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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)

ANNOUNCEMENT OF ANNUAL RESULTS
FOR THE YEAR ENDED DECEMBER 31, 2023

FINANCIAL HIGHLIGHTS

	Year ended December 31,	
	2023	2022
	RMB'000	RMB'000
Research and development expenses	(111,743)	(157,830)
Administrative expenses	(52,881)	(94,370)
Other expenses	(30,552)	(55)
Finance costs	(578)	(959)
Other income and gains	8,567	23,776
Share of loss of an associate	(1,633)	(1,430)
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Loss before tax	(188,820)	(230,868)

BUSINESS HIGHLIGHTS

- Net loss of the Group for the year ended December 31, 2023 amounted to approximately RMB188.8 million, representing a decrease of 18.2% from approximately RMB230.9 million in 2022.
- Research and development expenses for the year ended December 31, 2023 amounted to approximately RMB111.7 million, representing a decrease of 29.2% from approximately RMB157.8 million recorded in 2022.

- As of December 31, 2023, cash and cash equivalents amounted to approximately RMB369.4 million, representing a decrease of 18.1% from approximately RMB451.3 million as of December 31, 2022.
- Basic and diluted loss per share for 2023 amounted to RMB0.72 (2022: RMB0.84).
- As of December 31, 2023, net gearing ratio was 5.4% (2022: 6.8%).

The Board is pleased to announce the audited consolidated annual results of the Group for the year ended December 31, 2023 together with the comparative figures for the year ended December 31, 2022 as follows:

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the year ended December 31, 2023

	<i>Notes</i>	2023 RMB'000	2022 <i>RMB'000</i>
Other income and gains	4	8,567	23,776
Research and development expenses		(111,743)	(157,830)
Administrative expenses		(52,881)	(94,370)
Other expenses	6	(30,552)	(55)
Finance costs	7	(578)	(959)
Share of loss of an associate		(1,633)	(1,430)
LOSS BEFORE TAX	5	(188,820)	(230,868)
Income tax expense	8	—	—
LOSS FOR THE YEAR		(188,820)	(230,868)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		(188,820)	(230,868)
Attributable to:			
Owners of the parent		(175,893)	(204,236)
Non-controlling interests		(12,927)	(26,632)
		(188,820)	(230,868)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (<i>RMB</i>)	10	(0.72)	(0.84)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As of December 31, 2023

	<i>Notes</i>	2023 RMB'000	2022 RMB'000
NON-CURRENT ASSETS			
Property, plant and equipment		29,588	59,561
Other intangible assets		137,710	137,542
Investment in an associate		36,595	23,228
Financial assets at fair value through profit or loss ("FVTPL")		50,469	50,000
Prepayments, other receivables and other assets	<i>11</i>	9,116	8,611
Right-of-use assets		1,318	16,419
Goodwill		144,630	144,630
		<hr/>	<hr/>
Total non-current assets		409,426	439,991
CURRENT ASSETS			
Inventories		3,980	–
Prepayments, other receivables and other assets	<i>11</i>	35,055	90,210
Cash and cash equivalents		369,438	451,318
		<hr/>	<hr/>
Total current assets		408,473	541,528
CURRENT LIABILITIES			
Lease liabilities		1,579	7,616
Other payables and accruals	<i>12</i>	14,627	19,795
Amounts due to related parties		472	472
Deferred income		3,391	963
		<hr/>	<hr/>
Total current liabilities		20,069	28,846

	<i>Notes</i>	2023 RMB'000	2022 <i>RMB'000</i>
NET CURRENT ASSETS		388,404	512,682
TOTAL ASSETS LESS CURRENT LIABILITIES		797,830	952,673
NON-CURRENT LIABILITIES			
Lease liabilities		183	10,489
Deferred income		3,210	6,554
Deferred tax liabilities		20,580	20,580
Total non-current liabilities		23,973	37,623
Net assets		773,857	915,050
EQUITY			
Equity attributable to owners of the parent			
Share capital		243,937	243,937
Treasury shares		(29,438)	(29,438)
Reserves		533,913	668,715
Non-controlling interests		748,412	883,214
		25,445	31,836
Total equity		773,857	915,050

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. CORPORATE AND GROUP INFORMATION

Shanghai Bio-heart Biological Technology Co., Ltd. is a joint stock company with limited liability incorporated in the People's Republic of China (“**PRC**”). The registered office of the Company is located at Room 302, 3/F, Building 4, No. 590 Ruiqing Road, East Zhangjiang Hi-Tech Park, Pudong New Area, Shanghai, PRC.

