

Appendix 4D and 31 December 2020 Half Year Report

Hydrix Limited ('Hydrix' or 'the Company') (ASX: **HYD**) today released its **Appendix 4D** for the six months ended 31 December 2020 (**1H21**) and a **Business Update**.

First Half Highlights:

Financial

- First half total revenues of \$5.1 million and a \$0.8 million cash operating loss;¹
- Hydrix Services pipeline remains healthy at above \$50 million;
- Raised \$13.0 million via oversubscribed Placement to key institutional investors and an Entitlement offer to existing shareholders;
- Extinguished \$3.5 million secured debt remaining under the Finance Facility; and
- Closed the half year in a strong cash position with \$9.2 million on hand.

Hydrix Medical

- Sold first five AngelMed Guardian heart attack warning devices which were implanted in patients in Singapore;
- Entered into exclusive agreement to distribute Phyzhon Health Inc's cardiac guidewire in Australia; and
- Presented two medical symposiums on the "Time-to-Door" benefits of the AngelMed Guardian device to leading Asia-Pacific Interventional Cardiologists.

Hydrix Services

- Hydrix Services awarded two International Good Design Awards; and
- Appointed USA-based, experienced medtech Business Development Executive (January).

Hydrix Ventures

- Hydrix Ventures investments increased \$0.83m to \$3.1m, of which 28% was attributable to revaluation in fair values.

Hydrix Executive Chairman, Gavin Coote commented:

"While the impacts of COVID-19 in particular on the Hydrix Services Business revenues were more than originally anticipated, our revenue pipeline and balance sheet are strong, and we are excited by the transformational potential from high growth product revenues beginning FY2022 from Hydrix Medical."

Business Update: A strong Balance Sheet to drive future growth

The Company significantly advanced its **'Buy, Build, Invest' strategy** and its financial strength in support of high growth strategic initiatives. These ongoing achievements reposition the Company's valuation prospects from a pure-play design and engineering services business to now include valuation growth from distributing high margin cardiac and medtech products, and capital returns from investments made in medtech clients.

While revenues of the Services Business were impacted by COVID-19 disruptions leading to a cash operating loss for the half, the pipeline remains healthy at above \$50 million level. In January, we appointed an experienced medtech Business Development Executive in the USA to increase our direct access to the largest healthcare market in the world.

We completed our first sales of the AngelMed Guardian heart attack warning device and supported the first patient implants in Singapore. This device is a 'first of kind' cardiac product and satisfies an unmet patient need. We also entered into an exclusive agreement to distribute a new cardiac guidewire device from Phyzhon Health, Inc.

AngelMed completed the FDA required 12-month battery testing for the next generation Guardian device and will submit the results to the FDA around the end of February. In AngelMed's opinion, data from the battery testing demonstrated battery performance commensurate with satisfying the FDA requirements. AngelMed anticipates a response from the FDA within 90 days of submission.

We are evaluating several high potential product growth opportunities and exploring various pathways to accelerate first implants of AngelMed Guardian in Australia, and to undertake first-in-human trials of Phyzhon's cardiac guidewire device.

Group financial outlook

In terms of the financial outlook for the full year FY2021, client engagement activities are picking up and we anticipate stronger second half sales, setting the business up for solid growth in FY2022. More than likely, the timing of these sales will not convert into revenues in time to clawback the first half cash operating loss result. We anticipate cash operating breakeven¹ for the second half.

We strengthened the balance sheet in the first half by raising A\$13 million through equity issuances and extinguishing \$3.5 million of secured debt, placing the business in a strong capital position with \$9.2 million of cash on hand at 31 December 2020.

Notwithstanding the potential need to finance new strategic growth initiatives in the future, we expect our current cash position is sufficient to operate the existing business beyond June 2022 based on anticipated improvement in services revenues and profitability, plus moderate investment in Hydrix Medical's product distribution business.

First Half Group Financial Accounts (Audited)

Group revenues were \$5.1 million, including \$3.7 million in project related fee for service revenues, \$52,000 in sales of AngelMed Guardian devices, and other income of \$1.4 million, primarily from government grants in support of COVID-19 business interruptions.

The evolving COVID-19 business interruptions during the first half had a material impact on the business' revenues as compared to the prior year revenue of \$8.2 million. Impacts included clients deferring and reducing project budgets due to difficulties completing their funding programs, reduced budgets, cash preservation and lock-down access to critical supply chain facilities. The Company's revenue generating business development activities were heavily restricted by mandatory lockdowns in domestic travel, and international travel to northern hemisphere clients, conferences, and trade events.

