ASX Release

Acrux strategy focuses on Female Testosterone for low libido

Melbourne, Australia; 28 April 2026: Acrux Limited (ASX:ACR, "Acrux" or the "Company") is pleased to announce the release of its new strategy that focuses on high value, innovative, transdermal IP. This follows a thorough review of the business by the new Chief Executive Officer and the Executive Team.

The review considered:

1. the performance of the company's existing, commercialised Topical Generic drugs in the US and the potential for geographic expansion;
2. the potential for Topical Generic drugs currently under development;
3. changes in the clinical and regulatory environment for Hormone Replacement Therapy, particularly in Women's Health;
4. the potential for leveraging existing Acrux know how and R&D;
5. FDA feedback on Phase I & II clinical trials for Female Testosterone already completed by Acrux and a viable pathway to proceed to Phase III; and
6. commercialisation strategies for Female Testosterone and, specifically, co-development.

Based on the team's analysis and assessment of Acrux's options, the new strategy has moved from purely focusing on Topical Generics to bringing Acrux's Female Testosterone product to market for the treatment of Hypoactive Sexual Desire Dysfunction or HSDD (currently an area of high unmet need). The strategy is presented in the company's new Strategic Update deck released today.

Chief Executive Officer and Managing Director, John Warmbrunn, commented:

"Female Testosterone is a great opportunity that Acrux is incredibly well positioned to exploit. The core revenue we are generating from our Topical Generics portfolio underpins and supports our capacity to bring this product to market. Our proven capability in registering and commercialising products gives us great confidence that we can gain an early mover advantage. The direction provided by the FDA, and our long-term existing relationships with potential partners, means that a co-development pathway is clearly the best option to commercialise the product.

With a huge unmet need for women with Hypoactive Sexual Desire Dysfunction (HSDD), Acrux is looking forward to making a significant contribution to women's health globally.

In joining Acrux, it has been wonderful to find that there are significant new opportunities to apply the extraordinary skills and talents that our scientists have acquired over 25 years."

ENDS

Approved for release by the Board of Acrux Ltd

For more information, please contact:

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About Acrux

Acrux is a dynamic Australian drug delivery specialist with unique expertise in developing and commercialising patient preferred healthcare products for global markets.

Acrux talent create value through the development and commercialisation of healthcare products using owned or acquired technologies. Acrux's products are patient preferred, protected by patent or other means, using innovative drug delivery.

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

Strategic Update

April 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 and 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

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

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.*

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

References:
^ 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

Female Testosterone catalyses investment proposition

Phase III Ready Asset

Phase I & Phase II Clinical Trials have demonstrated a strong efficacy and safety profile. No material adverse events recorded.

Significant, Fast-Growing Market

~4.9m US menopausal women suffer from Hypoactive Sexual Desire Disorder (HSDD) with a total addressable US population of ~12m sufferers. By 2030, ~130,000 women will enter menopause globally each day.

Early Mover Advantage

There is no existing Female Testosterone treatment approved for HSDD in the US despite ~2.0m women using off-label treatments. Acrux has a unique opportunity to be early to market with an approved formulation.

Co-Development Pathway

Acrux will de-risk and expedite the regulatory and market entry process with a major global partner. **Acrux has significant, long-term existing relationships potential co-developers.**

Existing commercial portfolio

Acrux stands apart from clinical-stage developers with an existing portfolio of in-market, approved products that generate revenue to subsidise and support further R&D into high-value products and technology.

IP & Know-How

Acrux has a significant and successful corporate history of commercialising transdermal solutions and applications. Acrux is uniquely placed to leverage its 505 (b)(2) pathway IP for the Female Testosterone market.

HSDD: Problem and Solution

What is Hypoactive Sexual Desire Disorder?

- HSDD affects ~4.9m menopausal women in the US.
- HSDD impacts ~10% of all adult women, most commonly as low or absent sexual desire and/or response to stimulation.
- Other symptoms include low self-esteem, reduced energy, depression, anxiety and interpersonal conflict.

Benefits of treating HSDD with Testosterone

- HSDD efficacy in postmenopausal women demonstrated in 36 randomised clinical trials.
- ~52% noted improved sexual function 6 – 8 weeks after treatment initiation.
- Anecdotal benefits included improved mood, energy and cognitive function.

