



## ASX Release

8 August 2022

### **Acrux's sixth generic application accepted by FDA for review**

**Melbourne, Australia; 8 August 2022:** Acrux Limited (ASX:ACR, "Acrux" or the "Company") is pleased to announce that the US Food and Drug Administration (FDA) has accepted for review Acrux's application for a generic version (Abbreviated New Drug Application or 'ANDA') of cold sore treatment, Acyclovir Cream, 5%.<sup>1</sup>

#### **Key Highlights**

- Acrux has submitted an ANDA application to the FDA for Acyclovir Cream, 5%, which has now been accepted for review;
- Annual addressable market sales for the product exceed US\$29 million as measured by IQVIA<sup>2</sup>; and
- This announcement marks Acrux's sixth ANDA accepted for review by the FDA

#### **FDA accepts for review Acrux's submission**

Acrux has submitted an ANDA to seek approval from the FDA to market its generic version of cold sore treatment Acyclovir Cream, 5%. The FDA has notified Acrux that the application is sufficiently complete to be accepted for review. The reference listed drug is Zovirax® Cream, 5% which is marketed by Bausch Health in the United States.

While the FDA administers the review process, the time to ultimate approval is influenced by the number and nature of questions which may arise as the FDA progresses their review. Once the FDA has granted approval, Acrux can finalise preparations with its contracted commercial partner to commence marketing and sales of the product in the United States.

#### **US\$29 million addressable market**

The total addressable market for the product including existing generics exceeds US\$29 million. There are currently two approved and marketed ANDA products.

#### **The Acrux product portfolio**

The Company currently has three products which are actively marketed plus three additional products which have been accepted for FDA review (including Acyclovir Cream, 5% announced today).

Beyond that, Acrux is advancing a carefully planned pipeline of products in varying stages of development either at Acrux or with our contracted manufacturing partners.

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<sup>1</sup> Acyclovir Cream, 5% is used to treat herpes labialis (cold sores) in immunocompetent adults and adolescents 12 years of age and older.

<sup>2</sup> IQVIA December 2021. Annual product sales for previous twelve months is the addressable market.



Our main priority is to support the development of our pipeline products which are in the later stages of the development cycle and are therefore closer to commercialisation.

The Company currently has 16 products in various stages of development and commercialisation.

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

“Acrux is extremely pleased to advance another product from its pipeline to FDA regulatory review. Our key focus is on the continuing transformation of Acrux into a company with a diversified on-market portfolio and a well-planned pipeline of commercially valued products. Today’s advancement of Acyclovir Cream, 5% through to the final regulatory stage before commercialisation is a great example of that strategy in action.

“We have several exciting product development milestones on the short-term horizon including two new product launches expected in the current financial year along with two further expected regulatory approvals that will subsequently be commercialised.”

**Approved for release by the Acrux Board of Directors.**

**For more information, please contact:**

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

**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)