



## ASX Announcement

### **Nitroglycerin Ointment commercialisation in the United States**

**Melbourne, Australia; 13 December 2024:** Acrux Limited (ASX:ACR) ('Acrux' or the 'Company') is pleased to announce that commercial launch activities have commenced for Nitroglycerin Ointment, 0.4% in the United States market.

This product is the Company's sixth ANDA that has been approved by the United States Food and Drug Administration (FDA) since 2021 and the product is a generic version of Rectiv® (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 fourth commercialised product in the United States**

The ANDA is a generic version of Rectiv® Ointment (Nitroglycerin Ointment, 0.4%) which is a topical treatment for moderate to severe pain due to anal fissure. The FDA recently notified Acrux that the submission has been approved, product has been manufactured and Acrux's licensee, TruPharma has commenced its commercial launch activities for the of the product in the US market.

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 excited to again commercially partner with TruPharma for another ANDA product which has been developed in house by the Acrux R&D team. This further demonstrates the capability of the Acrux team to execute the Company's strategy to develop and commercialise our pipeline of topical products. Commercial rights for the product are available for countries outside the United States."

Authorised by the Board of Directors.

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<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)

### **About TruPharma**

TruPharma, LLC is a front-end pharma sales and marketing company focused on commercializing branded and generic prescription drugs for the U.S. Market. TruPharma has a diverse portfolio of products distributed across multiple channels. TruPharma is operated by a team of experienced executives focused on getting complex products FDA-approved and into the market. For more Information: [www.trupharma.com](http://www.trupharma.com)