that testosterone therapy in doses that result in blood levels within the physiological range for premenopausal women **improves** sexual desire, arousal, orgasm and sexual self-image and **reduces** personal distress in postmenopausal women with HSDD.

Acrux's Testosterone* MDTS# has the advantages of acting as a "**patchless**" patch with good pharmacokinetic evidence of absorption

^ Davis, SR, Baber, R, Panay, N, Bitzer, J, Perez, SC, Islam, RM, Kaunitz, AM, Kingsberg SA, Lambrinoudaki I, Liu J, Parish SJ, Pinkerton J, Rymer J, Simon JA, Vignozzi, L, Wierman ME, (2019). Global Consensus Position Statement on the Use of Testosterone Therapy for Women. The Journal of Clinical Endocrinology & Metabolism. Vol 104(10), pp. 4660-4666.

** Acrux Testosterone is not yet registered for this indication. # MDTS – Metered Dose Transdermal System*

Testosterone: A Transformative Opportunity in Women's Health



Core Indication HSDD

HSDD is the primary clinical application for testosterone therapy in women, serving as the foundation of treatment.

Potential beyond HSDD

- **Sexual Health Spectrum**

Testosterone influences multiple aspects of female sexual function including FSAD and orgasmic disorders beyond HSDD.

- **Cognition and Memory**

Emerging research links testosterone to cognitive performance and healthy aging in women.

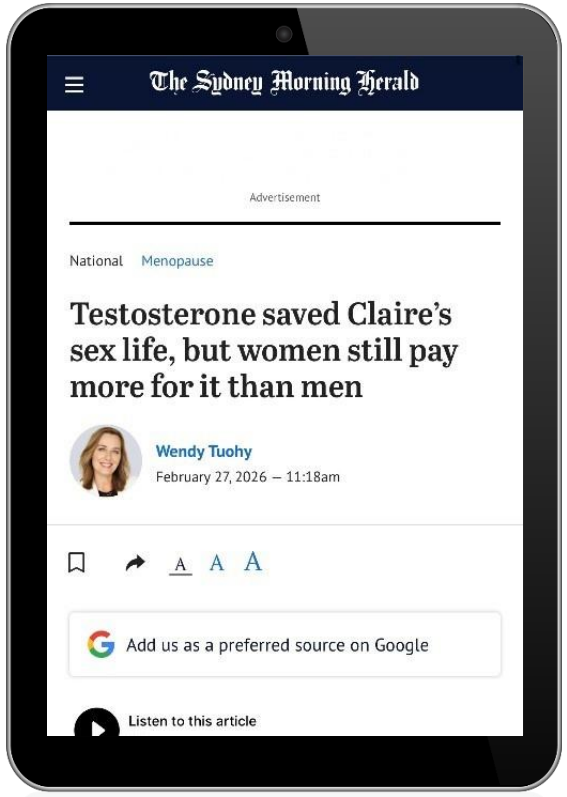
- **Bone and Musculoskeletal Health**

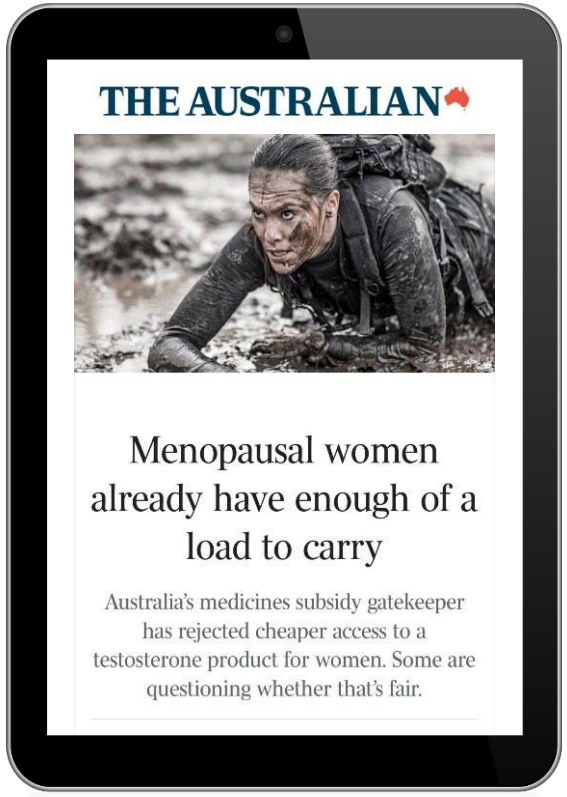
Testosterone supports skeletal integrity, muscle strength, and physical well-being in women.

Female Testosterone Awareness

Female Testosterone is gaining significant mainstream patient population awareness and traction across key global markets.









Acrux's story

1998:
Acrux incorporated to commercialise unique drug delivery technology invented at **Monash University**

