

Accelerating progress and an improved global outlook for Telehealth

Q1 FY20 Highlights:

- Progress underpinned by increasing global adoption of telehealth solutions due to COVID-19;
- Completed beta testing of maternity care platform, HeraCARE; ahead of schedule;
- Commenced Mayo Clinic clinical study on smart foetal heart rate monitor, HeraBEAT™ Plus;
- Appointed global healthcare expert with extensive knowledge and expertise of US market, and finalised US strategy to target the multibillion US maternity market;
- FDA updated guidance for the use of Non-Invasive Foetal and Maternal Monitoring Devices for patient monitoring to allow patients to use Foetal dopplers in the home; and
- Significant interest from hospitals and healthcare providers globally seeking advanced Telehealth solutions.

HeraMED Limited (ASX: HMD) ('HeraMED' or the 'Company'), a medical data and technology company leading the digital transformation of maternity care with its proprietary in-home maternity care platform, is pleased to provide an update on its progress for the three months period ending 31 March 2020 (Q1 FY20).

During the period, the Company achieved several milestones, including the completion of development testing of its proprietary, fully integrated, hybrid maternity care solution, HeraCARE; commenced a clinical study with Mayo Clinic for the foetal and maternal heart rate monitor, HeraBEAT™; appointed US healthcare expert Alexander Radke as US General Manager of Operations and launched US market strategy.

CEO and Co-founder, Mr David Groberman said: "I am encouraged by the significant progress made during the quarter with the highlight being the completion of beta testing of our hybrid, comprehensive maternity platform HeraCARE.

"The COVID-19 pandemic has resulted in fundamental changes to global healthcare system infrastructure and Governments globally are increasingly adopting innovative telehealth and monitoring solutions for patients at home. The shifts in processes that would previously have taken years, are now happening in months, even weeks, and on a global scale.

"With a CE, TGA and FDA-cleared foetal ultrasonic heart rate monitor (now also available for home use by the pregnant women under the new FDA guidelines), 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. As a result, we are seeing a fast-tracked adoption of our Hybrid, digital, homecare-based solution.

"The COVID-19 pandemic also presents many challenges, with travel restrictions impacting client engagement, logistics and the deployment of new technology. Furthermore, manufacturing capabilities are also affected, and the supply chain continues to be impacted.

"We are very encouraged by the number of enquiries about both HeraCARE and HeraBEAT Plus from leading healthcare providers globally and we are responding to these opportunities as quickly as possible, he said.

Completion of HeraCARE beta testing ahead of schedule

Beta testing of the hybrid maternity care solution, HeraCARE was completed well ahead of schedule and the Company is now progressing to pilot testing and clinical trials. The platform is designed to transform the prenatal care market by using patient data to accurately monitor the pregnancy, predict potential scenarios, and ultimately reduce the number of complications.

Key features of the HeraCARE platform

- Developed in collaboration with world leading healthcare providers, leveraging obstetric research;
- Fully integrated hybrid pregnancy management platform combining hardware and software to provide more accurate results;
- Artificial Intelligence and Machine learning to provide valuable insights (currently under R&D);
- Provides mother and physician with an enhanced understanding of both mother and baby's health;
- An ecosystem with social networking, health and nutrition advice; and

- Personalised 24/7 best practice support service.

The platform, developed by HMD, with significant contributions from several top-tier healthcare organisations and experts, encompasses hardware and software to leverage the HeraBEAT foetal and maternal heart rate monitor, and uses the data to create an entire pregnancy management ecosystem. Current development work is focused on incorporating Artificial Intelligence, a digital platform and smart devices to offer expectant mothers improved clinical outcomes at a lower cost.

Clinical study to evaluate HeraBEAT Plus

As announced on 10 February 2020, Mayo Clinic has begun preparations for an extensive clinical study to evaluate the HeraBEAT Plus solution. The HeraBEAT device is designed to allow accurate and continuous measurement of both foetal and maternal heart rates throughout the pregnancy. The study will evaluate the usability, accuracy and medical value of the HeraBEAT smart foetal heart rate monitor.

HeraBEAT is a wireless Foetal Ultrasound Doppler-measuring device, designed to be used by the expectant mother at home. The HeraBEAT device uses a smartphone interface with real-time instructions for mothers to determine foetal and maternal heart rates.

Progressing development of OrionAI

During the quarter, HMD further strengthened its database of pregnancy monitoring information via the receipt of a large dataset of pregnancy records. The data is high quality, comprehensive and includes cardiotocography data, or birth stage monitors, as well as nonstress test data, encompassing earlier stages of pregnancy.

OrionAI is HMD's cloud-based, machine learning SaaS platform. The data enables HMD to accelerate the commercial development of the OrionAI platform, designed to analyse thousands of pregnancy records in real time to detect and prevent pregnancy complications.

US market

During the quarter, Alexander Radke was appointed as US General Manager of Operations. Mr Radke, based in New York, brings extensive knowledge and expertise of the US healthcare system and has significant experience within the industry. Mr Radke has been instrumental in designing and launching the strategy to enter the US market which began on 7 April 2020.

