

HeraMED now focusing on commercial opportunities following outstanding Clinical study results

Q3 FY20 Highlights

- Independent clinical study at Joondalup Health Campus completes with outstanding results, confirming the accuracy of the HeraBEAT device when compared to professional hospital grade CTG machine
- Results validate and support HeraBEAT device for remote monitoring of foetal heart rate
- Clinical validation from top tier healthcare providers underpins the Company's commercialisation strategy and the key advantages of the technology and can now be leveraged into all existing and future commercialisation opportunities
- Partnership with leading virtual care platform eCare21 in US

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 ending 30 September 2020 (Q3 FY20).

JHC Clinical trial

The highlight of the quarter was the release of the outstanding clinical study results from the Joondalup Health Campus trial that confirm the accuracy of the HeraBEAT device against a hospital grade Cardiotocography CTG machine. Furthermore, the results confirmed the ease of use and user satisfaction by expectant mothers at the clinic, and at home, as well as the effective electronic transmission of the foetal heart rate (FHR) trace by the mother to the antenatal care team for review and consultation.

The clinical study was undertaken at Joondalup Health Campus (JHC), Western Australia and led by Associate Professor Paul Porter (the "Study"). The Study was designed to evaluate the usability, accuracy, and reliability of the HeraBEAT device, by expectant mothers, initially at the antenatal clinic and then at home.

CEO and Co-founder Mr. David Groberman said: *"These results mark the culmination of many years of hard work by the HeraMED team to develop a clinically validated foetal and maternal heart rate monitor for pregnant women to be used remotely and in telehealth consultations.*

"The results represent an important milestone in HeraMED's history as they represent the first comprehensive, independent clinical validation of the accuracy and usability of our technology which can now be leveraged into all existing and future commercialisation opportunities."

Highlight of the results

The accuracy of the HeraBEAT device was found to be excellent when compared to the industry gold standard CTG (Phillips Avalon) machine. The device was used 126 times and the limits of agreement (95%) were between -1.5, +0.9 beats per minute (BPM) and a mean difference of approximately 0.3 BMP.

The FHR was detected on 100% of occasions by clinicians (n=52) and importantly, the FHR was detected on 100% of occasions by the expectant mothers when using the device without assistance.

These results were achieved both in the clinic (42 occasions) and at home (32 occasions). The average time to locate the FHR by expectant mothers at home was 1.1 minutes with an average total FHR tracing time of 4.4 minutes. The FHR trace was deemed clinically interpretable (as assessed by obstetric staff) in 100% of clinician performed assessments and in 97% of maternal home use.

Using the international medical standard System Usability Scale (SUS) to usability of expectant mothers, the device was very well-reviewed by the pregnant women, ranking in the 96-100% percentile for usability and user satisfaction.

Partnership with eCare21 in US

On 16 September 2020, HMD announced it had signed a Letter of intent (“LOI”) with leading provider of virtual care, eCare21, to integrate its technology into the eCare21 platform. HeraMED and eCare21 will continue to focus on finalising a binding commercial agreement in the coming weeks.

eCare21 is an established, US-based, virtual care platform that combines telehealth and remote patient monitoring into an integrated SaaS solution, enabling an end-to-end solution for virtual care. eCare21, powered by Dell Technologies ensures providers can give patients access to remote care and analyze patient data, enabling better patient care and outcomes. eCare21 allows providers to manage chronic conditions remotely and streamlines provider and patient communications to help avert acute medical events. eCare21 has a large and established customer base of healthcare providers, focusing on patients with chronic conditions, who subscribe to its virtual care platform.

As part of this partnership, HeraMED’s HeraCARE platform, including its clinically validated in-home foetal and maternal heart rate monitor HeraBEAT, will be fully integrated into the eCare21 platform. The integrated solution which is expected to simplify the deployment of virtual care for maternal health patients and providers is expected to be available by the end of 2020.

“We are delighted to be partnering with a well-established virtual care operator such as eCare21. The integration of the HeraCARE platform into the eCare21 platform is expected to result in a rapid take up of HeraCARE across healthcare providers.” David Groberman added.

Collaboration with Mayo Clinic extended

On 21 July 2020, HMD announced a new agreement with Mayo Clinic for the development of its HeraCARE pregnancy management platform that includes an equity investment to support the project.

The Company has now received the USD\$100,000 investment in the form of project funding (in return for receiving 1,581,538 Shares) and is receiving ongoing 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.