2001:
First US patent granted

2003:
Recuvyra®
Veterinary product licensed to Elanco globally

2004:
ASX listing

2007:
Evamist® licensed to KV Pharmaceutical in US

ESTRADIOL

2011:
Axiron® launched by Eli Lilly

MALE TESTOSTERONE

2016:
Lenzetto® launched in Europe by Gedeon Richter

ESTRADIOL

2022:
Lidocaine 2.5% and Prilocaine 2.5% Cream) launched in USA

2024:
Launch Dapsone 5%, Gel

2024:
Launch Nitroglycerine 0.4%, Ointment

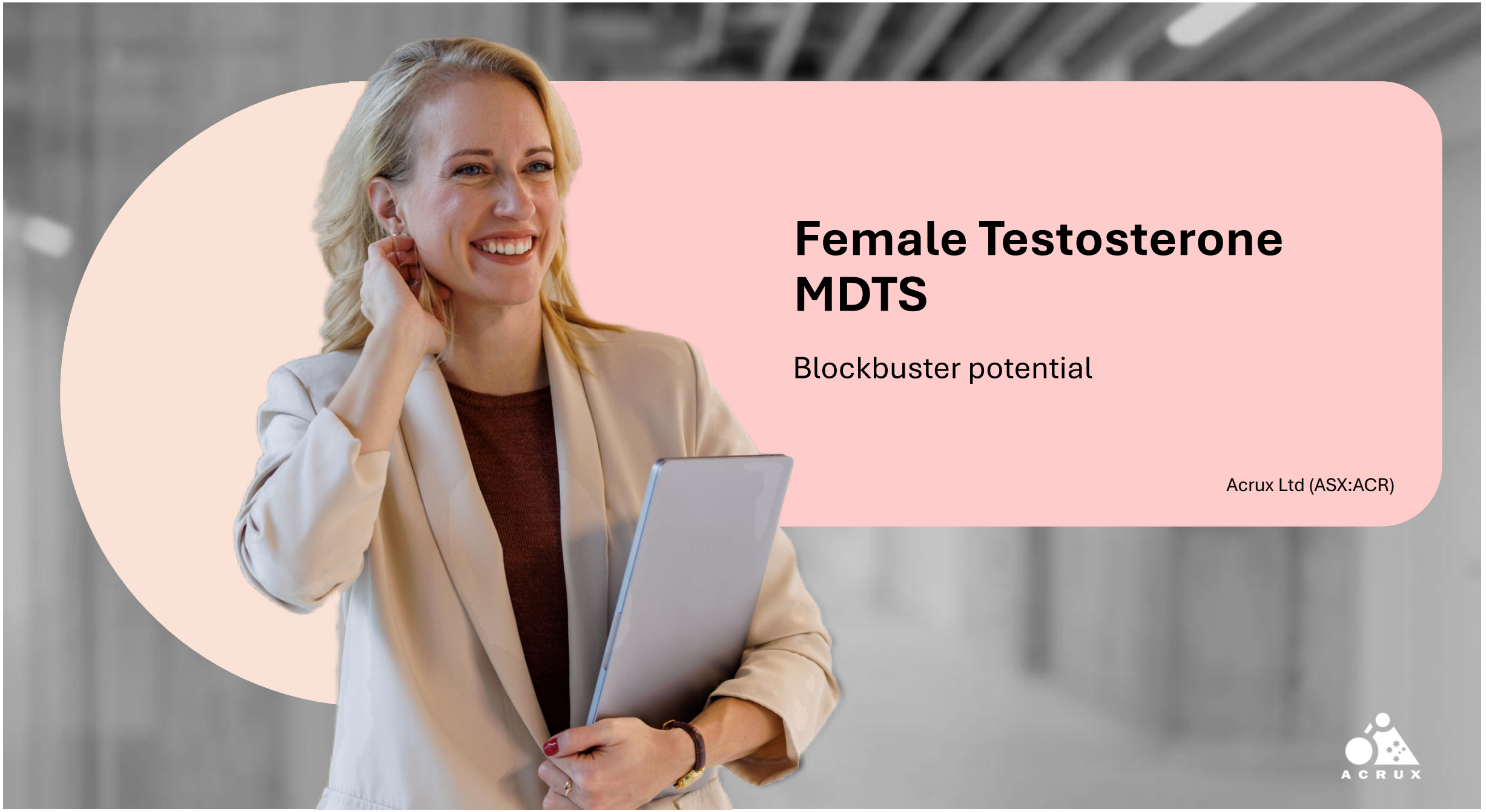
2025:
Launch Dapsone 7.5%, Gel

2026
Female Testosterone MDTS

Innovative Skin Delivery Technology

Topical Generics

MDTS

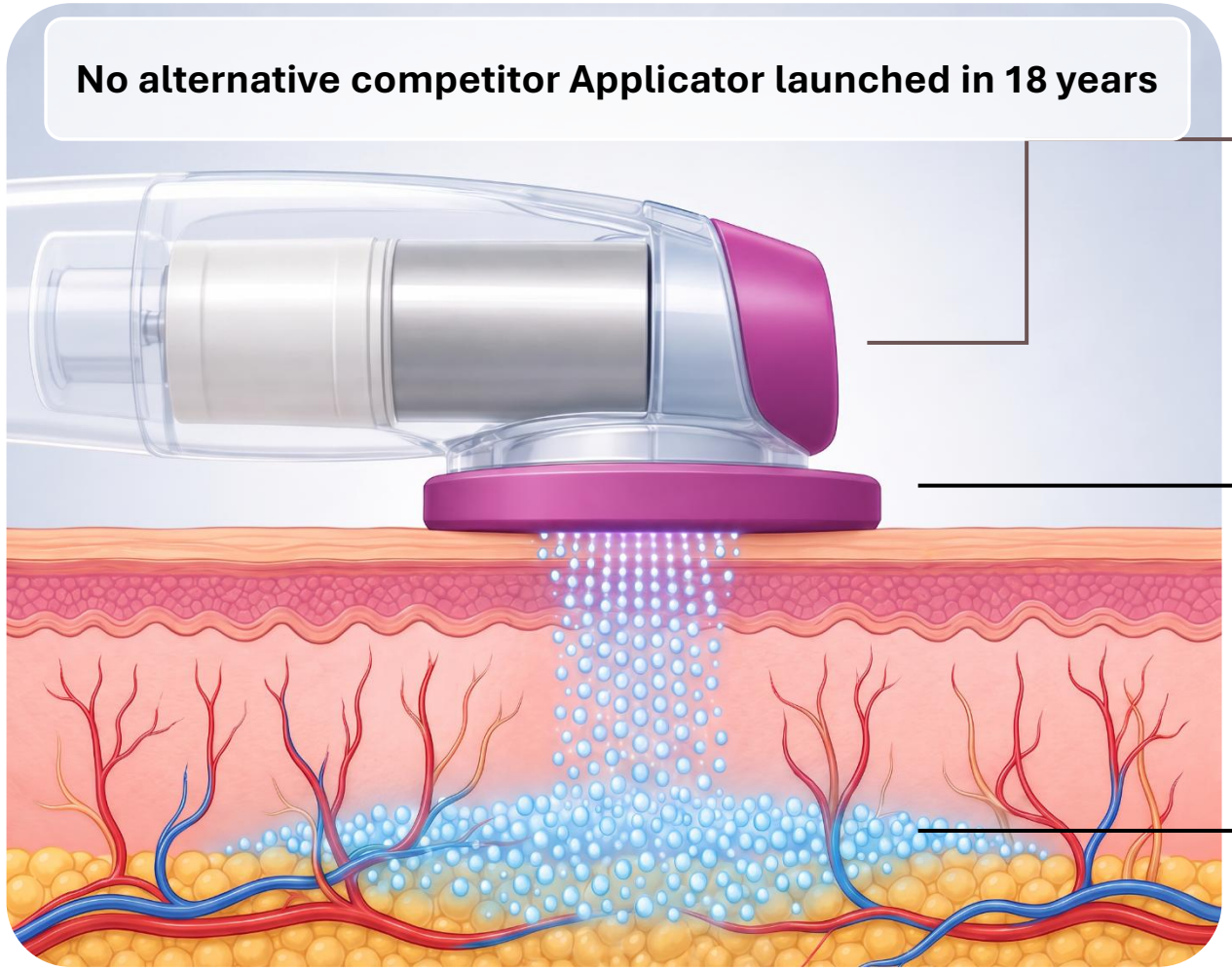


Female Testosterone MDTS

Blockbuster potential

Acrux Ltd (ASX:ACR)

Acrux Proven MDTS Technology



Proprietary MDTS (Metered Dose Transdermal System) Applicator

Delivers a controlled spray of Female Testosterone through the skin

Patchless Patch™ forms an invisible reservoir within the skin

Lenzetto® and Evamist® delivery technology ensures high scalability once in market.

