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## Shanghai Bio-heart Biological Technology Co., Ltd. 上海百心安生物技術股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 2185)

### VOLUNTARY ANNOUNCEMENT FIRST COMMERCIAL CASE OF IBERIS® RDN SYSTEM IN EUROPE

This announcement is made by Shanghai Bio-heart Biological Technology Co., Ltd. (the "Company", together with its subsidiaries, the "Group") on a voluntary basis to provide the shareholders and potential investors of the Company with updated information in relation to the latest business advancement of the Group.

The board of directors of the Company (the "Board") is pleased to announce that in February, 2025, Iberis® Multi-Electrode Renal Artery Radiofrequency Ablation Catheter System ("Iberis® RDN system") developed by a subsidiary of the Company, Shanghai AngioCare Medical Technology Co., Ltd.\* (上海安通醫療科技有限公司) ("AngioCare"), completed the first commercial procedure in Germany. The procedure was performed by a team led by Dr. Saarraaken Kulenthiran at the University Hospital of Saarland. There were no reported complications or adverse events. The case was supported jointly by Biosensors International Group, Ltd. ("Biosensors") and Angiocare.

As commented by Biosensors, 'Our transradial (TR) Iberis® Renal Denervation (RDN) catheter offers a less invasive, more ergonomic, and effective treatment. In this case, a hypertensive patient (on six medications) with an abdominal aortic aneurysm (AAA) faced a high embolization risk with transfemoral access, making TR the ideal choice.'

AngioCare and Biosensors entered into a strategic partnership covering various geographical regions including but not limited to the European Union countries, the Asia–Pacific region and the Latin America (LATAM) region, regarding the commercialization of Iberis® RDN system.

As of the date of this announcement, Iberis® RDN system is the only renal denervation ("RDN") product approved globally with both transradial approach ("TRA") and transfemoral approach ("TFA"). TRA makes RDN safer, more effective and cheaper. Our ultimate goal is to bring outpatient RDN procedures to patients around the world. AngioCare has obtained CE marking for Iberis® RDN system in 2016 in Europe, with a post market clinical trial namely "RADIUS-HTN" ongoing.

#### **About Biosensors**

Biosensors is a company incorporated in Bermuda. Biosensors is a subsidiary and one of the business entities of the cardiovascular and cerebrovascular business division of Bule Sail Medical Co., Ltd. (藍帆醫療股份有限公司), a company listed on the Shenzhen Stock Exchange (Stock Code: 002382). Biosensors has operations worldwide and is headquartered in Singapore. The European headquarters are located in Morges, Switzerland. With the combination of a direct sales network and distributors across the world, Biosensors is dedicated to serving the needs of the healthcare community and is committed to, the support of bona fide medical education, advancing the progress of medical science and improving patient care, through training courses, scientific summits and symposia and related events on a regular basis, both in international forums and at national level. Biosensors also participates in some of the major cardiology congresses throughout the world – doing so in a way that complies with all ethical and legal requirements.

#### **ABOUT RADIUS-HTN**

The Renal Artery Denervation Using Radial Access in Uncontrolled Hypertension (RADIUS-HTN) (the "RADIUS-HTN Trial") is designed to evaluate the Company's Iberis® RDN system in patients with uncontrolled hypertension. The RADIUS-HTN Trial will compare the effectiveness of renal denervation performed via TRA and TFA. The principal investigator for the RADIUS-HTN Trial is Professor Felix Mahfoud, a Professor of Cardiology at the University of Basel and Chairman of the Department of Cardiology at University Hospital Basel, Switzerland and the chair of ESC Communication Committee and the Scientific Documents Committee of the EAPCI. On March 27, 2023, the first patient was enrolled in Bordeaux, France. The procedure was performed by a team led by Dr. Antoine Cremer at the Centre Hospitalier Universitaire de Bordeaux. There were no reported complications or adverse events.

Warning under Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that Iberis® RDN system will be ultimately commercialized successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

# By Order of the Board Shanghai Bio-heart Biological Technology Co., Ltd. Philip Li WANG

Chairman and executive director

Shanghai, the People's Republic of China, March 3, 2025

As at the date of this announcement, the Board comprises Mr. Philip Li WANG as Chairman and executive director, Mr. Yunqing WANG and Ms. Peili WANG as executive directors, and Mr. Yiqing CHEN, Mr. Xubo LU and Mr. Yifei JIANG as independent non-executive directors.