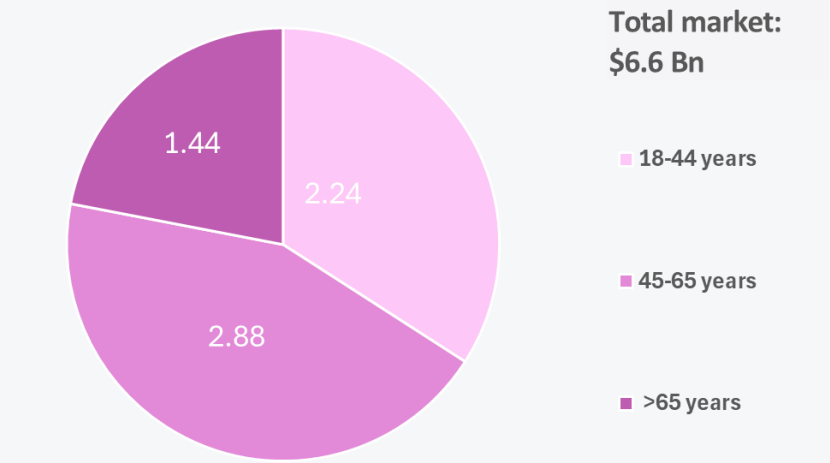
References:

- 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, and 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
- Statista for USA population information

Significant Global Market Opportunity

Approximately 60 million women in the US are affected by menopause with an estimated 4.9 million menopausal women suffering from HSDD. **Acrux estimates the US menopausal market for HSDD alone could deliver a commercial value of ~US$2.88 billion per annum**. Already 2 million US women are estimated to use off-label testosterone products for HSDD. Globally, approximately 120 million women are estimated to have HSDD by 2030.

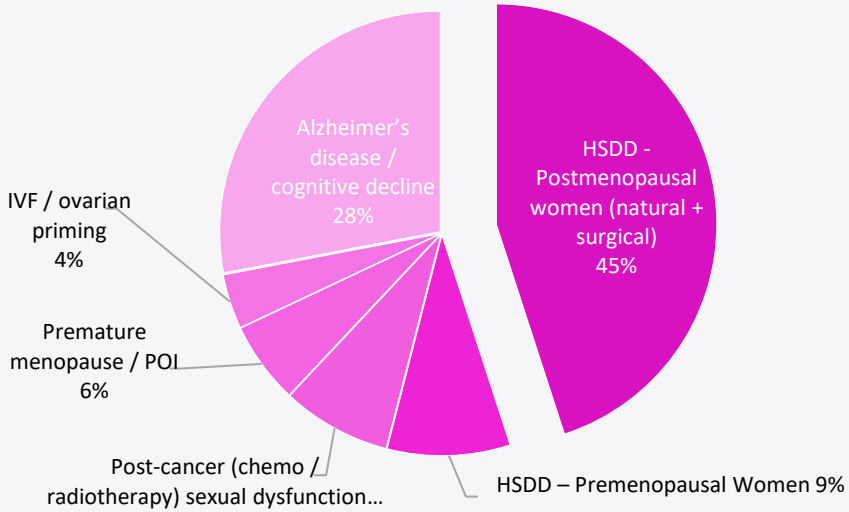
Estimated US HSDD Market Potential p.a. (US$Bn)



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
- 75% women would speak to doctor & 82% of these initiate discussion with healthcare provider.
- No rebates assumed.

Global population potential indications* for Female Testosterone



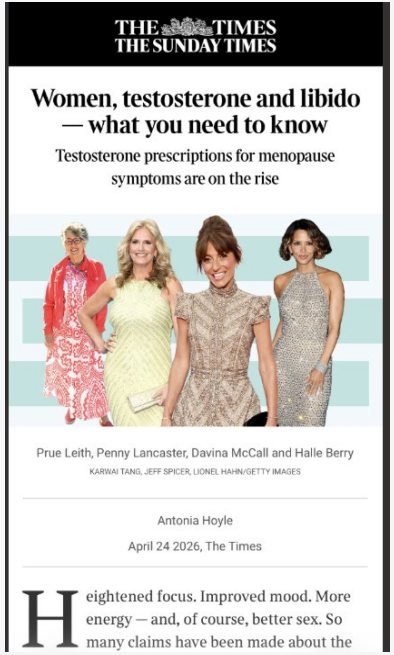
*There is no known published market report that segments the testosterone market exclusively for women by indication/population. The percentages shown are derived estimates constructed from information, real-world prescribing patterns, epidemiology, and other therapy information. Estimates are intended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