Global Positioning of Testosterone Therapy for Women

FDA “Black box" warnings: On hormone therapy products for over 20 years, its strongest caution creating a significant barrier for providers and patients.

Safety & Efficacy : Inconsistent treatment outcomes and dosing raised risks and patient safety issues.

First evidence-based guidelines: For testosterone therapy in women worldwide from Global Consensus Position Statement (GCS) in 2019.

GCS noted an unmet medical need for a testosterone transdermal product formulated for female clinical use. **Female Testosterone MDTS® (4.5 mg per spray) has been shown to achieve this clinically.**

Off-Label Prescribing: Testosterone therapy for women is often based on male formulations and lack standardised dosing.

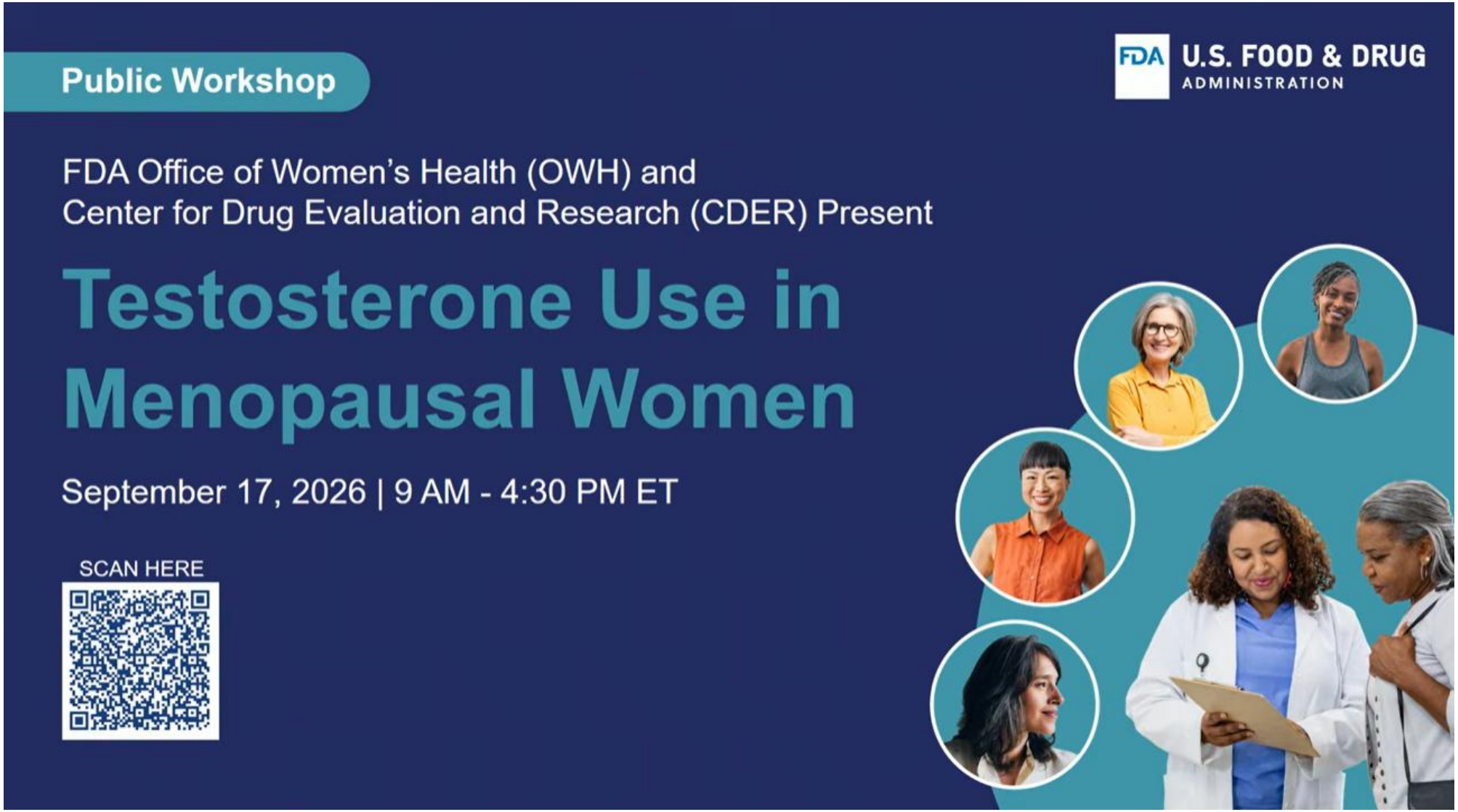
Regulatory & Research Gaps: Absence of female-specific products and regulatory clarity hindered pharmaceutical innovation.

Removal of Black box warnings: FDA with renewed focus on menopause and hormone-therapy policy, seeks to encourage treatments.

