ASX Release

30 May 2022

Acrux announces successful patent litigation outcome

Melbourne, Australia; 30 May 2022: Acrux Limited (ASX:ACR, "**Acrux**") is pleased to announce that the patent litigation relating to its Abbreviated New Drug Application (ANDA) for a generic equivalent to Aczone® (dapsone) Gel 7.5%[1] has now been concluded in its favour.

On May 27, 2022, the U.S. District Court for the District of New Jersey dismissed all claims against Acrux DDS Pty Ltd in the patent litigation between Almirall, LLC and Acrux DDS Pty Ltd, after the invalidity of Almirall's U.S. Patent No. 9,517,219 was affirmed by the U.S. Court of Appeals for the Federal Circuit.[2] [3] [4] [5]

This dismissal clears all patent litigation related to Acrux's Paragraph IV Certification submitted with its ANDA, and will allow Acrux to launch its generic equivalent to Aczone® Gel, 7.5% in conjunction with its commercial licensee once the product has completed the regulatory review and approval process with the US FDA.

Acrux CEO and Managing Director, Michael Kotsanis said:
"This successful legal decision for Acrux now paves the way for us, on approval, to launch our generic product from a development pipeline of fifteen. New product launches provide additional revenue streams and are a key component of our corporate vision and strategy that focuses on profitably growing our business and creating value for shareholders."

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Authorised for release by the Board of Acrux Limited.

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[1] Aczone® Gel, 7.5% is indicated for the topical treatment of acne vulgaris.
Aczone® Gel, 7.5% is a registered trademark of Amirall, LLC.

[2] Acrux DDS Pty Ltd is a fully owned subsidiary of Acrux Ltd.

[3] Acrux announced on 8 June 2021 that Almirall, LLC, owner of Aczone® Gel, 7.5% had initiated patent litigation against it. Acrux's Paragraph IV certification submitted concurrently with its March 2021 ANDA submission to the US Food and Drug Administration (FDA) for review, asserted that the relevant Orange Book[4] listed patents were invalid, unenforceable and/or would not be infringed by Acrux's ANDA product.

[4] The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the US FDA under the US Federal Food, Drug, and Cosmetic Act and related patent and exclusivity information.

[5] The Court of Appeals affirmed the invalidity of all claims of the '219 patent as previously adjudged by the U.S. Patent and Trademark Office in Inter Partes Review No. IPR2019-00207 (Almirall, LLC v. Amneal Pharm. LLC, No. 20-2331 (Fed. Cir. May 6, 2022).

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About Acrux

Acrux (ASX: ACR) is a specialty pharma company with a successful track record of developing and commercialising a pipeline of topically applied pharmaceutical products.

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 a range of topical and dermatological 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