During the year, the Company and its subsidiaries (together, the “**Group**”) are principally engaged in the research and development of bioresorbable scaffold (“**BRS**”) products and renal denervation (“**RDN**”) system.

The Company was listed on the Main Board of The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) on from December 23, 2021.

2.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards (“**IFRSs**”), which include all standards and interpretations approved by the International Accounting Standards Board (“**IASB**”). They have been prepared under the historical cost convention. These financial statements are presented in RMB and all values are rounded to the nearest thousand (RMB'000) except when otherwise indicated.

2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The Group has adopted the following new and revised IFRSs for the first time for the current year's financial statements.

IFRS 17	<i>Insurance Contracts</i>
Amendments to IAS 1 and IFRS Practice Statement 2	<i>Disclosure of Accounting Policies</i>
Amendments to IAS 8	<i>Definition of Accounting Estimates</i>
Amendments to IAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction</i>
Amendments to IAS 12	<i>International Tax Reform – Pillar Two Model Rules</i>

The new or amended IFRSs that are effective from January 1, 2023 did not have any significant impact on the Group's accounting policies.

2.3 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

The Group has not applied the following revised IFRSs, that have been issued but are not yet effective, in the financial statements. The Group intends to apply these revised IFRSs, if applicable, when they become effective.

Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture³</i>
Amendments to IFRS 16	<i>Lease Liability in a Sale and Leaseback¹</i>
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current (the “2020 Amendments”)¹</i>
Amendments to IAS 1	<i>Non-current Liabilities with Covenants (the “2022 Amendments”)¹</i>
Amendments to IAS 7 and IFRS 7	<i>Supplier Finance Arrangements¹</i>
Amendments to IAS 21	<i>Lack of Exchangeability²</i>

¹ Effective for annual periods beginning on or after January 1, 2024

² Effective for annual periods beginning on or after January 1, 2025

³ No mandatory effective date yet determined but available for adoption

These issued but not yet effective IFRSs are not expected to have any significant impact on the Group's financial statements.

3 OPERATING SEGMENT INFORMATION

For resource allocation and performance assessment, the Group's chief executive officer, being the chief operating decision maker, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole and hence, the Group has only one reportable segment and no further analysis of this single segment is presented.

The Group did not record any revenue during the reporting periods and the Group's non-current assets are substantially located in the PRC, accordingly, no analysis of geographical segment is presented.

4 OTHER INCOME AND GAINS

An analysis of other income is as follows:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Other income		
Government grants*	948	1,086
Bank interest income	4,000	4,010
Others	—	4
	<hr/>	<hr/>
Total other income	4,948	5,100
	<hr/>	<hr/>
Gains		
Foreign exchange differences, net	1,731	18,676
Gains on lease termination, net	1,419	—
Fair value gains on financial assets at FVTPL	469	—
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Total gains	3,619	18,676
	<hr/>	<hr/>
Total other income and gains	8,567	23,776
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* The Group has received certain government grants related to assets. The grants related to assets were recorded in deferred income and recognised in profit or loss over the useful lives of the relevant assets after the relevant conditions are met. Government grants related to income that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future related costs are recognised in profit or loss in the period upon actual receipt.