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

Female Testosterone Awareness

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


THE TIMES
THE SUNDAY TIMES

Women, testosterone and libido — what you need to know

Testosterone prescriptions for menopause symptoms are on the rise

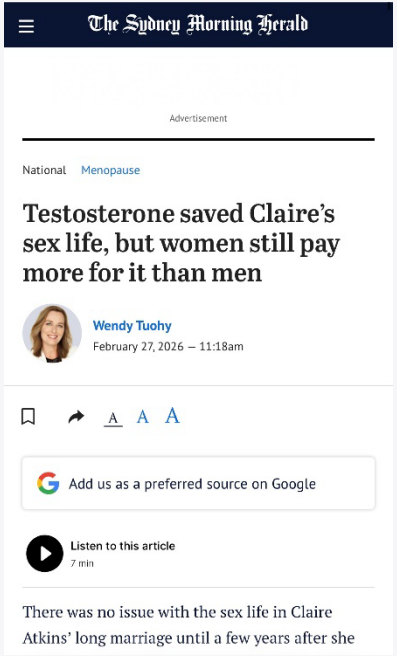
Prue Leith, Penny Lancaster, Davina McCall and Halle Berry

KARWAI TANG, JEFF SPICER, LIONEL HAHN/GETTY IMAGES

Antonia Hoyle

April 24 2026, The Times

Heightened focus. Improved mood. More energy — and, of course, better sex. So many claims have been made about the


The Sydney Morning Herald

Advertisement

National Menopause

Testosterone saved Claire's sex life, but women still pay more for it than men

Wendy Tuohy

February 27, 2026 — 11:18am

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There was no issue with the sex life in Claire Atkins' long marriage until a few years after she


THE AUSTRALIAN

Menopausal women already have enough of a load to carry

Australia's medicines subsidy gatekeeper has rejected cheaper access to a testosterone product for women. Some are questioning whether that's fair.

By MAGDALENA SIMONIS

05:00 am April 08, 2026 6 mins read


The New York Times Magazine

'I'm on Fire': Testosterone Is Giving Women Back Their Sex Drive — and Then Some

Female Testosterone: A New Global Market for Acrux

Acrux has significant IP in testosterone products, regulatory engagement and transdermal spray application technology and is uniquely positioned to exploit global demand for female testosterone products.

Acrux has had positive engagement with the US FDA regarding the clinical pathway required to register our Female Testosterone treatment.

Clinical spotlight on HSDD

- In the early 2000s, the World Health Initiative found the overall risks exceeded benefits from certain hormone products, not including testosterone, but creating a misconception.
- **July 2025: The unmet clinical need of HSDD in post-menopausal women was a key aspect of the *FDA Expert Panel on Menopause and Hormone Replacement Therapy for Women.***
- In 2025, the landscape shifted, with recent approvals in the UK, Australia, New Zealand and South Africa of products treating HSDD in post-menopausal women.

+ Core Acrux expertise & IP

- Acrux has a strong history of pioneering transdermal drug delivery systems, turning opportunities into marketed products.
- **Our R&D has led to multiple first-in-class, hormone formulations such as Axiron®, Evamist® and Lenzetto®.**
- Our clinical journey began with addressing an unmet need in women for HSDD.
- **Acrux's Phase II trials demonstrated significant improvement, confirming efficacy and safety**.
- The Female Testosterone MDTS spray was developed for women using Acrux's applicator and Patchless Patch™ technologies.
- **505 (b)(2) exclusivity**
- Decades of research, proven know-how and expertise in regulatory pathways underpin Acrux's commitment to advancing patient care.

+ Head start with strong US FDA Regulatory Engagement

- 2002: Pre-IND* meeting held with FDA to discuss potential populations and Phase II protocol design, IND application lodged.
- 2005: Pre-IND meeting held with FDA to discuss safety requirements, end of Phase II meeting to discuss Phase III program planned, program ceased.
- October 2025: Acrux submitted a Pre-IND package to the FDA.
- **November 2025: US Department of Health & Human Services removes US FDA *Black Box warnings* from female hormone replacement therapy products.**
- **January 2026: Acrux's registration pathway clarified by the FDA.**

* Pre-investigational New Drug

Acrux Proven MDTS Technology

Acrux's proven Meter Dose Transdermal System (MDTS) technology is an ideal mode of administration for Female Testosterone. The spray is applied to the abdomen, reducing the risk of incidental contact and transfer on other parts of the body. Utilising the same delivery technology as Lenzetto and Evamist ensures high scalability once in market.

