

Hydrix Medical - Business Update

Hydrix Limited (ASX: HYD, '**Hydrix**' or the '**Company**') is pleased to provide an update on progress of various key milestones within its Hydrix Medical business.

Key Market Update Highlights:

- Positive battery test results submitted to US FDA for approval of the AngelMed Guardian
- Senior Industry Executive appointed to role of Director of Sales and Operations for Hydrix Medical
- Working towards initial Guardian implants in Australia under special access schemes
- Regulatory submissions of the Guardian to the Australian TGA and Singapore HSA are ready to lodge once FDA approval is granted

While we have not yet commenced initial special access scheme implants of the AngelMed Guardian in Australia, we continue important discussions and planning with multiple stakeholders to reach this major milestone. Subject to the ongoing COVID situation, we remain confident implants can commence in the June quarter following on from the successful implants completed in Singapore.

AngelMed Guardian Update

The USA FDA mandated 12-month battery testing for the Guardian was completed by AngelMed with the results submitted to the FDA on 25 February 2021. Very pleasingly, and as expected, there were no anomalies in the test results. AngelMed remains optimistic about receiving FDA approval of the upgraded battery for commercial use in the near term, and this remains a significant milestone also for Hydrix Medical.

AngelMed USA has completed four patient implants with the upgraded battery Guardian in the USA under its FDA IDE early access scheme with a further 60 patient implants identified. This is the same Guardian device which Hydrix Medical is supplying for Singapore patient implants and which it will use for Australian implants.

We have continued to build market awareness off the back of the Singapore patient implants. Our activities have included:

- Supporting Singapore-based cardiologist Dr Lesley Lam for his seven implants, with an 8th pending;
- Meeting with Dr Lam and his patients at their 6-month follow up check-ups, capturing valuable insights about the significant Quality of Life improvements the patients are experiencing, and confirming all implanted devices are functioning as expected, with no anomalies recorded;
- Engaging Key Opinion Leaders (KOLs) in scientific webinars and presenting at trade events;
- Presenting and discussing patient outcome benefits to cardiologists at the Singapore National University Heart Centre public hospital & the National Heart Center;
- Exploring pathways for patients to receive Academy of Medicine Table of Surgical Benefits reimbursement status prior to HSA approval; and
- Working with Austrade and other relevant parties to facilitate regulatory and go-to-market discussions in Japan, Thailand, Malaysia, and Indonesia for the AngelMed Guardian.

Following on from the seven successful AngelMed Guardian device implants in Singapore, Hydrix Medical has continued its progress towards initial implants in Australia, under special access schemes. Discussions with medical practitioners, hospitals, and patients are being positively received. We anticipate sponsoring up to 10 patient implants in Australia over a 6-month period beginning the June quarter.

The purpose of performing early access scheme implants prior to receiving full regulatory approval is to establish local medical based evidence and case studies, and to build awareness and confidence in the benefits the Guardian provides for improving patient outcomes.

Hydrix Medical has completed all preparatory documentation to immediately submit regulatory applications in each of Australia and Singapore, once AngelMed receives FDA approval. The Australian TGA regulatory approval process is anticipated to take 6-12 months and the Singapore HSA regulatory approval process 9-12 months. These are indicative timeframes only.

Hydrix Medical has also begun the Medical Services Advisory Committee (MSAC) application process in Australia to establish surgical code for the reimbursement of fees pertaining to implant procedures. The Company will also begin the Prostheses List Advisory Committee (PLAC) process to establish a device reimbursement code for the Guardian once it submits its TGA application. An Australian healthcare economic report to support reimbursement of the procedure fees and device costs has been prepared to lodge with these applications.

Further, documentation and mapping out approval processes for Regulatory approvals in Malaysia, Hong Kong, Thailand, Indonesia, and Japan are also being developed. Preliminary exploration and discussions with prospective sub-distributors in those jurisdictions are getting underway. AngelMed receiving FDA approval is an important step to advance these country specific programs.

Phyzhon Health Guidewire update

Phyzhon Health is nearing a final production run of its cardiac guidewire device to supply Hydrix Medical first-in-human (FIH) trials. We expect product to be available in Australia sometime in April or May. Phyzhon's capacity to manufacture and supply has been delayed due to COVID disruptions in the USA.

Hydrix Medical has received Australian TGA clinical trial notice permitting supply of the Phyzhon guidewire to progress FIH trials at a Melbourne-based hospital. Leading cardiologists and FIH trial program administrator are in place to begin the program once product is available.

Phyzhon is finalizing preparations for an independent regulatory body to complete a CE Mark review. This has been delayed due to USA COVID.

Senior Executive Appointment

To support the ongoing growth and market development of Hydrix Medical, we are pleased to announce Ms. Vickie Edwards will commence with Hydrix Medical in the role of Director Sales & Operations in mid-April. Vickie is a 25+ year seasoned Medical Device industry executive with deep clinical and commercial experience bringing new interventional cardiac devices to market. Her broad commercial experience in sales, marketing, field operations, finance and regulatory affairs further strengthens our organisational capabilities. Vickie will have primary day-to-day focus on driving growth in sales and field clinical engineering for AngelMed and Phyzhon within our exclusive distribution jurisdictions. General Manager Paul Kelly will continue his focus on expanding and accelerating strategic growth initiatives.

Hydrix Group Update

We continue to actively explore various medtech related “Buy, Build, Invest” initiatives with high potential growth and expansion for Hydrix Medical and the Group.

We will lodge the Hydrix Limited 4C Appendix for the March 2021 quarter towards the end of April and anticipate providing a broader market update at that time. We remain confident about the growth opportunities for the business.

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.