Historical Barriers

New Global Pathway

US FDA public forum highlights unmet need



US FDA public forum take out messages



Acrux's Female Testosterone MDTS is a strong match to the FDA's requirements

- Female specific product needed
- Dosage control essential for women
- High risk for off label use of male testosterone
- FDA approved product needed
- FDA looking to work with sponsors

https://drive.google.com/file/d/18iVb3aqXWVd3aDqy3hdiWHcCIDHg6wYO/view?usp=sharing

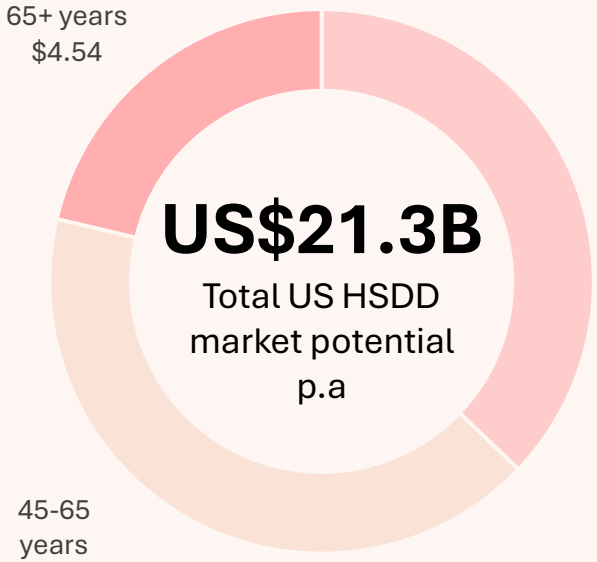
Significant Global Market Opportunity

~60m
women in the US estimated to be affected by menopause

~4.9m
menopausal women estimated with HSDD

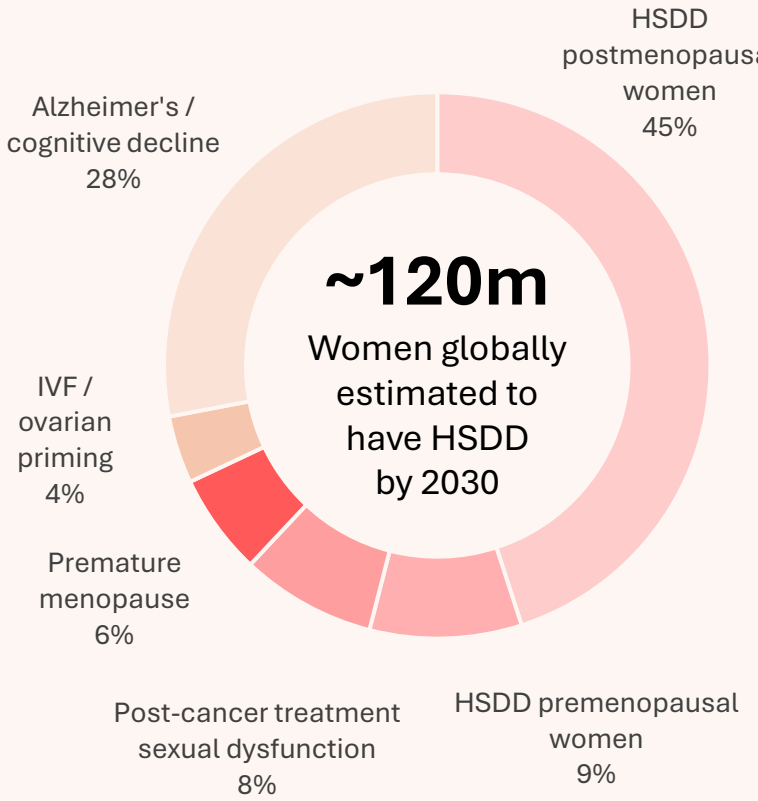
~2m
US women are estimated to use off-label testosterone products for HSDD

Estimated US & EU HSDD Market Potential p.a. (US$B)



Assumptions: 12.3% 45-65y, 8.9% 18-44 y and 7.4% >65 y have HSDD; Cost of annual treatment = $USD 300 per month; 40% may women respond to treatment/clinically meaningful improvements; and 75% women would speak to doctor & 82% of these initiate discussion with healthcare provider.
References: Hill K., (1996) The demography of menopause, Maturitas 23:113-127. Parish SJ et al, (2021) International Society for the Study of Women's Sexual Health Clinical Practice Guideline for the Use of Systemic Testosterone for Hypoactive Sexual Desire Disorder in Women J Sex Med 18:849-867.

Potential Global Population for Female Testosterone*



**There is no known published market report that segments the testosterone market exclusively for women by indication/population. The percentages shown are derived estimates constructed from information, real-world prescribing patterns, epidemiology, and other therapy information. Estimates are intended for strategic and illustrative purposes and are not sourced from a single proprietary market report."*



