

Commercialization study confirms a \$2 billion revenue opportunity for the US medical market relating specifically to depression.

- **Leading US-based, medically focused, strategic consulting organization (The Ametus Group) has delivered a commercialisation assessment on Medibio's CHR technology relating to depression.**
- **The Ametus Group and their Principals have a global footprint across the USA, Europe, and Asia and have assisted many companies in bringing medical device products to market.**
- **The key points from the comprehensive assessment are:**
 - **US\$2.3bn revenue opportunity in the US which is likely to be highly profitable**
 - **existing reimbursement codes which may be leveraged for commercialisation**
 - **ready acceptance of the technology upon the receipt of FDA approval**
 - **no competing FDA approved evidence-based products to assist Clinicians**
 - **potential market share of 5% within 5 years which would generate annual revenue of approximately US\$100 million**

Sydney, Australia – 6 February 2015: Medibio Ltd (MEB or the Company) has released details of a comprehensive commercialisation study on its CHR depression test technology for the US Market. The study was conducted by The Ametus Group based in Minnesota USA, one of the leading independent medical consulting groups in the United States.

The study was commissioned in 2014 with the brief to undertake an assessment and validation of the US market specifically for the use of the company's CHR technology for the diagnosis of depression. The brief included a detailed clinical, regulatory, and reimbursement plan, and the evaluation of business models including distribution channels, likely uptake rates, and revenue forecasts.

The key takeaways from the commercialization study are:

- **Based upon primary market research there is a need and desire to utilize the CHR technology as a device for both the initial differentiated diagnosis of depression and also for ongoing monitoring of therapy effectiveness. Over 90% of clinicians surveyed would use a CHR based diagnostic once clinically proven and reimbursable with Primary Care Physicians (PCP) the likely first adopters in the US.**
- **There is a series of existing CPT™ codes and payment structures, which cover electrocardiographic monitoring for up to 48 hours, which could be leveraged for MEB's business plan in the US. These codes can be used by any physician in the US who could be expected to diagnosis mental health conditions. Based on their current usage, it can be presumed that the supervision and payment conditions today for the diagnosis of cardiac disease will be sufficient for physician adoption for mental health diagnosis.**

- The current average US\$45 per test rebate net to Medibio under the codes should support strong margins based on Medibio’s likely cost structures.
- Ametus believes that if a reimbursement strategy is based around expanding indications for payment from existing payors/insurers within the existing CPT & ICD9 codes full national reimbursement coverage is possible within 24 months from FDA approval.
- Ametus define the total revenue opportunity, based on depression alone, at US\$2.3 billion with a potential market share of 5% within 5 years. This would generate revenue of approximately US\$100 million annually

The results of the study are timely given MEB’s recent announcement that it has entered into an agreement with the Johns Hopkins University School of Medicine to undertake a study designed to clinically validate the company’s CHR technology for the diagnosis of depression and support an application for FDA certification.

A complete copy of the study which includes The Ametus Group assessment of projected outcomes is available on the company’s website www.medibio.com.au ⁽¹⁾

The Ametus Group

The Ametus Group, with offices in Minnesota and Texas, USA and global partners in Europe and Asia, has over 25 years of experience in marketing and sales in the medical device industry. The Ametus Group has played an integral part in strategic business development, sales leadership, product management and marketing communications for their medical technology clients, developing comprehensive strategic marketing plans and growing revenue. Their highly experienced team have successfully launched a broad range of diagnostic, implantable and surgical products in the medical device industry.

The Ametus Group assists device manufacturers to commercialize their products and maximize revenue by developing go-to-market strategies for both established and emerging companies. The Ametus Group team has been involved in over 60 product launches and led sales and marketing activities in over 80 countries. Their area of expertise includes cardiovascular, colorectal surgery, emergency medicine, ENT, In-vitro diagnostics, laparoscopic surgery, neurosurgery, plastic surgery, urology, primary care, acute care and mental health.

In commenting on the study Dr. Matt Mesnik, MEB’s US-based Chief Medical Officer said:

“I am delighted that this independent study has confirmed our views of the size of the opportunity and demand for our CHR technology in the US. I have personally had the pleasure to work closely with AMETUS on several projects in the past. Each time they demonstrated their knowledge and experience of the industry and provided valuable market analysis, regulatory, reimbursement, and go to market strategies.”

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Further Information:	
Medibio Shareholder Enquiries to: Dr Matt Mesnik Chief Medical Officer: Medibio Limited matt.mesnik@medibio.com.au T: +1 736 670 4265 <i>Note - as Matt is based in USA he will be available until 3pm EST</i>	Medibio Shareholder Enquiries to: Kris Knauer CEO: Medibio Limited kris.knauer@medibio.com T: +61 (0)411 885979

⁽¹⁾ The study has been prepared The Ametus Group and as such the results and conclusions are those of Ametus not those of Medibio.