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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

Iberis® multi-electrode RDN system (RDN) is expected to be approved in Hainan pilot zone for urgent clinical use

This announcement is made by the board (the “**Board**”) of directors (the “**Directors**”) of Shanghai Bio-heart Biological Technology Co., Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to keep the shareholders of the Company (the “**Shareholders**”) and potential investors informed of the latest business development of the Company.

The Board is pleased to inform the Shareholders and potential investors that the Company’s Iberis® multi-electrode RDN system (RDN) product has been approved by the ethics committee of Ruijin Hainan Hospital* (瑞金海南醫院), and will soon apply to the Hainan Medical Products Administration and the Hainan Provincial Health Commission for formal access and commercialization.

According to the policy of Hainan Lecheng International Medical Tourism Pilot Zone and with reference to the “Notice of the People’s Government of Hainan Province on Printing and Distributing the “Regulations on the Management of Imported Medical Devices Urgently Needed for Clinical Use in the Hainan Free Trade Port Boao Lecheng International Medical Tourism Pilot Zone”” (《海南省人民政府關於印發〈海南自由貿易港博鰲樂城國際醫療旅遊先行區臨床急需進口醫療器械管理規定〉的通知》) (Qiongfú [2020] No. 28) and the “Notice on Several Measures to Further Optimize Regulatory Services to Support the High-Quality Development of Hainan Boao Lecheng International Medical Tourism Pilot Zone” (《關於進一步優化監管服務支持海南博鰲樂城國際醫療旅遊先行區高質量發展若干措施的通知》) (Qiong Yaojian [2021] No. 70), the acceptance of the RDN product into Ruijin Hainan Hospital was applied based on the urgent clinical needs of medical institutions in the pilot zone and the innovative policy for the drugs or medical devices that have been approved for marketing in the United States, the European Union, Japan and other countries or regions but have not been approved for registration in the PRC and cannot be replaced by domestic marketed products. According to Frost & Sullivan, as disclosed in the Company’s prospectus published on December 13, 2021, the total number of hypertension patients in China in 2019 was approximately 317.4 million. In order to make the Company’s RDN products benefit the hypertension patients in China as soon as possible, the Company responded to the policy to carry out the application.

The RDN technology will bring new hope to patients who can not achieve ideal blood pressure level through drug treatment, and is expected to achieve long-lasting, stable and 24-hour uninterrupted blood pressure control, reduce drug use, and break the predicament that patients can only rely on drugs to lower blood pressure. The RDN product of Bio-heart obtained CE certification in 2016. During this application process, the product's advantages of multielectrode circumferential ablation, being able to access renal artery branches for ablation and being able to perform the surgery through both transradial and transfemoral approaches have been unanimously recognised by the expert review committee.

If the final application is successful, the product will be approved for urgent clinical use in Hainan Boao Pilot Zone. On one hand, it is expected to help the Company achieve product revenue earlier; At the same time, the Company hopes to take this as an opportunity to build a RDN surgery training centre in Boao, Hainan to conduct surgery training and patient education in advance. The application is strategically important to the Company's RDN products.

This announcement is made by the Company on a voluntary basis to provide information to the Shareholders and potential investors of the Company. There is no assurance that the Company will ultimately develop, launch and/or commercialize the product successfully.

Shareholders and potential investors of the Company are advised to exercise caution 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, November 18, 2022

As at the date of this announcement, the Board of the Company comprises Mr. Philip Li WANG as Chairman and executive Director, Mr. Yunqing WANG and Ms. Peili WANG as executive Directors, Mr. Quan ZHOU and Mr. Ji CHEN as non-executive Directors, and Mr. Charles Sheung Wai CHAN, Mr. Xubo LU and Mr. George Chien Cheng LIN as independent non-executive Directors.

* *For identification purpose only*