

Collaboration and clinical trials with leading healthcare providers represent important validation of technology, as part of well-defined commercialisation strategy

Q2 FY20 Highlights

- COVID-19 presents favourable market tailwinds and a unique opportunity to fast-track adoption of digital health and maternity care;
- HeraMED is well-placed to deliver high-quality pre- and post-natal care to improve the safety, efficiency and cost of maternal healthcare and is focused on a fast-tracked adoption of its homecare-based solution;
- Solid progress on commercialisation strategy, as evidenced by extended collaboration agreement including project funding and a confirmed trial at Mayo Clinic in the United States and Joondalup Health Campus in Western Australia;
- Signed agreement with Freeman Road and PHI Group, a leading healthcare advisory group to secure further clinical studies and research projects in Australia;
- Progressed discussions with further leading healthcare providers in the US as potential partners;
- Signed distribution agreement with Advanced Pregnancy Solutions, a subsidiary of MedTech Edge Pty, an Australian medical devices and healthcare technology supplier to distribute and build exposure; and
- Successfully raised A\$2.55m via a placement to sophisticated and institutional investors and an SPP; to strengthen the balance sheet and accelerate commercial rollout of the platform.

HeraMED Limited (ASX: HMD) (“HeraMED” or the “Company”), a medical technology company leading the digital transformation of maternity care with its proprietary remote monitoring maternity care platform, is pleased to provide an update on its progress for the three months period ending 30 June 2020 (Q2 FY20).

With a CE, TGA and FDA-cleared foetal ultrasonic heart rate monitor that is available for professional and home use, supported by a comprehensive in-home maternity care platform, HeraMED is very well-placed to deliver high quality pre- and post-natal care to significantly improve the safety, efficiency and cost of maternal healthcare.

During the period, HeraMED made solid progress on its well-defined commercialisation strategy to collaborate with top-tier healthcare providers to drive adoption with an initial focus in USA and Australia, representing key regions of strategic growth. The Company achieved several milestones including the signing of two new strategic agreements in US and Australia and the commencement of a clinical study in Australia, a significantly improved pipeline across multiple geographies, and a strengthened distribution network in Australia.

The two important new agreements signed during the period relating to the clinical study pipeline included a key milestone in the US which was the extension of a collaboration with Mayo Clinic. Mayo Clinic are one of the largest and most widely acclaimed academic health systems in the world. An agreement was also signed with Freeman Road and PHI Group, a leading healthcare advisory group to secure further clinical studies in Australia. Importantly a clinical study has begun with Joondalup Health Campus in Western Australia to evaluate the technology against a hospital CTG machine, evaluating usability, ease of use and user satisfaction by the clinic.

The distribution network was strengthened by the signing of an exclusive agreement with Advanced Pregnancy Solutions, a subsidiary of MedTech Edge Pty an Australian medical devices and healthcare technology supplier, to distribute and build exposure.

CEO and Cofounder Mr. David Groberman said: “The growing global demand for innovative remote monitoring and maternity telehealth solutions continued during the period and we are humbled by the growing interest from leading healthcare providers in relation to both HeraCARE and HeraBEAT Plus.”

“We are proud and excited to extend our collaboration with Mayo Clinic. This new agreement is a major milestone for HeraMED, and further emphasizes the paradigm shift in the mindset of healthcare systems and the belief in the opportunity that HeraMED’s solutions are adding to virtual management of maternal and foetal wellbeing. Our strategy is to cooperate with top-tier healthcare providers to drive adoption; This achievement strengthens our relationship and aligns perfectly with our goals. We are confident it will become a significant catalyst in our goal to deliver accessible and high-quality care for pregnant moms and their providers.”

“During the period, we generated further clinical validation for our product offering with the commencement of a clinical study at Joondalup Health Campus in Western Australia.”

“HeraMED also completed a A\$2.55 million capital raise, significantly strengthening the Company’s cash balance and demonstrating strong support from the market for the next phase of its commercialisation strategy.

