

## Hydrix On Track for Cardiac Product Sales in H1 CY22

**Hydrix Limited (ASX: HYD)** ('Hydrix' or the 'Company') is pleased to provide the following updates regarding its progress towards commencing commercial cardiac product sales in CY2022.

Hydrix's mission is to develop, invest in, and commercialise new and innovative medical technologies which satisfy large unmet market needs, significantly improve patient quality of life, and reduce cost burdens of chronic health diseases on global healthcare systems.

A primary focus for Hydrix is investment in cardiovascular device technologies, with cardiovascular disease being the world's leading cause of death. In pursuing this important and game changing strategy, Hydrix has acquired exclusive distribution rights for 'The Guardian', the world's first implantable continuous heart attack monitoring device which can alert acute coronary syndrome patients of an impending heart attack. Distribution rights extend to eight countries including Japan, Singapore, Australia and New Zealand. Hydrix also has distribution rights in Australia and New Zealand for the Phyzhon FFR, a fibre optic pressure sensor guidewire is used as part of this process for interventional cardiology procedures.

Ms. Vickie Edwards, who joined Hydrix as Director Sales & Operations of cardiac products in April 2021, is driving the go-to-market strategy for these highly innovative technologies and is supported by a leadership team consisting of 40-year cardiac devices market veteran, General Manager Mr. Paul Kelly, and Ms. Ai Wee Ng, Regional Manager in Singapore. This experienced team has decades of know-how in cardiac product development, sales, and marketing, having previously worked together distributing pacemakers, stents and angioplasty products.

### **Ms. Edwards shares the following Status Report on preparing the business for product sales, stating:**

"Despite the ongoing hospital embargoes on elective surgeries and non-hospital employee access disruptions caused by COVID-19 outbreaks in key markets, the Hydrix team is taking important steps towards initial commercial sales anticipated for CY2022. I am happy to report on the following progress on 'The Guardian':

- FDA PMA supplemental approval for the upgraded Guardian device was granted to Angel Medical Systems Inc., USA in June 2021, enabling Hydrix to file for Regulatory Approval in Australia with the Australian Therapeutic Goods Authority (TGA);
- Subject to TGA approval being received in early H1 CY2022, we anticipate commencing direct to market commercial sales in H1 CY2022;
- Regulatory Approval was filed with the Health Sciences Authority (HSA) in Singapore in the September quarter, and subject to receiving approval early in H2 CY2022, we anticipate commencing direct to market commercial sales in H2 CY2022;
- New Zealand Medsafe Web Assisted Notification of Devices (WAND) Database inclusion has been confirmed and Hydrix is taking steps towards commencing direct to market commercial sales in New Zealand;
- Hydrix has commenced applications for private health reimbursement in Australia and these approvals are anticipated to follow once the TGA approves 'The Guardian' for commercial distribution;
- Active discussions are underway with potential sub distributors in Indonesia, Malaysia, Thailand & Hong Kong and work has commenced on regulatory submissions which we anticipate lodging in this December 2021 half; and

- After a successful CSANZ (the influential Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand) conference in August, Hydrix is engaged in positive and productive discussions with cardiovascular physicians across multiple specialty clinical teams in Australia and New Zealand for commencement of first implants of 'The Guardian.'

In addition:

- The Phyzhon First-In-Human FFR study is ready to commence subject to COVID-19 hospital restrictions. Hydrix's Field Clinical Engineers are undertaking usability testing of the product platform and training with Phyzhon USA ahead of starting clinical trials; and
- Angel Medical Systems (USA), the supplier of The Guardian, continues to make commercial sales for implant since receiving FDA approval in June.

Ms Edwards continued: "I am proud of the substantial traction we have made in a short period of time and look forward to some really exciting announcements in the near future."

'The Guardian' market opportunity alone has potential to be a significant catalyst for Hydrix. For example, 'The Guardian':

- Satisfies an unmet need for more than 500,000 APAC-region patients suffering annually from acute coronary syndrome events (*including silent heart attacks*);
- Has no competitive product in the market;
- Can deliver strong gross profit margins based on predicate market pricing in the USA and Singapore;
- Has the potential to deliver substantial revenues to Hydrix - capturing even 1% to 3% of the unmet market need equates to annual product revenues to Hydrix of \$35 million (~5,000 units) to \$100 million (~15,000 units); and
- Would deliver strong cash flow earnings based on these volumes and gross profit margins.

This announcement is authorised for release by the Board of Directors of Hydrix Limited.

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### About Hydrix Limited

Hydrix Limited (ASX: HYD) is a powerful product innovation company. Hydrix purpose is to enhance the health, safety, and wellbeing of one Billion lives. The company leverages its powerful product innovation capability across multiple growth platforms: **Hydrix Services** design and engineer client products which transform industries; **Hydrix Ventures** generate equity returns through investing in high potential companies; and **Hydrix Medical** bring innovative medical technologies to market.