ASX Market Update

Medibio Limited (ASX: MEB)

Medibio appoints US-based CRO for its validation trials

- **Medibio has appointed NAMSA, a leading US-based Regulatory Advisory and Clinical Research Organisation, to assist with trial design and regulatory discussions with the US FDA.**
- **NAMSA has a global footprint across the USA, Germany, France, China and the UK and has assisted many companies in bringing medical device products to market.**
- **NAMSA will work with Johns Hopkins University in the USA, and the Black Dog Institute in Australia to ensure that Medibio's validation studies are designed to test and satisfy FDA-approved end-points.**

Sydney, Australia – 5 December 2014: Medibio Ltd (**MEB** or the **Company**) is pleased to announce that it has appointed NAMSA, a respected US-based regulatory advisory and clinical research organization to coordinate its recently announced US clinical study to ensure that the Company's depression validation study meets FDA regulatory requirements.

NAMSA with offices in Minnesota, California, and Ohio, USA has over 45 years of experience with medical device, IVD, regenerative medicine, clinical, bio-statistical and combination product testing services. NAMSA has played an integral part in developing US domestic and international standards for testing medical devices, materials and combination products. Its quality systems have been assessed by the FDA during multiple successful inspections; and their accredited and highly experienced experts have specialized knowledge in many regulatory jurisdictions.

NAMSA has begun work on protocol development and project implementation tasks, including pre-submission consultations with the FDA. NAMSA will also liaise with the Black Dog Institute in Australia and Johns Hopkins University in the USA, to develop robust trial protocols to the highest possible standards. NAMSA will co-ordinate and monitor the US trial and prepare and manage regulatory submissions to the FDA. Working with both the FDA and MEB's clinical research collaborators NAMSA will ensure that the Company's validation study end-points meet FDA requirements, such that a successful completion of the validation studies will support a regulatory submission for approval to the FDA. Pending approval by the FDA and regulators in other jurisdictions MEB plans to launch its diagnostic for depression as quickly as possible.

In commenting on the appointment of NAMSA as CRO Dr. Matt Mesnik, MEB's US-based Chief Medical Officer said***: "We are delighted to be working with NAMSA. Its regulatory expertise is of the highest standard and their highly experienced staff have specialized regulatory knowledge globally. We look forward to working with the NAMSA team to achieve what will be very important regulatory milestones for the Company"***

About the US Validation Study

Medibio recently announced that it had reached an agreement with Johns Hopkins University School of Medicine for Johns Hopkins to Conduct a clinical study regarding the use of circadian heart rate variability ("CHR") designed to confirm the Company's findings that CHR can provide objective physiological data to differentiate between individuals with clinical depression and individuals without clinical depression. The study will also assess the clinical validity of a proprietary software algorithm, developed by Medibio, that detects depression by measuring CHR variability clinically. The data collected from the study will support an application for FDA certification of Medibio's proprietary software algorithm. The US study is expected to be completed within 12 months.

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About Medibio Limited

Medibio (ASX: MEB) is a medical technology company developing a new diagnostic test for depression and other mental health disorders. This test is based on measured differences in circadian heart rate and measures of heart rate variability. The technology is based on the discovery that circadian heart rates are sensitive measures for depression and other mental health disorders. The technology consists of a heart monitor that sends recordings wirelessly to the internet where a proprietary algorithm analyses and delivers a quantifiable diagnosis. The Technology has the potential to be the first FDA-approved objective, evidence based approach to the diagnosis of depression and other affective disorders. The technology has already benefited from 10 years of laboratory research and Medibio intends to undertake a number of pivotal studies to validate its clinical utility. Located in Melbourne, Victoria, Medibio is listed on the Australian Stock Exchange.

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