

ASX Announcement 30/10/2020

Hydrix announces exclusive agreement to distribute novel cardiovascular technology

Key Highlights:

- Hydrix Medical to distribute Phyzhon Health's disposable fibre optic pressure sensor guidewire used for interventional cardiology procedures
- Phyzhon's novel product improves the stent selection and insertion by Interventional Cardiologists for patients with coronary artery disease, improving patient and healthcare outcomes
- 4-year plus exclusive distribution rights for Australia & New Zealand with a potential annual market demand of up to 125,000 units

Hydrix Limited (ASX: **HYD**, '**Hydrix**' or the '**Company**') is pleased to announce that it has entered into an exclusive agreement with Phyzhon Health Inc. ('**Phyzhon**'), to distribute Phyzhon's PHYRARI FFR-WIRE product in Australia and New Zealand, in the interventional cardiology field of use. The product is primarily for use by interventional cardiologists during procedures which manage blockages in coronary arteries.

Commenting on the Company's milestone, Executive Chairman Gavin Coote, said:

"The announcement of our exclusive rights to distribute Phyzhon's disruptive medical device on the back of announcing a A\$10 million Institutional capital raise, demonstrates our transformational strategy to also sell medical devices is gaining traction.

"With a significantly strengthened capital position and share register, we are very well placed and confident about growth prospects."

Market Opportunity

Patients identified as having coronary artery disease typically undergo an angiogram to determine which arteries require treatment. During this procedure, a technology called Fractional Flow Reserve (FFR) is often used to measure blood pressure differences either side of a coronary artery stenosis (narrowing of the artery) to determine the amount of blood flow to the heart muscle. This information guides stent selection, or whether stenting is required at all. Currently, measurement and treatment is achieved via multiple insertions of cannulas, catheters, and guide wires. The PHYRARI FFR-WIRE combines both FFR, through fibre optic technology, and the ability to deliver a stent, allowing the cardiologist to use it for both diagnostic purposes and delivery of therapy including stents, improving the overall efficiency of the procedure and providing beneficial outcomes to the patient.

In speaking about the opportunity, Paul Kelly, Hydrix Medical General Manager, said "we are very excited to bring this technology to market in Australia & New Zealand. Phyzhon's novel product design has the potential to transform Percutaneous Coronary Intervention (PCI) procedures and stent selection. The incorporation of fibre optic pressure sensing technology into the guidewire makes it a more economical, user-friendly means to take pressure readings of narrowed coronary arteries."



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There are approximately 125,000 Selective Coronary Angiograms each year in Australia, of which, approximately 45,000 PCI procedures are then performed to stent the blockage. The PHYRARI FFR-WIRE has the potential to increase the frequency of taking pressure sensing readings during PCIs from an approximate 12,000 use-cases currently, to potentially becoming a mainstream technique during Coronary Angiograms and all PCIs.

Mr Kelly further added, "Phyzhon's unique product design makes it possible to deliver immediate clinical benefits to patients and cardiologists and has the potential to reduce surgery times and costs as compared to current clinical products and procedures. Guidewire products are single use making this a very attractive market opportunity for Hydrix."

The PHYRARI FFR-WIRE is currently progressing through US FDA 510K approvals which is anticipated to be granted in the first quarter of calendar year 2021. Once Phyzhon receives FDA approval, Hydrix will submit an application to the TGA for approval. In the interim, Hydrix will pursue opportunities to supply the product in Australia under early access schemes. Subject to the timing of TGA approval being granted, Hydrix anticipates the potential to begin commercial distribution in Australia commencing mid-to-late calendar year 2021.

Distribution Agreement Terms

The exclusive rights to distribute Phyzhon's product in Australia and New Zealand expands Hydrix Medical's portfolio of products targeting cardiovascular health and reflects another significant milestone achievement for the Company.

The initial term of the distribution agreement expires 4 years after TGA approval is granted, with an option to renew for a further 1 year. The distribution agreement may be terminated prior to its expiry by either party for cause.

Hydrix is responsible under the distribution agreement for marketing Phyzhon's product, meeting agreed sales targets, and securing TGA approval for the product.

-ENDS-

This announcement was 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.