



12 October 2026

FDA provides Acrux with clear regulatory pathway for Female Testosterone MDTs

Highlights

- FDA confirmed the clinical Phase III regulatory pathway for Female Testosterone metered-dose transdermal spray (MDTS) in postmenopausal women with HSDD.
- The FDA confirmed that Acrux will be eligible to apply for a 3-year exclusivity period when the company makes its submission.
- A recent FDA public workshop commentary highlighted the unmet need for a female-specific, controlled-dose testosterone treatment for women with HSDD.
- Investor webinar to be convened this afternoon at 3pm AEDT.

Melbourne, Australia; 12 October 2026: Following formalisation of the minutes from its recent end-of-Phase II meeting with the U.S. Food and Drug Administration (FDA), Acrux provides an update on the regulatory pathway for Female Testosterone MDTs.

The update also incorporates key themes from the FDA's recent public workshop on the need for an FDA-approved testosterone treatment for women with hypoactive sexual desire disorder (HSDD).

Positive Female Testosterone MDTs end-of-Phase II FDA meeting outcomes:

Following formalisation of the minutes from its recent end-of-Phase II meeting, Acrux now has greater clarity on the Phase III development pathway for Female Testosterone MDTs and increased confidence in being the first female testosterone product for women in the US market.

Key outcomes include:

- The FDA confirmed that two adequate and well-controlled 24-week Phase III trials will demonstrate reproducible efficacy for HSDD in postmenopausal women and support approval. An additional 28 weeks of data, for a total of 52 weeks, will inform safety for chronic treatment.
- It advised that the two trials need not be identical in design, providing Acrux with flexibility, such as different timing intervals, as it finalizes the trial designs. The feedback was in line with standard FDA guidance.
- The FDA provided additional, alternative approaches to patient reported outcome co-primary endpoints in line with the 2016 FDA's draft Guidance "Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs for Treatment". This means Acrux can select the most appropriate end points for the trial.
- The FDA acknowledged that testosterone MDTs should be considered as a new formulation, and that a chronic dermal and systemic safety study would be in line with its guidelines. Acrux is now finalising the protocol for this study.

Exclusivity

The FDA offers 3 years data exclusivity for the first approval of an established active ingredient for a new indication for an established drug when new clinical studies in support of its application. The agency confirmed that Acrux's Phase III trials and new formulation meet this requirement. Therefore, the company will be eligible to apply for a three-year exclusivity period at the time of submission.

If granted, this significantly increases Acrux's commercial opportunity by preventing the launch of competitor products for the first three years after registration. In recognising Acrux has a new formulation that enables a new indication, the FDA also recommended a minimal preclinical package of chronic dermal and systemic safety.

Acrux CEO John Warmbrunn said:

"It is an important time to be receiving feedback from the FDA on Female Testosterone MDTs. The guidance provides greater clarity on our regulatory pathway and aligns closely with key themes from the FDA's public workshop, including the unmet need for an FDA-approved testosterone product for women, the importance of controlled dosing, and the need to maintain testosterone exposure within the physiological range."

Acrux's Female Testosterone MDTs is wonderfully aligned with these objectives. And our Phase III Clinical Trial will answer critical questions for treating HSDD.

These regulatory and market signals are also supporting constructive discussions with potential co-development partners as we progress Female Testosterone MDTs into Phase III development."

FDA public workshop on testosterone use in menopausal women

In September, the FDA held a public workshop examining testosterone use in menopausal women, including the current treatment gap, the need for female-specific dosing and formulation, and the evidence required to support future product development.

Key themes from the FDA workshop included:

- Significant unmet need for an FDA-approved testosterone treatment specifically developed for women.
- The importance of controlled female-appropriate dosing and maintaining testosterone within the physiological range.
- FDA openness to engage with sponsors on evidence-based product development.

A short video featuring key excerpts from the FDA workshop is available here:

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

Acrux Product Development and Technical Affairs Director Felicia Colagrande, who has worked at Acrux for 25 years since its spin out from Monash University said:

“It is exciting to see Acrux’s long-standing expertise in transdermal drug delivery being applied to such an important area of unmet need in women’s health. Female Testosterone MDTs builds on the company’s established capability in controlled transdermal delivery and reflects the kind of practical innovation Acrux has developed over many years.”

Investor Webinar

Shareholders and investors are invited to register for the investor webinar to be held this afternoon at 3.00pm AEDT using the the following link:

https://us02web.zoom.us/webinar/register/WN_zr980BfsSLK34AF53x3xHw#/registration

Once registered, participants will receive a confirmation email containing details on how to access the webinar.

The webinar will also cover key themes from the FDA’s recent public workshop, followed by an investor Q&A.

Authorised for release by the Board of Acrux Limited.

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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.

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