Group cash operating costs were \$6.4 million (pcp \$8.5 million), of which \$4.9 million pertain to Hydrix Services (pcp \$7.4 million), \$0.6 million to Hydrix Limited (pcp \$0.7 million), \$0.5 million to Hydrix Medical (pcp \$0.4 million), and \$0.4 million discretionary 'buy, build, invest' initiative costs (pcp \$NIL). Group wage costs were \$4.6 million, down from \$6.0 as compared to the first half of the prior year.

Interest paid excluding interest expenses on lease liabilities under AASB 16 was \$0.24 million, including early prepayment and penalty interest fees to Pure Asset Management after prepaying the remaining \$3.5 million of debt under that finance facility, three-years ahead of the maturity date.

Subsequent to 31 December 2020, the Group made a partial repayment of a shareholder loan in February in the amount of \$0.5 million, further deleveraging the balance sheet. The Company anticipates no further early repayments of remaining shareholder loans.

Hydrix Services & Limited

The core business made a \$0.80 million cash operating loss¹ compared to the prior year first half cash operating loss of \$0.33 million. Overall, a reasonable outcome relative to the material year on year \$3.1 million revenue decline primarily attributable to COVID-19 disruptions. Employee and other discretionary cash operating costs were managed down by the business to the maximum extent given the lower revenues and fluidity of the trading environment.

The business continued with ongoing employee training and development programs, and internal development which advance proprietary engineering systems and increase the value of our client project management systems and product innovation capability.

The business is developing cardiac platform technologies to accelerate client cardiac assist device product commercialisation. These platform technologies are being shared with, and demonstrated to, global cardiac assist device companies and have been very well received. We are confident that as our platform technology matures; it will enable us to win meaningful cardiac assist device client projects.

Goodwill Impairment

As noted in the Financial Accounts, the Company made a \$1.27 million intangible asset impairment write-off pertaining to Goodwill created on acquisition of Hydrix Services in November 2017. Management considered various factors when assessing the carrying value of Goodwill as it is required to do under generally accepted accounting standards.

The revenue pipeline of the business remains healthy at above \$50 million. However, Hydrix Services revenues have been impacted by COVID-19, and while management expects this situation to improve as global vaccinations are completed and business investment improves, the fluidity of COVID-19 over the near term increases the risks of an asset impairment. As such, management deemed it prudent to recognise the impairment risk.

The long-term prospects of the Group remain strong, and the powerful product innovation capability of Hydrix Services is an important part of the long-term growth strategy and competitive advantage of the Group.

Hydrix Medical

Hydrix Medical incurred operating costs of approximately \$0.5 million relating to its growth strategy. These costs relate to cost of goods sold, regulatory and reimbursement approval application processes, general management and field clinical engineering personnel, sales and marketing initiatives to build market awareness and drive future demand, and planning and preparation of the first-in-human trials of the Phyzhon guidewire expected to commence next quarter.

Hydrix Ventures

Hydrix Ventures used Hydrix Services engineering employees to work on Hydrix Ventures investee company projects. No revenue was recorded, and these engineering costs were recorded in Hydrix Services. These costs have the potential to be recovered by Hydrix Ventures via future equity capital gains. In the half, Hydrix Venture investments increased value by \$0.83 million including a \$0.23 million revaluation increase on existing investee companies, a majority of which represented a 54% increase in one portfolio asset.

Hydrix Medical Outlook Update
AngelMed Guardian

Hydrix Medical continues to consult with key stakeholders for early access scheme approvals and implants of the AngelMed Guardian in Australia. Subject to reaching commercial and regulatory arrangements, without any further COVID-19 disruptions, the potential for initial implants of the AngelMed Guardian in Australia in the March 2021 quarter remains a possibility.

Hydrix Medical is working with local stakeholders on potential pre-Regulatory implant programs focusing on patients experiencing ongoing acute coronary syndrome events. We are working towards a small clinical trial, and associated research paper, to advance awareness among Australian cardiologists of the patient benefits which the Guardian device provides, crucially getting patients to hospital faster (i.e., 'Time to Door') than patient symptoms alone.