1. **MDTS or MD-Lotion Applicator**

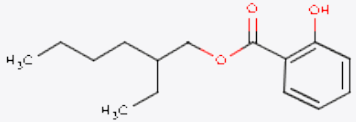
   Used for simple, accurate & flexible dosing. Applied to the abdomen.

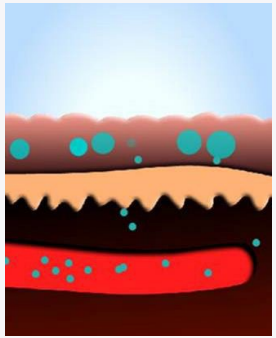
2. **ACROSS Enhancers**

   Allow drugs to pass through skin more rapidly.

3. **Patchless Patch™ Reservoir**

   Forms an invisible reservoir within the skin.





Female Testosterone Strategy

Acrux will seek to co-develop the Female Testosterone solution to enable an expedited pathway through the proposed Phase III trial and ensure a fast market entry. Given no product is currently registered in the US with female appropriate dosing Acrux has a unique opportunity to take advantage in the near-term.

1 Expedited Market Entry Strategy

- **Clinical & Regulatory Strategy:**
  - Shortened regulatory pathway as Phase II clinical trials completed.
  - Define regulatory & clinical strategies for US and the rest of the world through consulting with regional authorities (e.g. TGA, FDA, EMA).
  - Market entry based on regional regulatory requirements.
- **Partnering Strategy:**
  - Co-develop with global partner with clinical trial expertise, sale force access, hormone product experience and market education and advocacy.
  - No current female testosterone product approved in the US

2 Product Positioning

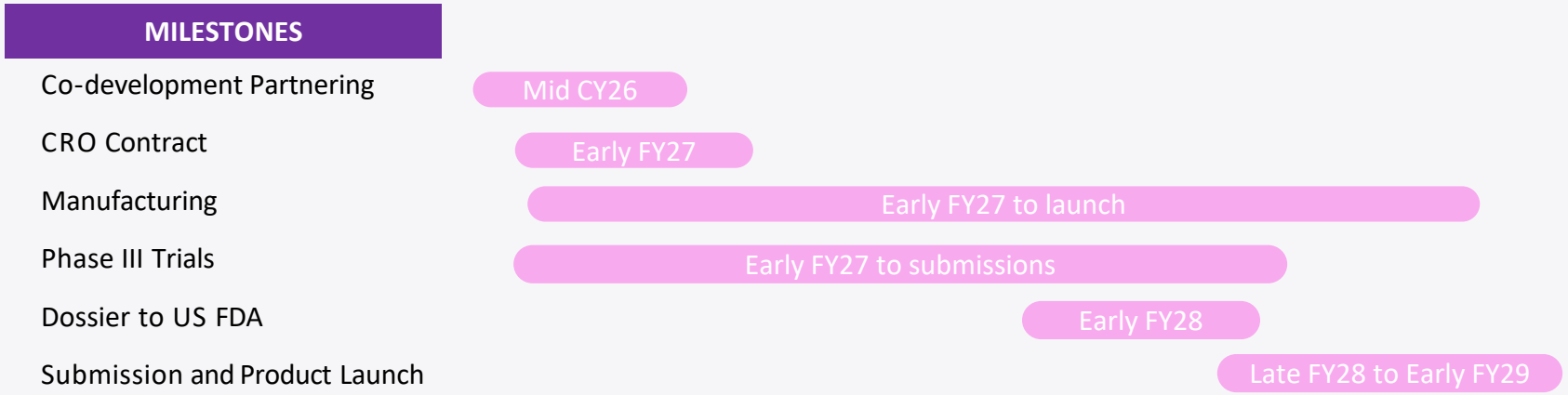
- **First-line and first-choice dosage form for treatment of HSDD:**
  - Once a day administration.
  - Applied to the abdomen.
- **Enhancing sexual desire:**
  - With decreased sexual concerns including sexual distress.
  - Enhancement in overall mood and energy.
- **Complement to hormone therapy:**
  - Highlighting testosterone's role in comprehensive hormone optimisation, especially alongside estrogen–progesterone approaches.