During the next quarter, the Company will continue to focus on progressing its ongoing studies and leverage results and relationships to secure further validation across the US and Australia, to drive adoption and aligns with our commercial focus”

Agreement with Mayo Clinic and broader US strategy

HeraMED’s US market entry strategy focuses on leveraging relationships with healthcare institutions to initially target healthcare providers including hospitals and doctors. The HeraCARE platform is expected to deliver a number of complementary benefits to existing healthcare providers including cost reductions, increased satisfaction and overall better maternity care outcomes.

As part of this strategy HeraMED has extended its collaboration with Mayo Clinic, with a new agreement for the development of its HeraCARE pregnancy management platform.

Under the agreement, Mayo Clinic will provide project funding, expert medical know-how and guidelines in the field of prenatal care, and a license to Mayo’s library of educational content in the space. The agreement has commenced.

Importantly, a number of discussions are also underway with several other leading maternal healthcare providers across the US in relation to undertaking pilot studies of HeraCARE. The Company anticipates that these discussions will lead to further collaboration agreements, to be announced in the coming months. The Company will leverage the results and findings from ongoing testing and pilots to target additional healthcare providers globally.

Clinical study at the Joondalup Health Campus and broader Australian strategy

On 27 July 2020, HMD announced final approvals, including ethics committee approval to commence a clinical study at the Joondalup Health Campus in Western Australia.

The study is focused on evaluating the usability, acceptability, accuracy and reliability of remote pregnancy monitoring using HeraBEAT plus and strongly supports HMD’s strategy to build relationships and work with key opinion leaders in the healthcare industry. The Study is recruiting 60 expectant mothers over the age of 18 years with a singleton pregnancy from 12 weeks gestation and is attending the Joondalup Health Campus antenatal clinic. It is estimated that the study will be completed within 2 months.

On completion of the study, HMD anticipates it will have the required scientific and clinical data supporting the technology’s accuracy, usability, efficiency and acceptability by both clinical staff as well as expecting mothers. The data generated will help support an expedited rollout of the HeraCARE platform to the Australian and international markets.

Furthermore, HeraMED has entered into a cooperation agreement with Freeman Road Pty Ltd to expand its Australian footprint and arrange and lead clinical studies to promote HMD’s telehealth offering, HeraBEAT and HeraCARE in the health sector.

Freeman Road, in cooperation with PHI (Partnering in Health Innovations) is a well-connected healthcare advisory group, founded by prominent Physician and Researcher Associate Professor, Dr. Paul Porter. The group has an extensive network of global consultants with diverse expertise and collaborating across several locations, including Perth, Queensland, Singapore, Boston, Oxford, Helsinki, and Israel.

HMD and Freeman Road will design and manage comprehensive pilots and clinical studies to evaluate the clinical effectiveness and acceptability of remote pregnancy monitoring using the medical-grade HeraBEAT foetal and Maternal heart rate device.

Exclusive agreement with Australian distributor

In line with its growth strategy, HMD signed an exclusive distribution agreement with one of MedTech Edge's wholly owned subsidiary, Advanced Pregnancy Solutions which was incorporated exclusively to focus on accelerating the commercialisation of HeraCARE.

Under the terms of the agreement, Advanced Pregnancy Solutions will leverage its extensive network to establish relationships with a broad range of top-tier medical institutions and pioneers to amplify HMD's exposure as an innovative telehealth solution and secure pilot projects and clinical studies ahead of commercial agreements.

Global markets

While the Company is primarily focusing on the US and Australia as key markets of strategic importance, it is also committed to supporting and cooperating with partners in several other territories.

Turkey: The first shipment of units has been sent and received by HeraMED's exclusive Turkish distributor Medizane following the completion of translation and localization of the collateral materials including product, marketing etc, and local ministry of health certifications. HMD and Medizane have been working in collaboration to analyse, evaluate and target potential clients with the updated platform and SaaS business model.

India: HeraMED's Indian distributor *Her Healthcare at Home* has been working closely with several leading physicians and key opinion leaders evaluating and validating the HeraBEAT plus solution. Feedback to date has been positive, allowing *Her Healthcare at Home* to begin promoting the technology to different medical organisations.

