



12 January 2021

## **Acrux receives FDA approval for its generic testosterone topical solution**

**Melbourne, Australia; 12 January 2021:** Acrux Limited (ASX:ACR) ('Acrux' or the 'Company') is pleased to announce that the US Food and Drug Administration ('FDA') has approved its generic product based on Perrigo's Testosterone Topical Solution, 30mg/1.5mL.

In August 2018, Acrux submitted an Abbreviated New Drug Application ('ANDA') to seek approval from the FDA to market a generic product equivalent to Perrigo's Testosterone Topical Solution, 30mg/1.5mL. The FDA has notified Acrux that the submission has now been approved and that Acrux can manufacture and market the generic drug.

As announced on 12 October 2020, Acrux has entered into an exclusive sales, marketing and distribution agreement with Dash Pharmaceuticals ("Dash"). Dash will be responsible for the commercialisation of the product in the United States, including the coordination of commercial manufacturing and management of marketing and distribution.

In the United States, sales generated by the product with which Acrux's generic will compete exceeded USD\$25 million in the 12 months to the end of September, 2020, based on IQVIA data.

Acrux and Dash will share the profits generated from the sales of the product.

**Acrux CEO and Managing Director, Michael Kotsanis said:**

"FDA approval is a major milestone for Acrux and its generics strategy. It is a testament to the hard work and dedication of the product development and regulatory team. We are excited to partner with Dash Pharmaceuticals to bring this product to market in the current financial year."

Authorised by the Board of Acrux Limited.

**For more information, please contact:**

### **General enquiries**

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### **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](http://www.acrux.com.au)

### **About Dash Pharmaceuticals.**

DASH is a privately held, specialty pharmaceutical company. The company markets, sells, and distributes generic pharmaceutical products, packaged in the “DASH” label. The DASH team continually evaluates and identifies generic product opportunities, across multiple dosage forms and therapeutic categories for sale in retail, institutional and other US pharmaceutical markets. Through partnerships with quality pharmaceutical developers and manufacturers around the world, the company co-develops and licenses products for its distribution.

For further information on Dash Pharmaceuticals LLC, visit [www.dashpharm.com](http://www.dashpharm.com)