5 LOSS BEFORE TAX

The Group's loss before tax is arrived at after charging/(crediting):

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Depreciation of property, plant and equipment*	16,411	14,826
Depreciation of right-of-use assets*	4,857	5,992
Amortisation of other intangible assets*	87	39
Government grants	(948)	(1,086)
Bank interest income	(4,000)	(4,010)
Foreign exchange differences, net	(1,731)	(18,676)
Auditor's remuneration	1,950	2,230
Expense relating to leases of low-value assets	17	12
Gains on financial assets at FVTPL	469	–
Share of losses of an associate	1,633	1,430
	<u>18,745</u>	<u>757</u>
Staff cost (excluding directors', supervisors' and chief executive's remuneration):		
– Wages and salaries	9,954	10,198
– Pension scheme contributions	1,119	1,059
– Equity-settled share award expense	5,231	19,970

* The depreciation of property, plant and equipment, depreciation of right-of-use assets, amortisation of other intangible assets and employee benefit expenses for the year are set out in “Administrative expenses” and “Research and development expenses” in the consolidated statement of profit or loss and other comprehensive income.

6 OTHER EXPENSES

An analysis of other expenses is as follows:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Loss on disposal of items of property, plant and equipment	30,510	1
Others	42	54
	<u>30,552</u>	<u>55</u>

7 FINANCE COSTS

An analysis of finance costs is as follows:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Interest on lease liabilities	578	959

8 INCOME TAX

The Group's principal applicable taxes and tax rates are as follows:

- (a) No provision for Chinese Mainland income tax has been provided for at a rate of 25% pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), as the Group's PRC entities have no estimated assessable profits during the year.
- (b) No provision for Hong Kong income tax has been provided for at a rate of 16.5% as the Group's Hong Kong entity has no estimated assessable profits during the year.
- (c) A reconciliation of the tax expense applicable to loss before tax at the statutory rate to the tax expense at the effective tax rate is as follows:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Loss before tax	<u>(188,820)</u>	<u>(230,868)</u>
Tax at the statutory tax rate of 25%	(47,205)	(57,717)
Effect of different tax rate of the subsidiaries operating in other jurisdictions and tax concession	1,835	(69)
Tax effect of income that is exempt from taxation	(321)	(398)
Expenses not deductible for tax	12,106	36,594
Additional deductible allowance for research and development costs	(18,654)	(16,280)
Tax effect of deductible temporary differences not recognised	43	72
Utilisation of deductible temporary differences previously not recognised	(1,218)	(2,083)
Tax losses not recognised	<u>53,414</u>	<u>39,881</u>
Tax charge at the Group's effective tax rate for the year	<u>–</u>	<u>–</u>

Deferred tax assets have not been recognised in respect of the following items:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Tax losses	744,888	515,920
Deductible temporary differences	<u>13,685</u>	<u>18,803</u>
	<u>758,573</u>	<u>534,723</u>

The Group has tax losses of RMB744,888,000 and RMB515,920,000, as of December 31, 2023 and 2022, respectively. Deferred tax assets have not been recognised in respect of these losses as it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

9 DIVIDEND

No dividend has been paid or declared by the Company during the year (2022: Nil).

10 LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The Company had no potentially dilutive ordinary shares in issue during each of the years presented. The calculation of the weighted average number of ordinary shares has excluded the treasury shares.

The calculation of basic loss per share is based on:

	2023	2022
Loss		
Loss attributable to ordinary equity holders of the Company (RMB'000)	(175,893)	(204,236)
Ordinary shares		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation (thousand)	243,417	243,745
Loss per share (RMB per share)	(0.72)	(0.84)

11 PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	2023 RMB'000	2022 RMB'000
Non-current:		
Prepayments for purchase of items of property, plant and equipment	503	4,222
Rental deposits	475	1,754
Value-added tax recoverable – non-current	7,756	2,271
Other deposits	382	364
	<u>9,116</u>	<u>8,611</u>
Current:		
Prepayments for research and development expenses and others	27,637	84,412
Rental deposits	1,294	–
Value-added tax recoverable – current	6,124	5,798
	<u>35,055</u>	<u>90,210</u>

The financial assets included in the above balances relate to receivables for which there was no recent history of default and past due amounts. As of the end of each of the reporting periods, the loss allowance was assessed to be minimal.

Value-added tax recoverable represents input VAT related to property, plant and equipment acquired and research and development expenses incurred which are expected to be recovered either through refund from tax bureaus or to be utilised in the future to offset the output VAT. The amounts that are expected to be recovered within one year are recorded as current assets, while those that are expected to be recovered after one year are recorded as non-current assets.