Brazil: Hapvida has deployed HeraBEAT devices throughout its network and HeraBEAT is now operating as a full pregnancy monitoring solution during labour as well as antenatal surveillance. This followed a stringent testing period which proved HeraBEAT as accurate and reliable. HeraMED and Hapvida have now entered discussions regarding the next stages of commercialisation cooperation.

Company financial overview

Successful A\$2.55 million via a placement to sophisticated investors and institutions as well as via an SPP. Proceeds from the placement will be used to strengthen the balance sheet and accelerate commercial rollout of the platform.

During the period, the Company implemented cost saving measures including a reduction in employee salaries by 25% and a reduction in director compensation by 50%. These measures were implemented for the months of March-June 2020. The cash balance as at 30 June 2020 was US\$2.264 million.

Net cash of US\$437K was used in operating activities compared with US\$828K for the quarter ending 31 March 2020, mainly due to a reduction in staff, administration and corporate costs. Receipts from customers were up from nil in the March 2020 quarter to US\$7K in the June 2020 quarter. Manufacturing and operating costs down from US\$19K in the March 2020 quarter to US\$12K. Staff costs down from US\$503K in the March 2020 quarter to US\$271K and administration and corporate costs were also down from US\$176K in March 2020 quarter to US\$140K.

ASX Listing Rule 4.7C.2 information

Pursuant to ASX Listing Rule 4.7C.2, the Company provides the below table as a comparison of actual expenditure against the “use of funds” table as disclosed in the Prospectus dated 15 October 2018 (“Prospectus”) (ASX announcement of 10 December 2018):

Opening cash 10.12.2018		1,008,523
Proceeds from the IPO		4,228,332
Receipts from customers		228,103
Additional capital raises		2,576,394
Total		8,041,352
Use of Proceeds Under Prospectus	Expenditure Amount (US\$)*	Actual Expenditure Amount (US\$)**
Expenses of the Offer	732,841	559,203
R&D, Engineering, Regulation & Clinical	1,071,050	1,589,626
Marketing & Sales	857,503	1,338,374
Loan Repayment	145,425	146,000
Corporate expenditure (General & Administration)	1,239,150	1,718,522
Other general and working capital	1,304,930	22,066
TOTAL	5,350,899	5,373,791
Expenses of additional capital raises		183,875
Product manufacturing costs		219,430
Total		5,777,069
Remaining cash 30.06.2020		2,264,283

* The Expenditure Amount as set out in the Prospectus has been converted from A\$ to US\$ at the date of the Prospectus for ease of comparison. In the Prospectus, the figures were in A\$.

** Staff costs that are presented in the Appendix 4C as an aggregate amount, were reallocated to R&D, M&S and G&A for ease of comparison

Explanation of variances

1. The variance in research and development is mainly attributed to the increased activity in R&D including among others, the development of the HeraCARE pregnancy management platform and expediting the development of the Company’s next generation pregnancy monitor EchoBEAT.
2. The variance in marketing and sales is mainly attributed to the Company’s activities in various markets and the need to support distributors. In addition, the Company added the HeraBEAT Plus and HeraCARE pregnancy management platform that is offered to healthcare providers with a different business model.
3. The variance in general and administrative expenses is mainly attributed to higher than expected costs related to the public entity as well as consultancy and professional services.

Payments to related parties of the entity and their associates

In item 6 of the attached Appendix 4C cash flow report for the quarter, payments to related parties and their associates of US\$76,000 comprised of director fees paid to executive and non-executive directors.

This announcement has been authorised by the Board of HeraMED Limited.

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About HeraMED Limited (ASX: HMD):

HeraMED is an innovative medical technology company leading the digital transformation of maternity care by revolutionising the pre and postnatal experience with its hybrid maternity care platform. HeraMED offers a proprietary platform that utilises hardware and software to reshape the Doctor/Patient relationship using its clinically validated in-home foetal and maternal heart rate monitor, HeraBEAT, cloud computing, artificial intelligence, big data and a digital social networking dashboard.

About HeraCARE

The Company's proprietary offering, HeraCARE, has been engineered to offer a fully integrated maternal health ecosystem designed to deliver better care at a lower cost, ensure expectant mothers are engaged, informed and well-supported, allow healthcare professionals to provide the highest quality care and enable early detection and prevention of potential risks.

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