3 Lifecycle Management

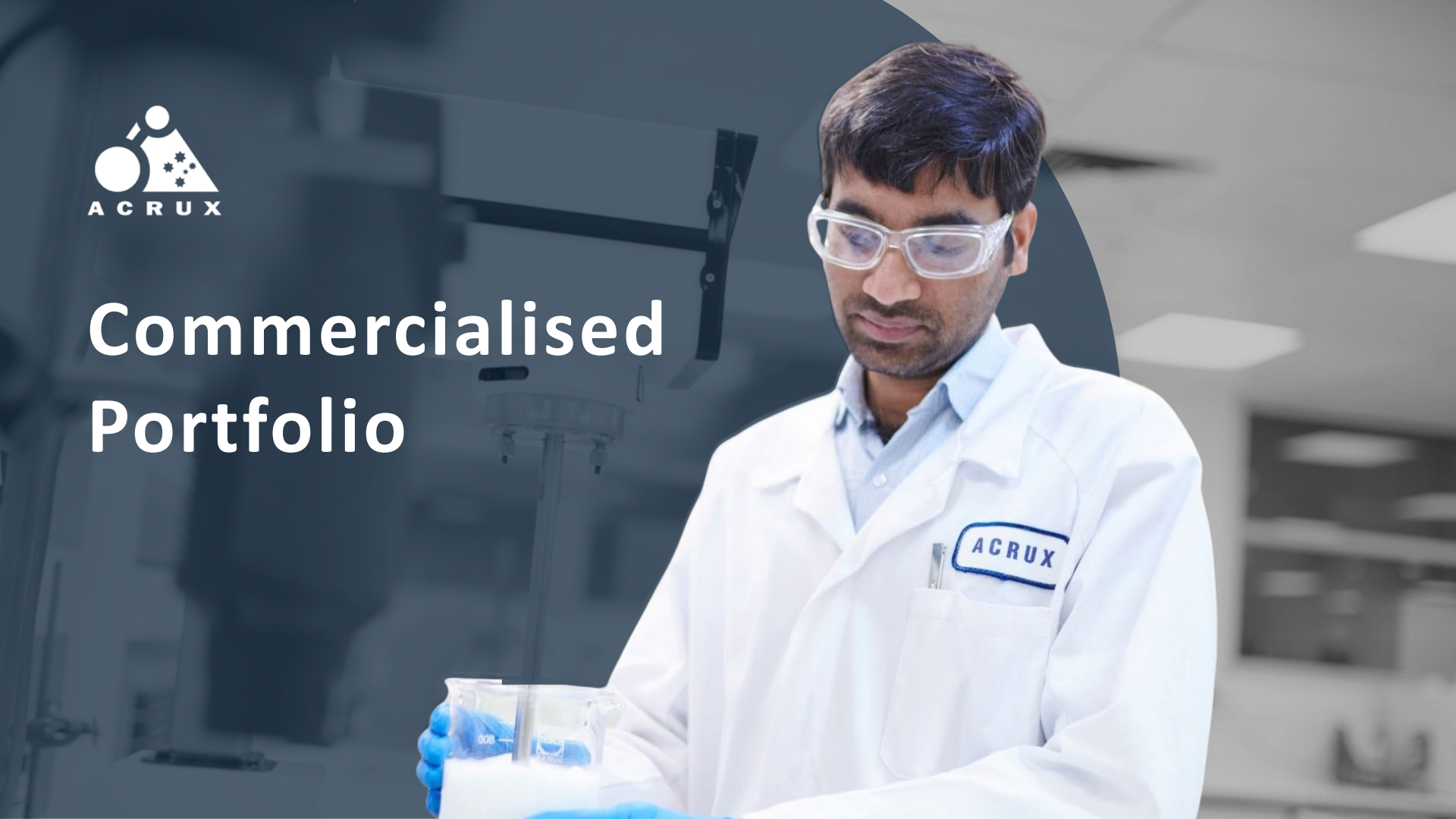
- **505 (b)(2) exclusivity period**
- **Exclusivity differentiation considerations:**
  - New improved MDTS applicator with patent protection.
  - Combination therapies with patent protection.
- **Expand proposed indication to include:**
  - Surgically postmenopausal women.
  - Women with premature menopause.
  - For post-chemotherapy/ radiotherapy.