Phase III Study

Development roadmap in place

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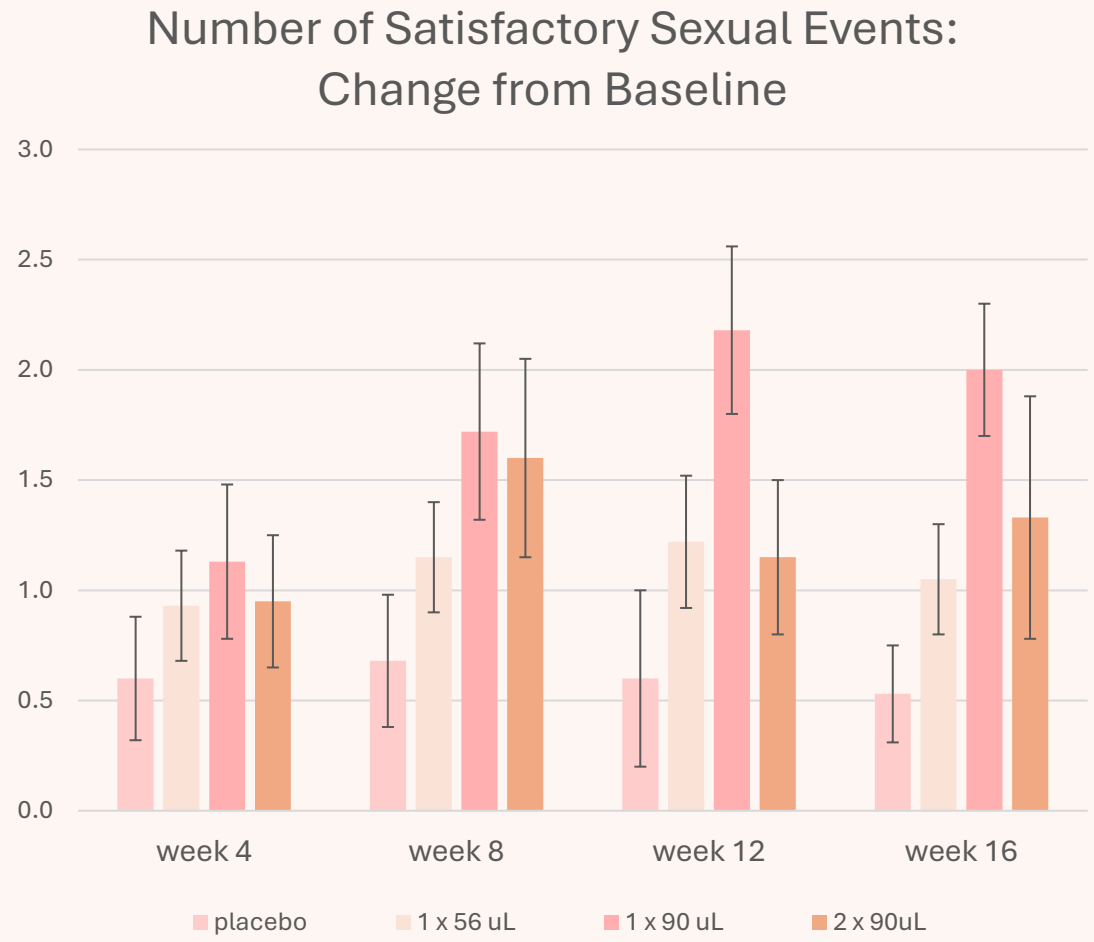
Clear Phase II Results



- Mean number of satisfactory sexual events increased compared to placebo at weeks 4, 8, 12 and 16 for **all of the testosterone groups**.
- Statistically significant increase in the primary endpoint in the 1 × 90 µL testosterone group in the intent-to-treat (ITT) population, with a mean increase of 2.00 satisfactory sexual events at week 16, compared to a mean increase of 0.53 events in the placebo group (the mean baseline frequency in each of these groups was 1.3-1.4).

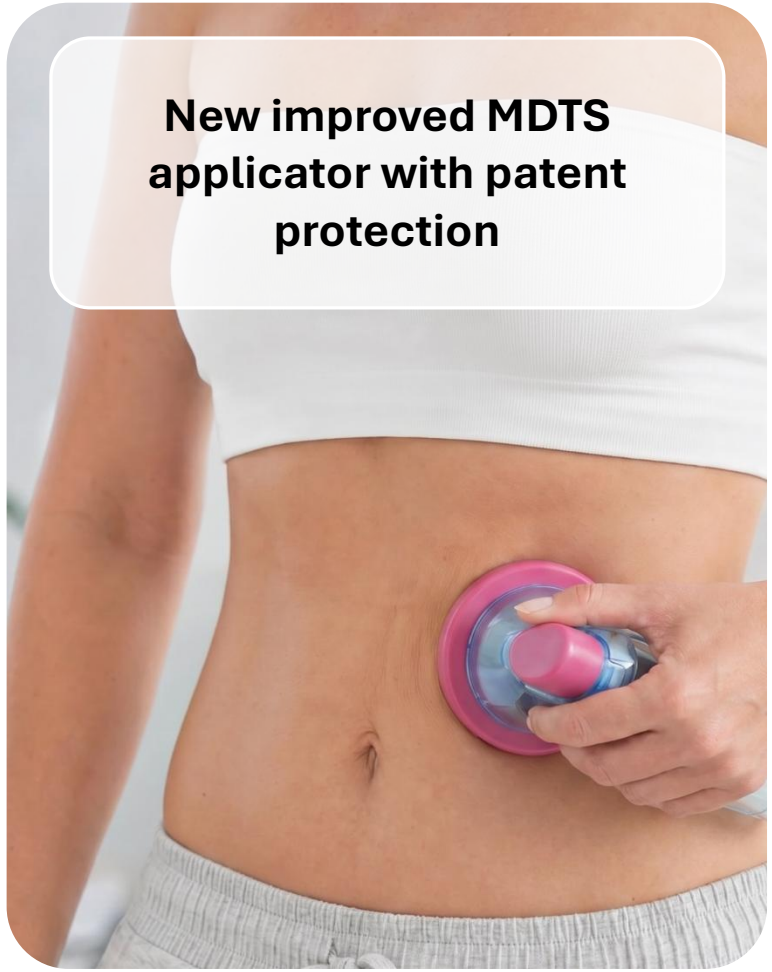
End-of-Phase II FDA meeting provides Acrux with clear regulatory pathway for Female Testosterone MDTS

Study Design	
Title	Two Phase III, Double-Blind, Placebo Controlled Study of the Safety and Efficacy of Testosterone Transdermal Spray for the Treatment of Sexual Dysfunction (Hypoactive Sexual Desire Disorder) in Postmenopausal Women
Period	• Base-line study 24 weeks. • Additional 28 weeks of data to inform safety for chronic treatment

Highlights of feedback

- Flexibility between two trial designs
- Alternative approaches to patient reported outcome co-primary endpoints
- Confirmed that Acrux will be eligible to apply for a 3-year exclusivity period when the company makes its submission.

