



ASX/Media Release

13 September 2021

Acrux's fifth generic dossier accepted by FDA for review

Melbourne, Australia; 13 September 2021: Acrux Limited (ASX:ACR, "Acrux" or the "Company") is pleased to announce that the US Food and Drug Administration (FDA) has accepted for review Acrux's Abbreviated New Drug Application (ANDA) for its generic version of Dapsone Gel, 5%.

Key Highlights

- Acrux has submitted an ANDA application to the FDA for Dapsone Gel, 5%, which has now been accepted for review
- Annual sales for the product are US\$30m as measured by IQVIA¹
- The product is used to treat acne
- The announcement marks Acrux's fifth ANDA accepted for review by the FDA

Acrux CEO and Managing Director, Michael Kotsanis said:

"Our team is pleased to achieve another milestone for our product development pipeline with this dossier submission. We will now work with the FDA to address any queries they may have on our dossier as we work towards approval and launch. This is another example of Acrux developing products which, on approval and launch will provide affordable alternatives to patients."

FDA accepts for review Acrux's submission

Acrux has submitted an ANDA to seek approval from the FDA to market its generic version of Dapsone Gel, 5%. The FDA has notified Acrux that the submission is sufficiently complete to be accepted for review. The reference listed drug is Aczone® Gel, 5% marketed by Allergan Inc in the United States.

Once approved by the FDA, Acrux will be able to commence marketing and sales of the product in the United States.

The product is used to treat acne. It helps decrease the number and severity of acne pimples and helps pimples that do develop to heal more quickly.

US\$30 million addressable market

The total addressable market for the product including existing generics is US\$30 million. There is one approved and marketed ANDA product as at September 2021.

¹ IQVIA June 2021. Annual product sales for previous twelve months is the addressable market.



Approved for release by the Acrux Board of Directors.

For more information, please contact:

Michael Kotsanis

Acrux Limited

CEO & Managing Director

P: + 61 3 8379 0100

E: michael.kotsanis@acrux.com.au

About Acrux

Acrux (ASX: ACR) is a pharmaceutical company dedicated to developing and commercialising topical pharmaceuticals. Incorporated in 1998 and using in house facilities and capabilities, Acrux has successfully developed and commercialised through licensees a number of topically applied pharmaceutical products in the US and Europe. Acrux is developing of a range of generic products for the US market by leveraging its on-site laboratories, GMP manufacturing suite, clinical and commercial experience to bring affordable products to market. Acrux encourages collaboration and is well positioned to discuss partnering and product development.

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