Further, there are 3 major milestones and goals for the collaboration:

- Completion of the HeraCare pilot and upon acceptance of a proof of concept by the Mayo Clinic. (resulting in 1,186,153 performance options)
- FDA clearance of HeraBEAT Plus for home care. (resulting in 1,581,538 performance options); and
- Commercial launch of the HeraCare Platform and generating its revenues (resulting in 1,581,538 performance options)

HeraMED continued collaboration with the Mayo Clinic includes a further clinical trial to extend the current FDA indications of the HeraBEAT device. In addition to the clinical trial, HeraMED is also working with the Mayo Clinic to undertake a pilot of the complete HeraCARE solution. HMD looks forward to updating the market as the trial and pilot begin.

Global Markets

While our focus during the quarter has been progressing the commercialisation strategy with leading healthcare providers, primarily in the US and Australia, the company continues to support and work in collaboration with our existing partners in other territories and support the strategy of partnering with global providers. HMD will update the market with developments in due course.

An updated investor Presentation was released on the ASX on 21st October.

Financial overview

During Q2 FY20 and early in Q3 FY20, the Company successfully raised a total of \$3.91m via a placement to institutional and sophisticated investors and an SPP to existing shareholders with the shortfall also placed to institutional and sophisticated investors. The funds are to be used to strengthen the balance sheet and accelerate the commercial rollout of HeraCARE.

The cash balance as at 30 September 2020 was US\$2.638 million. Net cash of US\$814K was used in operating activities compared with US\$437K for the quarter ending 30 June 2020.

Advertising and marketing expenses increased from US\$155K in Q2 FY20 to US\$218K in Q3 FY20. Staff costs were up from US\$271K in Q2 FY20 to US\$377K in Q3 FY20.

The company continues to invest in business development as well as sales and marketing initiatives, to capitalise on the commercial opportunities that exist following the most recent clinical trial results and remote monitoring tailwinds as a result of Covid-19.

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		243,065
Additional capital raises		3,810,809
Total		9,290,729
Use of Proceeds Under Prospectus	Budgeted Expenditure Amount (US\$)*	Actual Expenditure Amount (US\$)**
Expenses of the Offer	732,841	559,203
R&D, Engineering, Regulation & Clinical	1,071,050	1,844,841
Marketing & Sales	857,503	1,602,976
Loan Repayment	145,425	146,000
Corporate expenditure (General & Administration)	1,239,150	1,960,163
Other general and working capital	1,304,930	19,522
TOTAL	5,350,899	6,132,705
Expenses of additional capital raises		277,696
Product manufacturing costs		242,677
Total		6,653,078
Remaining cash 30.09.2020		2,637,651

* The Budgeted Expenditure Amount 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 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 including multiple improvements to the HeraBEAT technology, 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 re-allocation of some of the expenses across the suitable use of proceeds in the table, as well as higher than expected costs related to the public entity as well as consultancy and professional services.

4. The variance in general and working capital is mainly attributed to allotment of the manufacturing costs to a designated line and lower manufacturing costs due to the transition to a B2B and TaaS (Technology as a service) business model.

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\$95K comprised director fees paid to executive and non-executive directors.

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

-ENDS-

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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.

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")

30 September 2020

Consolidated statement of cash flows	Current quarter \$USD'000	Year to date (9 months) \$USD'000
1. Cash flows from operating activities		
1.1 Receipts from customers	15	22
1.2 Payments for		
(a) research and development	(33)	(65)
(b) product manufacturing and operating costs	(23)	(54)
(c) advertising and marketing	(218)	(475)
(d) leased assets	(47)	(78)
(e) staff costs	(377)	(1,151)
(f) administration and corporate costs	(160)	(476)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	1
1.5 Interest and other costs of finance paid	-	(1)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1	5
1.8 Other (GST/VAT refunds)	28	193
1.9 Net cash from / (used in) operating activities	(814)	(2,079)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(2)	(4)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$USD'000	Year to date (9 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	(2)	(4)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,234	2,830
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	(94)	(213)
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	1,140	2,617

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,264	2,045
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(814)	(2,079)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2)	(4)

Consolidated statement of cash flows		Current quarter \$USD'000	Year to date (9 months) \$USD'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,140	2,617
4.5	Effect of movement in exchange rates on cash held	50	59
4.6	Cash and cash equivalents at end of period	2,638	2,638

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	2,638	2,264
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)	2,638	2,638

6.	Payments to related parties of the entity and their associates	Current quarter \$USD'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	95
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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.

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

7. Financing facilities	Total facility amount at quarter end \$USD'000	Amount drawn at quarter end \$USD'000
<i>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.</i>		
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.		

8. Estimated cash available for future operating activities	\$USD'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(814)
8.2 Cash and cash equivalents at quarter end (item 4.6)	2,638
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	2,638
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.24
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 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: n/a	
8.6.2 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: n/a	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer: n/a	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

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: 29 October 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.