Lifecycle Strategy for Further Development



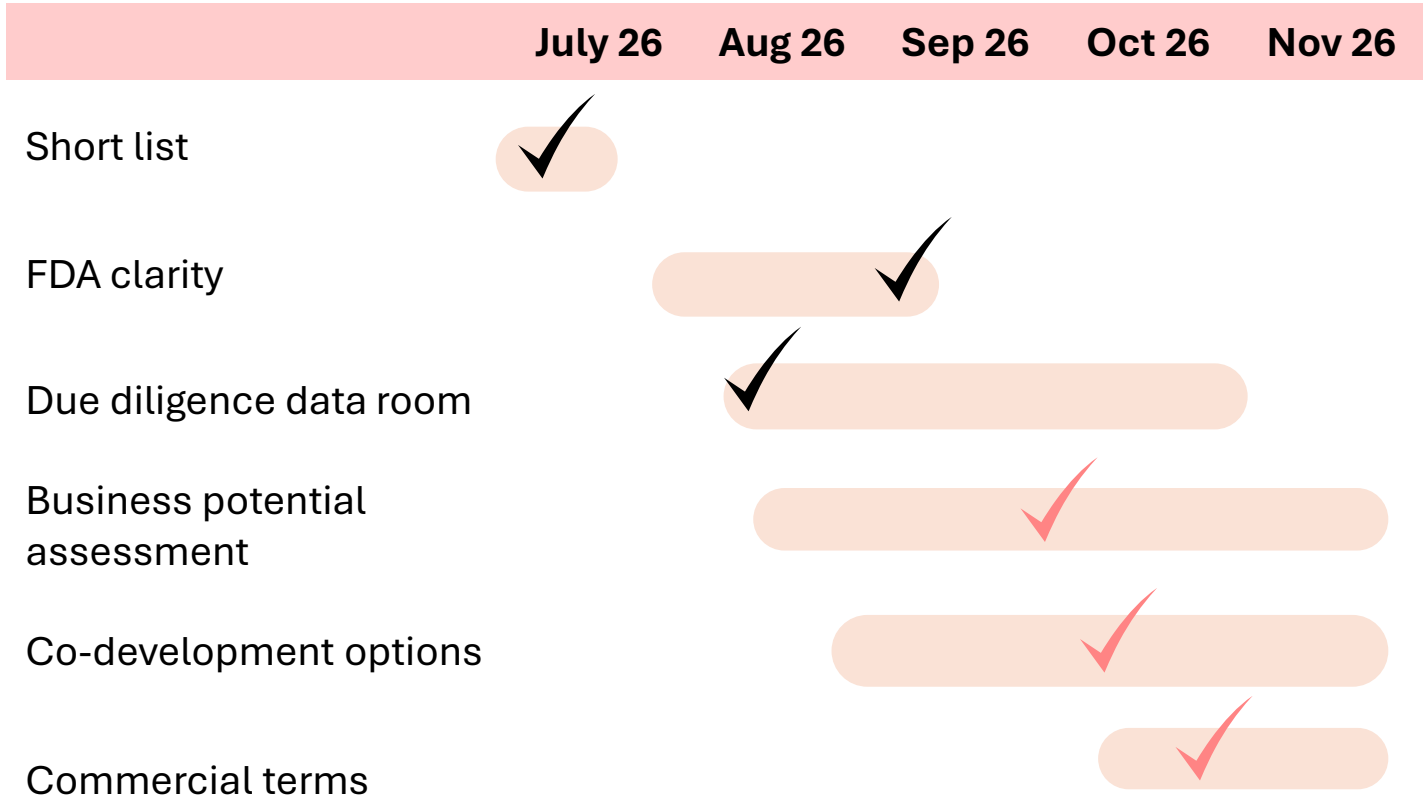


Expand proposed indication/ population to include:

- Female sexual interest/arousal disorder (FSIAD)
- Female sexual arousal disorder (FSAD)
- Women with premature menopause
- For women post-chemotherapy/ radiotherapy
- Potential as part of IVF treatment
- Cognitive symptoms

Co-development partner milestones

FDA clarity opens gateway to meaningful co-development discussion

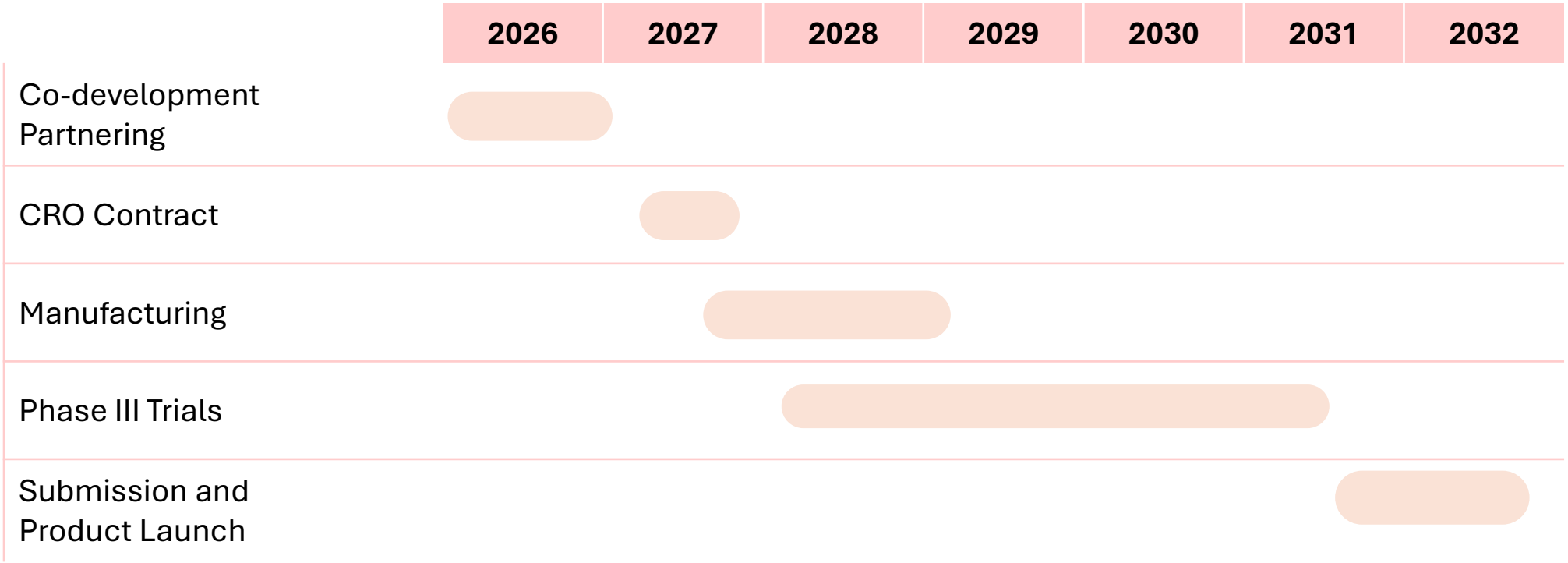


Strong interest from potential partners:

- Capacity to grow the market by increasing demand
- Expertise in women's health
- Openness to co-development
- Capability to leverage Phase III Clinical Trial
- Experience with Patchless Patch technology

First to market, co-development roadmap

Multiple near-term and medium-term milestones will ensure strong investor engagement and catalysts through to product launch in 2032





Acrux corporate structure and Topical Generic portfolio underpins Female Testosterone runway

Acrux Ltd (ASX:ACR)

Successful development and FDA registration of topical pharmaceuticals generates core Acrux income

FDA registered products commercialised in the US

- Nitroglycerin 0.4% ointment launched.
- Dapsone 5.0% gel launched.
- Dapsone 7.5% gel launched.
- Evamist® royalties continue.

