



ASX Release

## Nitroglycerin Ointment FDA approved in United States

**Melbourne, Australia; 4 December 2024:** Acrux Limited (ASX:ACR) ('Acrux' or the 'Company') is pleased to announce that the US Food and Drug Administration ('FDA') has approved the Company's sixth ANDA, a generic version of Rectiv<sup>®</sup> (Nitroglycerin Ointment, 0.4%).

### Key Highlights:

- Nitroglycerin Ointment, 0.4% is indicated for the treatment of moderate to severe pain associated with chronic anal fissure
- Annual addressable market sales for the product are growing and now exceeds US\$23 million<sup>1</sup>
- The announcement marks Acrux's sixth topical ANDA to be approved by the FDA

The ANDA is a generic version of Rectiv<sup>®</sup> Ointment (Nitroglycerin Ointment, 0.4%) which is a topical treatment for moderate to severe pain due to anal fissure. The FDA has notified Acrux that the submission has been approved.

In the United States, annual sales generated by the branded product and a generic competitor (with which Acrux's generic will compete) exceeded USD\$23 million and 47,000 packs based on sales reported by IQVIA<sup>1</sup>.

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

"We are very pleased to receive FDA approval for another ANDA product which has been developed in house by the Acrux R&D team. This approval again demonstrates the capability of the Acrux team to execute the Company's strategy to develop our pipeline of topical products."

Authorised by the Board of Directors.

<sup>1</sup> IQVIA August 2024. Product sales for previous twelve months.



**For more information, please contact**

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#### **About Acrux**

Acrux is a specialty pharma company with a successful track record of developing and commercialising a pipeline of topically applied pharmaceutical products. Drawing on 25 years of experience, Acrux has successfully marketed through licensees a number of products worldwide with emphasis on the United States. Acrux is formulating and developing a range of topical generic products by leveraging its highly skilled workforce, on-site laboratories, GMP manufacturing suite, technical, clinical and commercial experience to bring affordable products to market. Acrux encourages collaboration and is well positioned to discuss commercial partnering and product development opportunities.

For further information on Acrux, visit [www.acrux.com.au](http://www.acrux.com.au)

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