

ELI LILLY AND COMPANY AND ACRUX FILE LAWSUIT AGAINST LUPIN PHARMACEUTICALS INC FOR INFRINGEMENT OF PATENTS

Acrux (ASX: ACR) today announced that Eli Lilly and Company, Eli Lilly Export S.A. ("Lilly"), and Acrux DDS Pty Ltd ("Acrux") have filed a lawsuit against Lupin Pharmaceuticals Inc ("Lupin") for infringement of issued US patents that cover Axiron[®]. The patents are owned by Acrux DDS Pty Ltd, a wholly-owned subsidiary of Acrux Limited, and are exclusively licensed to Lilly.

The lawsuit was filed in the United States District Court for the Southern District of Indiana in response to a notice letter sent by Lupin regarding its filing with the FDA of an Abbreviated New Drug Application ("ANDA") for a Testosterone Metered Dose Transdermal Solution. The letter stated that the ANDA contains Paragraph IV certifications with respect to US Patents 8,419,307, 8,435,944, 8,784,878, 8,807,861 and 8,993,520, which are expected to expire between 2026 and 2030. These patents include claims relating to the application of testosterone formulations to the underarm and to the applicator used to apply Axiron[®].

A Paragraph IV certification alleges invalidity, unenforceability and/or non-infringement of a patent.

Lilly and Acrux are committed to asserting their intellectual property rights for Axiron[®]. As with prior notices, the conduct of the lawsuit will not have a material impact on its operating expenditure.

Contact

Michael Kotsanis, CEO and Managing Director: 03 8379 0100

About Acrux

- Acrux is an Australian drug delivery company, developing and commercialising a range of patient-preferred, patented pharmaceutical products for global markets, using its innovative technology to administer drugs through the skin.
- The Acrux technology, used in marketed products including AXIRON[®], Evamist[®] and Recuvyra[™], is based on a fast-drying, small volume, accurately dosed solution, containing penetration enhancers, that when applied topically, deposit drug through the skin for long acting delivery.
- Acrux has three products marketed by licensees in the USA, three products approved in Europe, and further products at earlier stages of development.

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