12 OTHER PAYABLES AND ACCRUALS

	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Accruals for research and development	6,596	4,819
Payroll payable	205	1,250
Accrued listing expenses	5,508	6,994
Accrued other expenses	1,798	1,952
Payables for purchase of items of property, plant and equipment	–	4,372
Other payables	520	408
	14,627	19,795

Other payables are non-interest-bearing and repayable on demand.

MANAGEMENT DISCUSSION AND ANALYSIS

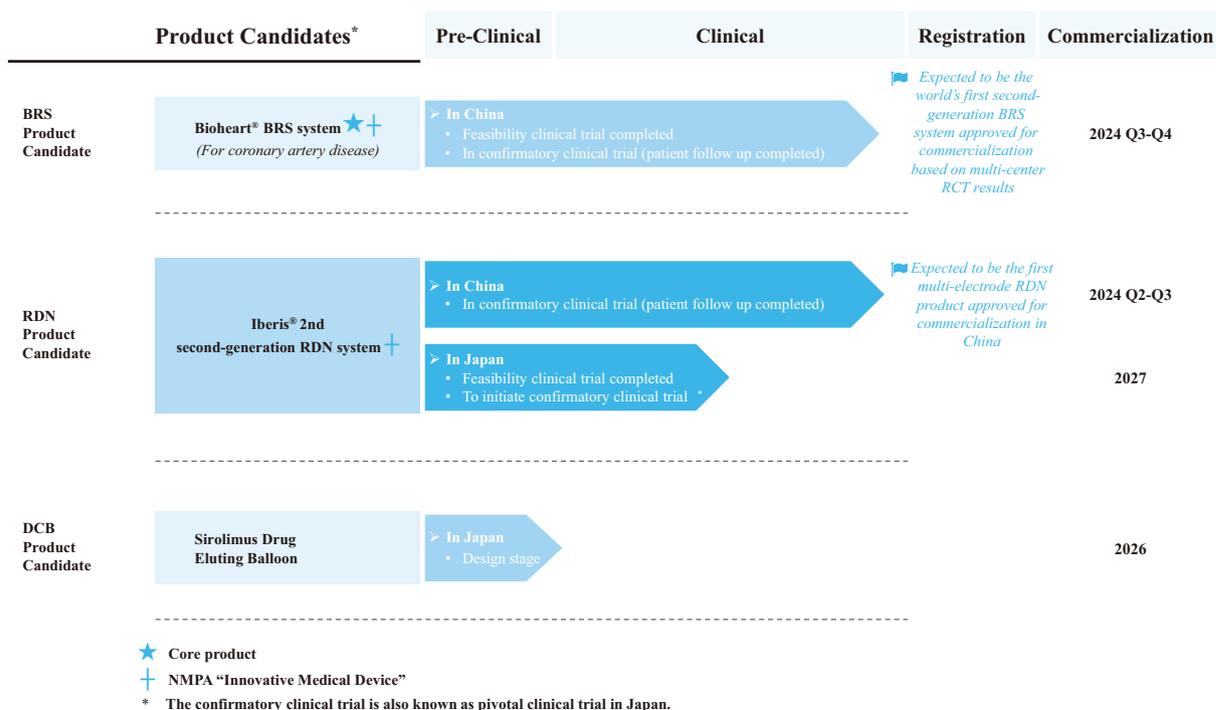
I. BUSINESS REVIEW

Overview

We are a leading innovative interventional cardiovascular device company in China with a current focus on two therapies: (i) BRS addressing the unmet medical needs of Chinese patients for the treatment of coronary artery diseases, and (ii) RDN addressing the unmet medical needs of patients for the treatment of uncontrolled hypertension and resistant hypertension.

