ASX Release

8 June 2021

Acrux confirms patent challenge for generic version of Aczone®

Melbourne, Australia; 8 June 2021: Acrux Limited (ASX:ACR, "**Acrux**" or the "**Company**") today announced that Almirall LLC has initiated patent litigation against Acrux in the U.S. District Court for the District of New Jersey, regarding the Company's Paragraph IV Abbreviated New Drug Application (ANDA) for Dapsone Gel 7.5% (a generic version of Aczone® Gel, 7.5%), asserting U.S. Patent No. 9,517,219 ("the '219 patent"), one of two patents listed in the FDA Orange Book for Aczone® Gel, 7.5%. Acrux's Paragraph IV certification asserts that the '219 patent is invalid, unenforceable and/or would not be infringed by Acrux's ANDA product. As referenced in the Company's ASX Release on 15 April 2021, this action is expected and formally initiates the patent litigation process under the Hatch-Waxman Act.[1]

Aczone® Gel, 7.5% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Authorised by the Board of Acrux Limited.

For more information, please contact:

Michael Kotsanis
Acrux Limited
CEO & Managing Director
P: + 61 3 8379 0100
E: michael.kotsanis@acrux.com.au

About Paragraph IV ANDA[1]

Under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, a company can seek FDA approval to market a generic drug before the expiration of patents related to the brand-name drug that the generic seeks to copy. To seek this approval, a generic applicant must provide in its application a "certification" that a patent submitted to FDA by the brand-name drug's sponsor and listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the

[1] https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions

Orange Book) is, in the generic applicant's opinion and to the best of its knowledge, invalid, unenforceable, or will not be infringed by the generic product. This certification is called a "paragraph IV certification".

Following notification from a company filing an ANDA with a Paragraph IV Certification, the patent owner has 45 days to file a patent litigation suit asserting patents listed in the Orange Book in a United States District Court in order to initiate the litigation process under the Hatch-Waxman Act.

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