Further Female HRT licensing expansion

- Lenzetto® licensed to Gedeon Richter in Australia

Realisation of generic pipeline via partnerships

- Ophthalmic, Otic, and Topical products packaged for 3rd party development
- Commercial discussions underway

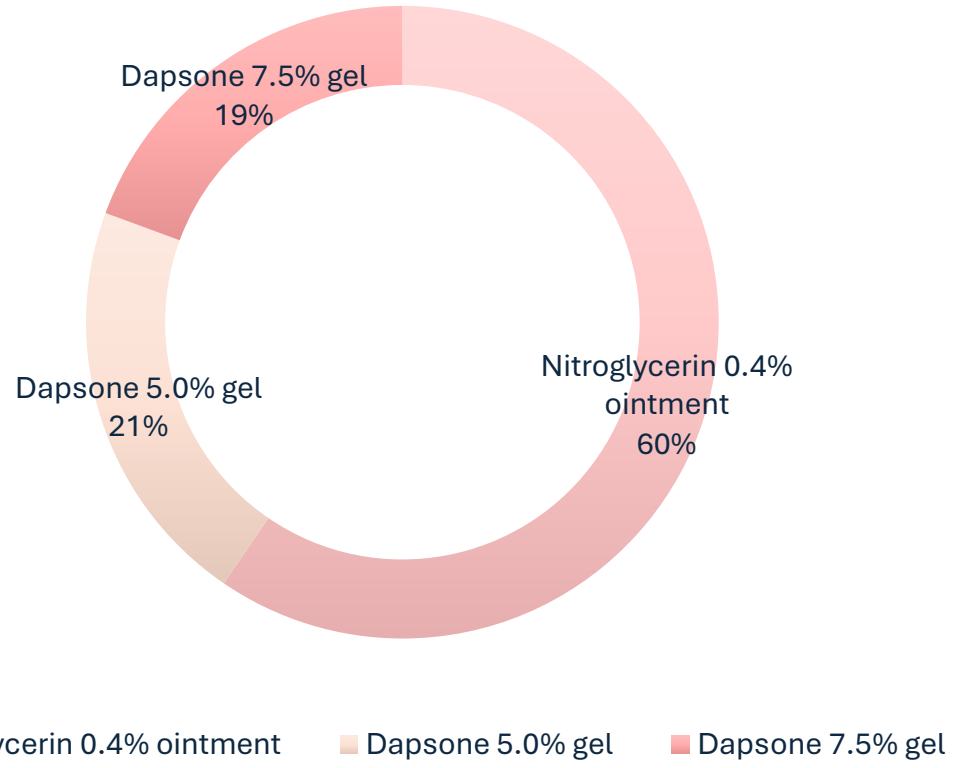
Unprofitable assets removed from portfolio

- Lidocaine and Prilocaine Cream sold to Padagis

Fixed cost structure of Generic Development reduced

Topical Generic Sales USD $ 2.76 M (AUD $ 4.12)

