



12 October 2026

ASX Limited
10th Floor, 20 Bridge Street
SYDNEY NSW 2000

Dear Sir/Madam,

**INVESTEE CORTICAL DYNAMICS LIMITED APPOINTS BENNO SCHMIDHAUSER AS
HEAD OF REGULATORY AFFAIRS**

Senior engineer, regulator and lawyer joins from the Therapeutic Goods Administration

Cortical Dynamics Limited today announced the appointment of **Benno Schmidhauser** as Head of Regulatory Affairs. He joins the company from the **Therapeutic Goods Administration (TGA)**, Australia's medical device regulator.

At the TGA since 2010, Mr Schmidhauser has been Technical Lead Engineering since 2011 and has acted as Director. He supervises the multidisciplinary engineering section whose work underpins medical device conformity assessment certification and governance oversight, providing expert technical and regulatory advice on software-based and AI-enabled devices, electrical safety and essential performance under the IEC 60601 series, cybersecurity, batteries, ventilators, additive manufacturing and high-risk implants. He has represented the TGA in engagement with industry, contributed to legislative reform, and supported the urgent delivery of emergency ventilators during the COVID-19 pandemic.

Before joining the regulator he spent more than a decade in the medical device industry in Europe and Australia. As Head of Surface Technologies and Biomaterials at Mathys Ltd Bettlach in Switzerland he ran ISO 13485, MDD and GMP manufacturing operations for orthopaedic devices, delivered CE certification for novel biomaterial designs and built new manufacturing facilities. At Mathys Medizinaltechnik he led new-technology and process development and served on the AO Technical Commission Materials Expert Group. He subsequently led medical device development and commercialisation across Europe, Asia and Australia, contributing to CE certification and FDA 510(k) outcomes.

Mr Schmidhauser holds an MSc in Engineering, a Juris Doctor and qualifications in business administration and project management, and was admitted as a lawyer in 2019. He is a registered ACT Professional Engineer, listed on the National Engineering Register in biomedical, mechanical and electrical engineering, a Fellow of Engineers Australia, a member of the Law Society of the Australian Capital Territory, and a member of the UL Standards & Engagement UL 4200 committee.

Mr Schmidhauser will lead regulatory strategy and submissions for BARM™ 2.0 and will carry joint responsibility for the company's quality management system.

About Cortical Dynamics

Cortical Dynamics Limited is an Australian medical device company developing the Brain Anaesthesia Response Monitor (BARM™). BARM™ uses EEG and AI-enhanced physiological algorithms to show the anaesthetist how deeply a patient is anaesthetised and how well pain is being controlled — two questions that existing depth-of anaesthesia monitors answer only partly. The technology originated in research at Swinburne University of Technology.

BARM™ 1.0 is cleared by the United States Food and Drug Administration (510(k) K213273), CE marked, registered with the TGA and approved by Korea's MFDS. BARM™ 2.0, the next-generation monitor, is in development and is the subject of the 2027 clinical trial programme.

Media

Ashley Zimpel, Chief Executive Officer

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David Breeze (Director) authorized the release of this announcement to the market.