Patients suffering cardiac events, including heart attacks, rely on recognisable symptoms to seek medical attention and in a large number of cases, a person may have no symptoms, or no recognisable symptoms such as the case with a silent heart attack. The Guardian early detection warning system can satisfy this unmet patient market need.

In January 2021, Hydrix showcased the Guardian device at Singapore LIVE, Asia's preeminent annual live course in cardiac interventions. Running a symposium titled "It's About Time," Hydrix arranged for Dr Leslie Lam, who has now completed seven Guardian implants in Singapore, to lead a panel, including American Key Opinion Leaders (KOLs) involved in patient implants under AngelMed's FDA approved clinical trial program upon which the FDA previously approved the first-generation device. This event was another critical market awareness initiative. A recording of the presentation is available to view [here](#).

This event followed on from a Scientific Webinar Hydrix featuring AngelMed KOLs presenting to leading Asian interventional cardiologists in August 2020, immediately after the initial Singapore implants were completed. These events have resulted in several meetings with various stakeholders from the medical profession in Singapore and new interest from nearby markets including Malaysia, Thailand, and Indonesia.

More than 500,000 people suffer some form of acute coronary syndrome event each year in the eight Asia Pacific jurisdictions into which Hydrix has exclusive rights to sell the Guardian device. Subject to market pricing being established, a 3.0% capture rate could generate \$100 million in revenues p.a. for Hydrix.

Phyzhon Health

Hydrix Medical continues to work with various stakeholders to facilitate, on behalf of Phyzhon Health, first-in-human trials of their cardiac guidewire at a Melbourne-based hospital. We anticipate this is more likely to start in the June quarter with delays due to internal hospital administration and completing product testing where the device is manufactured in the USA.

Hydrix obtained a TGA clinical trial notice in the December quarter. The clinical trial cardiology team are ready to start the trial once the product arrives in Australia and the hospital finalises its administration. Key benefits arising from the trial will include expanded awareness of the value and capabilities of the PHYRARI FFR-Wire System, and potential to accelerate sales under early access schemes.

Phyzhon Health anticipates obtaining CE Mark and FDA approval in the first half of calendar year 2021, subject to supply chain and public health body COVID interruptions. Once CE Mark is obtained, Hydrix Medical will lodge its application to the TGA for full regulatory approval. No private or public health insurance reimbursement is required in Australia or New Zealand for this device, which will be sold direct to hospitals.

Potential product revenues and margins from distributing Phyzhon's cardiac guidewire once full TGA regulatory approval has been obtained are expected to be meaningful. If Hydrix can capture 15% of the Australian market that could yield \$10+ million p.a. revenues.

In summary, potential significant milestone news flow for the 2H FY21 and 1H FY22 includes the following:

Q3 FY21	Q4 FY21	1H FY22
<ul style="list-style-type: none"> • AngelMed USA submission of battery testing results to FDA • Potential first implants of AngelMed Guardian in Australia under Authorised Prescriber Scheme (APS) 	<ul style="list-style-type: none"> • Potential FDA approval of AngelMed Guardian new battery • Potential to submit TGA (AUS & NZ) & HAS (SG) regulatory approval for AngelMed Guardian – immediately once FDA approved • Potential CE Mark approval of Phyzhon • Commencement of First in Human (FIH) Trials for Phyzhon in Melbourne Australia • Potential sales of Phyzhon under Authorised Prescriber Scheme in Melbourne, Australia 	<ul style="list-style-type: none"> • Potential AngelMed Guardian TGA regulatory approval in AUS • Potential AngelMed Guardian health reimbursement approval in Aus • Potential to begin appointments by Hydrix Medical of APAC sub-distributors for AngelMed Guardian • Potential TGA regulatory approval for Phyzhon
<p>Potential Hydrix Ventures portfolio updates & revaluation events Ongoing evaluation of several high-growth potential "Buy, build, Invest" initiatives</p>		

(1) Cash operating profit (or loss) is Earnings before Interest, Tax, Depreciation, Amortisation (EBITDA) and Share-based payments for a full year, and before costs associated with the Company's 'Buy, Build, Invest' strategy and other non-recurring costs.

-ENDS-

Authorisation: 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 1 billion lives. The company leverages its powerful product innovation capability across multiple growth platforms. These platforms include **Hydrix Services** design and engineering to create products which transform markets; **Hydrix Ventures** to pick winning investments in high potential innovative products; and **Hydrix Medical** to create new product revenue streams bringing cardiovascular technologies to market which improve patient mobility and quality of life.