12 months to Sept 26



Pooled Development Fund

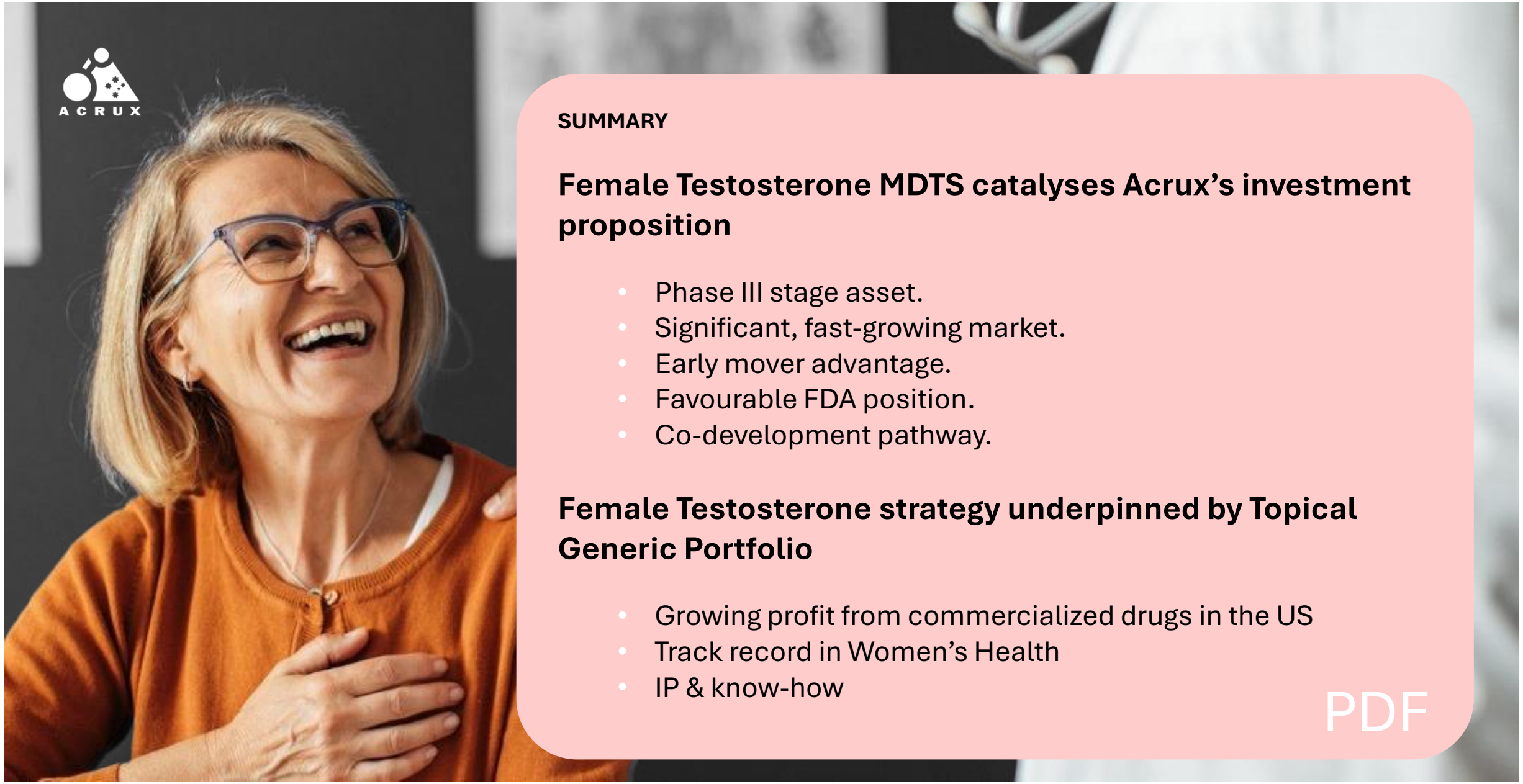
Purpose

- Pooled Development Fund Act 1992 was established by the Federal Government
- Increase the supply of capital to Australian small and medium-sized enterprises to enable those businesses to grow and develop their own markets, creating industry and jobs for Australia



Benefits

- ✓ Capital gains made by PDF shareholders are not taxable
- ✓ Shareholders can elect to treat dividends paid by a PDF as tax free
- ▪ Capital losses on the sale of PDF's are not deductible



SUMMARY

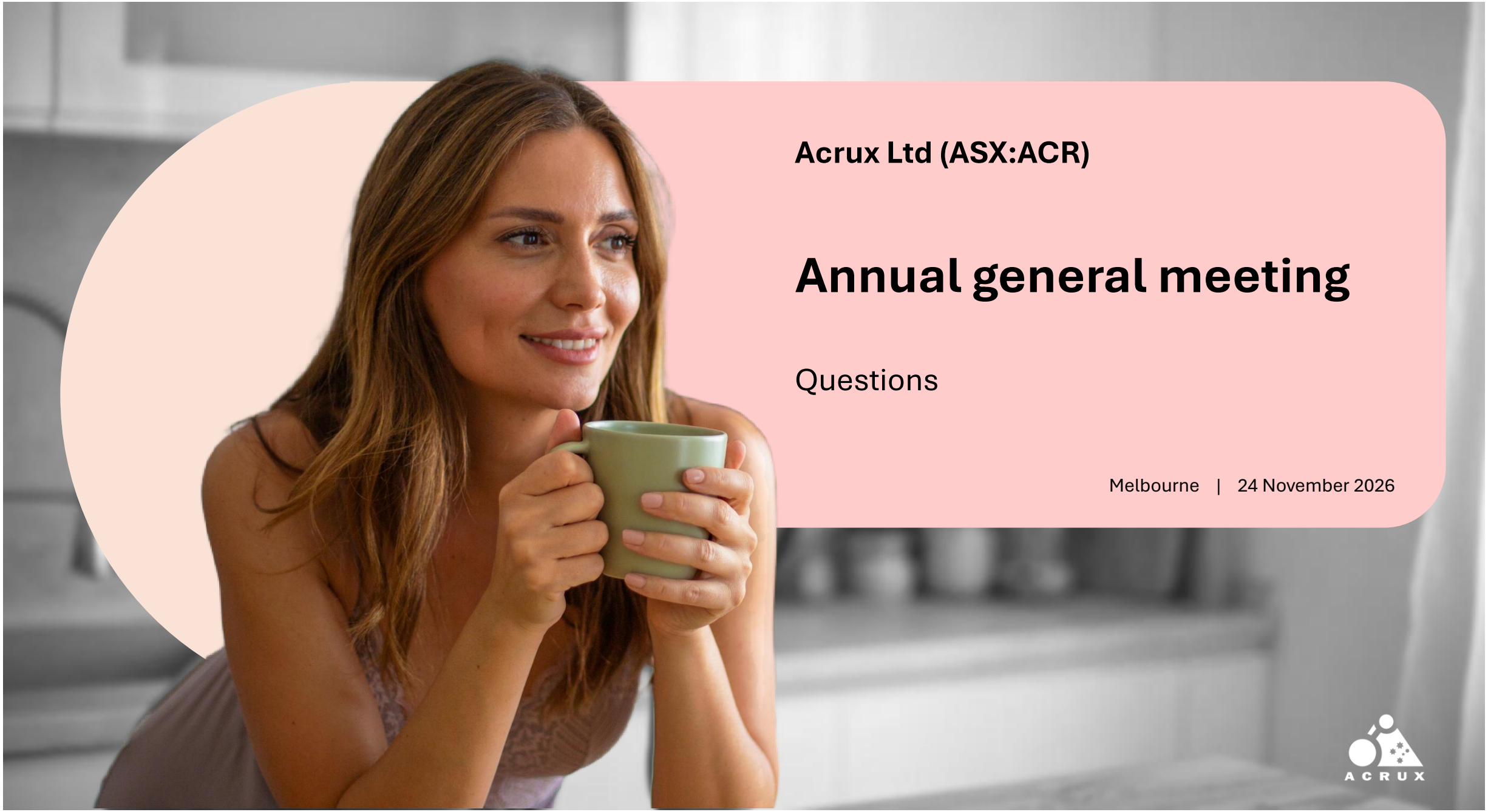
Female Testosterone MDTS catalyses Acrux's investment proposition

- Phase III stage asset.
- Significant, fast-growing market.
- Early mover advantage.
- Favourable FDA position.
- Co-development pathway.

Female Testosterone strategy underpinned by Topical Generic Portfolio

- Growing profit from commercialized drugs in the US
- Track record in Women's Health
- IP & know-how

PDF



Acrux Ltd (ASX:ACR)

Annual general meeting

Questions

Melbourne | 24 November 2026