ASX Announcement

10 February 2025

Hydrix Ventures Portfolio Company Gyder Surgical Secures FDA 510(k) Clearance for GYDER® Hip System

HIGHLIGHTS

- FDA 510(k) Clearance enables Gyder Surgical to market and sell their system in the U.S.A.
- Tranche of Gyder Surgical shares granted to Hydrix Ventures increases investment value to **$2.65m**

Hydrix Limited (**Hydrix**) (ASX: **HYD**) is pleased to announce that its client and investee company, **Gyder Surgical**, has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the **GYDER® Hip System**, a significant milestone towards commercialisation of this pioneering surgical navigation technology.

This FDA milestone achievement underscores Hydrix expertise in highly regulated, medical product development and innovation.

The GYDER Hip System is the world's first commercially available pin-less and image-less navigation solution for accurate positioning of the acetabular cup during anterior hip arthroplasty. This clearance follows its earlier approval by Australia's Therapeutic Goods Administration (TGA), reinforcing the system's regulatory momentum and commercial potential.

Further, under commercial terms, the FDA approval triggers a milestone equity payment to Hydrix Ventures (**Ventures**). This increases Ventures investment in Gyder Surgical by **$0.3 million** to a total book value of **$2.65 million** (based on the 30 June 2024 financial statements valuation assumptions).

Gyder Surgical CEO, **Sujit Dike,** commented:

"We are thrilled to receive FDA 510(k) clearance for the GYDER Hip System, a significant step towards making this groundbreaking technology available to surgeons in the U.S. This achievement would not have been possible without the dedication and expertise of the Hydrix team. Their ability to transform a complex technology into a market-ready solution has been outstanding. We deeply appreciate their partnership and commitment in overcoming the challenges along the way."

Hydrix Marketing Director, **Alan Morris**, added:

"The FDA clearance for the GYDER Hip System is a testament to the ingenuity of Gyder Surgical and the value of Hydrix's product development expertise. This approval significantly enhances Gyder Surgical's commercial prospects in the U.S. market. With approximately 700,000 hip replacement procedures annually, the U.S. market represents a substantial opportunity. We are proud to have played such an important role developing this groundbreaking technology. We look forward to the technology being adopted by surgeons."

The GYDER Hip System offers a highly efficient, surgeon-friendly solution designed for seamless integration into existing workflows, making it particularly well-suited for the expanding outpatient surgical market.

Surgical cases have already been successfully performed in Australia and India.

- Ends -

This announcement has been authorised for release by the Board of Hydrix Limited.

For further information, please contact:

Company Enquiries: Gavin Coote - Executive Chairman
info@hydrix.com
+61 3 9550 8100

Media Enquires: Rod North - Managing Director, Bourse Communications
rod@boursecommunications.com.au
+61 3 9510 8309

About Hydrix Limited

Hydrix Limited (ASX: HYD) is a powerful product innovation company. Hydrix's purpose is to enhance the health, safety, and well-being of a billion lives. The company leverages its powerful product innovation capability across three business segments: **Services**: design, engineer and deliver world first products and innovation; **Ventures**: invest in high potential MedTech clients; and **Medical**: distribute disruptive cardiovascular products.

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