The US maternity market is worth an estimated US\$111 billion¹ with over 3.75 million babies born each year². However, the US also records the highest maternal mortality rate in the developed world with 26.4 deaths per 100,000 live births³. The maternal mortality rate continues to grow due to several factors including:

- An expensive healthcare system with average out-of-pocket payments of > US\$3,000 per pregnancy;
- A national shortage in services; and
- Inflexible and limited insurance coverage.

As announced on 27 April 2020, the FDA recently released updated guidance for the use of Non-Invasive Foetal and Maternal monitoring devices to support patient monitoring during COVID-19, encompassing HMD's foetal heart rate monitor, HeraBEAT. The HeraBEAT device received FDA clearance for professional use in November 2019, however this recently updated guidance has expanded the cleared indications for use, to allow the HeraBEAT device to be used by pregnant women in the home, under the direction of a health care provider.

The US market represents a significant opportunity for the commercial acceleration of HeraCARE. The short term strategy will involve both leveraging existing relationships with leading US healthcare providers and targeting employers that provide insurance coverage. The longer-term strategy will leverage relationships with large health insurance companies and a broad network of hospital and obstetric departments, to offer expectant mothers, employers and insurance companies a significantly improved service offering with:

- Significantly reduced costs due to enhanced technology capabilities to provide a fully integrated service model;
- Improved support leveraging leading healthcare providers to offer pre and post-natal solutions; and
- Decreased complications and overall better outcomes for patients.

¹ <http://www.pbgh.org/maternity>

² <http://www.pbgh.org/maternity>

³ <http://www.pbgh.org/maternity>

COVID-19 impact

The COVID-19 pandemic has caused fundamental changes to global healthcare system infrastructure and many Governments globally are increasingly adopting telehealth solutions. World leading medical and professional organisations such as The American College of Obstetricians and Gynaecologists (ACOG) and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) have recognised and emphasised the need for extensive telehealth solutions, digital tools and a comprehensive homecare-based approach. The FDA, US Medicaid and Medicare, private insurers, the Australian Ministry of Health and many others are rapidly integrating this recommendation by updating their programs to adopt a wider range of telehealth solutions and reinventing their support and reimbursement models.

This has presented HMD with a range of opportunities and the Company has received multiple enquiries from interested parties globally, relating to its remote maternity care solutions.

Financial overview

Net operating cash outflows for the quarter amounted to approximately US\$828K, comprised of advertising and marketing expenditure of US\$102K, R&D expenditure of US\$26K and staff costs, administration and corporate expenditure of US\$679K. In Item 6 of the Appendix 4C cash flow report, the aggregate amount of payments to related parties and their associates totalled ~US\$111K. These payments consisted of fees and salaries paid to Directors.

Outlook

Following a strong start to 2020 and supported by a global shift towards the adoption of Telehealth, the Company believes it is well placed to continue to deliver material progress in the remainder of CY2020; including:

- Completion of development and initial launch of HMD proprietary fully integrated platform, HeraCARE;
- Completion of clinical trial for HeraBEAT, in collaboration with Mayo Clinic; and
- Commencement of trials and initial testing phases in the US.

-ENDS-

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

HeraMED Limited

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About HeraMED Limited (ASX: HMD):

HeraMED is an innovative medical data and technology company leading the digital transformation of maternity care by revolutionising the prenatal and postpartum 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.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

HERAMED LIMITED

ABN

65 626 295 314

Quarter ended ("current quarter")

31 March 2020

Consolidated statement of cash flows	Current quarter \$USD'000	Year to date (3 months) \$USD'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(26)	(26)
(b) product manufacturing and operating costs	(19)	(19)
(c) advertising and marketing	(102)	(102)
(d) leased assets	(28)	(28)
(e) staff costs	(503)	(503)
(f) administration and corporate costs	(176)	(176)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	1
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other – GST/VAT refunds	25	25
1.9 Net cash from / (used in) operating activities	(828)	(828)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$USD'000	Year to date (3 months) \$USD'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	-	-
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	-	-
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,045	2,045
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(828)	(828)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter \$USD'000	Year to date (3 months) \$USD'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	(23)	(23)
4.6	Cash and cash equivalents at end of period	1,194	1,194

5. Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts		Current quarter \$USD'000	Previous quarter \$USD'000
5.1	Bank balances	1,194	2,045
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	1,194	2,045

**6. Payments to related parties of the entity and their
associates**

- 6.1 Aggregate amount of payments to related parties and their
associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their
associates included in item 2

Current quarter \$USD'000
111
-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

7. Financing facilities

Note: the term "facility" includes all forms of financing arrangements available to the entity.

Add notes as necessary for an understanding of the sources of finance available to the entity.

	Total facility amount at quarter end \$USD'000	Amount drawn at quarter end \$USD'000
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-

7.5 **Unused financing facilities available at quarter end** -

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

N/A

8. Estimated cash available for future operating activities	\$USD'000
8.1 Net cash from / (used in) operating activities (Item 1.9)	(828)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	1,194
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	1,194
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	1.4

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: No. As the Group is in its formative stages it is yet to achieve sufficient revenue levels to generate net operating cash flows. Further details are included in our response to question 3 below.

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: Yes, the Company is progressing initiatives to raise further financial resources and believes its plans are reasonably likely to be successful.

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: Yes, the Company is managing its level of expenditure and the Company expects to raise further financial resources to continue its operations and meet its business objectives.

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Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 30 April 2020

Authorised by: The Board of Directors
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.