Development Roadmap: Target FY28 Market Launch

- Acrux is focused on progressing potential co-development partnerships in the near-term to de-risk the clinical trial process and expedite market launch.
- Acrux is well positioned with existing distribution and product agreements in place with potential co-development partners.
- Acrux will work proactively with its co-development partner to finalise the Phase III trial design and manufacturing protocols.
- Multiple near-term and medium-term milestones will ensure strong investor engagement and catalysts through to product launch in the US.



Commercialised Portfolio



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

Powerful Partnerships

Proven Product Portfolio

Infrastructure & Capabilities

Experienced Team

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.

Geographic expansion of FDA registered products

Further Female HRT licensing expansion

Unprofitable assets removed from portfolio

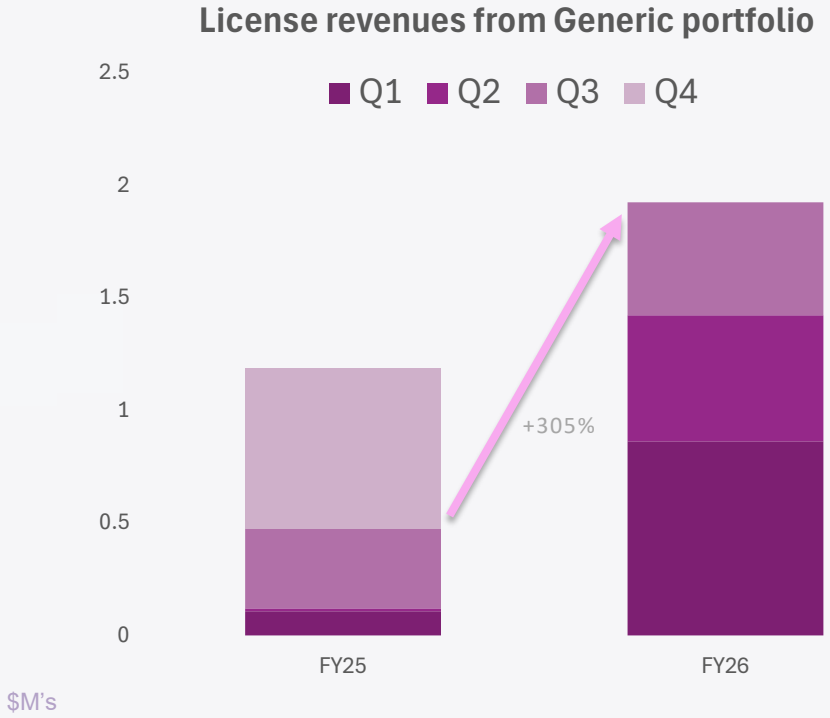
Realisation of generic pipeline via partnerships

- Ophthalmic, Otic, and Topical.

R&D focus moved to Female Testosterone and next generation products

Generic Portfolio Revenue Performance

- Acrux continues to generate strong financial performance from the Company's portfolio of generic pharmaceuticals that supports and subsidises group R&D activities.
- Quarterly revenues from product licensing are growing, driven by the launch of Nitroglycerine 0.4% Ointment at the end of Q2 FY25.
- With Q4 FY26 revenues to come, FY26 Product Licensing Income is on track to be more than double that of the prior year.
- Acrux will continue to review its asset portfolio to ensure the optimal product mix to deliver shareholder value. Proceeds from divestment of Prilocaine 2.5% and Lidocaine 2.5% cream were received in 1H FY26.



Summary

Female Testosterone catalyses Acrux's investment proposition

- Phase III ready asset.
- Significant, fast-growing market.
- Early mover advantage.
- Patient preferred application.
- Co-development pathway.
- Existing commercial portfolio.
- IP & know-how.

Highly Experienced Executive Team

John Warmbrunn, BSc, MBA
CEO and Managing Director

- Joined Acrux in 2025.
- 25 years industry experience.

Felicia Colagrande, BSc(Hons), MBA
Product Development and Technical Affairs Director

- 25 years with Acrux.
- 36 years industry experience.

Joanna Johnson, BEc, ACA
CFO and Company Secretary

- 5 years with Acrux.
- 30 years industry experience.

Mark Hyman, BSc
Product and Technical Director

- 11 years with Acrux.
- 37 years industry experience.