Products and Pipeline

As of the date of this announcement, we have a portfolio of three product candidates in various stages of development. The following diagram summarizes the status of our product candidates under development as of the date of this announcement:



Our Products and Product Candidates

BRS Product Candidate

Bioheart[®], our BRS product, is a self-developed temporary scaffold that will be fully resorbed by the human body over time. It is a BRS system used in percutaneous coronary intervention (“**PCI**”) procedures for the treatment of coronary artery disease. As of the date of this announcement, we held over 40 patents, with one registered in the U.S. and one registered in Europe. Bioheart[®] was recognized as an “innovative medical device” by the NMPA in February 2017 and is therefore eligible for an expedited approval process. On February 16, 2022, the Company completed the patient enrollment process for the clinical trial of Bioheart[®]. We expect to obtain the approval from the NMPA in Q3-Q4 2024.

RDN Product Candidate

Iberis[®] **2nd** is our self-developed second-generation RDN system. RDN is one of the few device therapies with proven clinical efficacy to treat uncontrolled hypertension and resistant hypertension and is considered by many industry experts as having the potential to transform the treatment paradigm of hypertension. As of the date of this announcement, we held over 20 patents in relation to Iberis[®] 2nd with one registered in Japan. Iberis[®] 2nd was recognized as an “innovative medical device” by the NMPA in November 2016 and is therefore eligible for an expedited approval process. On January 26, 2022, the Company completed the patient enrollment process for the clinical trial of Iberis[®] 2nd. On April 11, 2023, the Company announced that the randomized controlled trial (“**RCT**”) of Iberis[®] 2nd Multi-Electrode Renal Artery Radiofrequency Ablation Catheter System in patients with Essential Hypertension (“**Iberis-HTN**”) has achieved its primary clinical endpoint according to the Statistical Report that the Company received. Detailed data has been presented at China Interventional Therapeutics 2023. We expect to obtain the approval from the NMPA in Q2-Q3 2024.

We have contracted with the European Cardiovascular Research Center to conduct a European clinical trial evaluating Iberis[®] 2nd RDN system. At EuroPCR 2022, we finalized plans with clinical trial investigators on the RADIUS-HTN Trial. The European Cardiovascular Research Center will conduct the RADIUS-HTN Trial comparing the effectiveness of RDN performed via transradial arterial access (“**TRA**”) and transfemoral arterial access (“**TFA**”). We are the only company in the world to have CE Marking for

catheters that can be used for both TRA and TFA to treat high blood pressure. The TRA approach to vascular interventions is preferred by physicians and patients. Compared to TFA, TRA interventions reduce access site complications and shorten the duration of hospital stay with a reduction in procedural costs and increased patient gratification. Clinical trials in Japan for Iberis® 2nd are conducted in collaboration with Terumo, our strategic business collaborator. On March 27, 2023, the first patient under the RADIUS-HTN Trial was enrolled, and the procedure was performed at the Centre Hospitalier Universitaire de Bordeaux.

DCB Product Candidate

Our newly developed drug coated balloon (“**DCB**”) is a sirolimus drug-eluting balloon catheter designed for in-stent restenosis. Drug-eluting balloon (“**DEB**”) is a kind of DCB, which usually has a longer drug release period. The drug coating contains sirolimus, amphipathic liposomes, biodegradable polymers and dispersants in a certain ratio to achieve efficient transfer and durable release of the drug coating, which is safe and effective. By encapsulating sirolimus in biodegradable nanoparticles to form nano drug-loaded microspheres, this method achieves an ultra-long release of about 90 days in the target vessel tissue. The final microsphere micelles are formed by the self-assembly effect resulting from the amphipathic liposome with the dispersant and the nano drug – loaded microspheres through intermolecular forces. Due to the effect of amphiphilic liposomes, the transfer ability of the microsphere micelles into the target vessel tissue is greatly improved, and finally drug transfer and long release period are achieved.

As of the date of this announcement, current DCB products available in Japan market all use paclitaxel-based drug coating. Compared with paclitaxel, sirolimus’s unique cytostatic effect makes it have higher safety and wider therapeutic window, and has anti-inflammatory effect.

Coronary sirolimus DCB, as the recommended product for in stent restenosis and bifurcation vessels, will be an ideal supplement to our BRS products. We are now actively communicating with PMDA preparing for clinical study.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCT, BIOHEART®, OR ANY OTHER PRODUCT CANDIDATES.

Research and Development

Our research and development team has been focusing on developing medical devices for the treatment of coronary diseases, as well as uncontrolled and resistant hypertension. We have independently developed a number of innovative medical devices and commercialized our first-generation RDN product in multiple regions. As of the date of this announcement, we had:

- one Core Product, one RDN product candidate, as well as a sirolimus DCB product candidate in various stages of development;
- Over 80 registered patents and over 40 pending patent applications; and
- CE Marking and nine registration certificates for our first-generation RDN product commercialized in overseas markets.

Strategic Investments

On April 14, 2023, the Company, Hong Kong Bio-heart Biological Technology Co., Limited (“**HK Bio-heart**”), Shanghai Xinzhi Medical Technology Co., Ltd.* (上海心至醫療科技有限公司) (“**Xinzhi Medical**”), Ms. Jiaqi Hong, the spouse of Mr. Wang, and the other shareholders of Xinzhi Medical entered into a capital increase agreement, pursuant to which the Company agreed to make a capital increase of RMB15,000,000 into Xinzhi Medical in exchange for RMB361,144 of the registered capital of Xinzhi Medical, and the remaining RMB14,638,856 shall be credited as capital reserve of Xinzhi Medical. Together with the equity interest in Xinzhi Medical directly held by HK Bio-heart, the Group holds an aggregate of approximately 22.18% interest in Xinzhi Medical after the completion of the capital increase. Xinzhi Medical’s paclitaxel coronary DCB has been approved by the NMPA in May 2023. Additionally, Xinzhi Medical has three DCB products at clinical stage in its pipeline and the patient enrollment process for the clinical trial of rapamycin coronary DCB has been completed. Compared to the commonly used stents in clinical practice, DCB, as the complementary product of BRS, is able to offer treatment without implanting foreign objects into human bodies, thereby achieving the concept of “intervention without implantation”. By investing in Xinzhi Medical, we expect to enrich our portfolio in cardiovascular device through cooperation and achieving synergy between Xinzhi’s Medical DCB products and our pipeline. For details of the capital increase in Xinzhi Medical, please refer to the Company’s announcement dated April 14, 2023.

Manufacturing

After thorough consideration of the status of our product candidates under development and future competitive landscape, we have terminated the lease for one of our manufacturing plants located at east Zhangjiang Hi-Tech Park during the Reporting Period to reduce unnecessary expenses and allocate resources more efficiently towards the upcoming product commercialization phase. We expect to locate and establish a new manufacturing plant in other area before product commercialization to further enhance operational efficiency and reduce production costs.

Future and Outlook

Our goal is to become a world-renowned chronic disease management medical device platform. We plan to implement the following strategies to achieve this goal:

- rapidly advance the clinical development and commercialization of our product candidates, especially Bioheart® and Iberis® 2nd, in order to enjoy a “first-mover” advantage in the unmet BRS and RDN markets in China;
- enhance our sales efforts and strengthen our presence in the interventional cardiovascular device market in China;
- further enhance our research and development capabilities and expand our product portfolios;
- expand our manufacturing capabilities and build our in-house sales and marketing team;
- further expand our presence in China and globally; and
- actively seek opportunities for external partnerships, strategic investments and acquisitions to facilitate our future expansion.

II. FINANCIAL REVIEW

For the year ended December 31, 2023 and 2022, we incurred net losses of RMB188.8 million and RMB230.9 million, respectively. It is highly possible for us to incur net losses in the near future as we continued to invest in R&D of, seek regulatory approval for, and commercialize our pipeline products.

Other Income and Gains

Our other income mainly consists of government grants, bank interest income and others. Our government grants mainly include government subsidies for compensating our expenses relating to certain research and development projects.

Our other income and gains decreased from RMB23.8 million in 2022 to RMB8.6 million in 2023. The decrease was primarily attributable to the decrease of foreign exchange gains of RMB16.9 million.

Administrative Expenses

Our administrative expenses mainly consist of (i) employee benefit expenses, (ii) depreciation expenses, (iii) professional service expenses, and (iv) utilities and office expenses. Employee benefit expenses mainly include salaries, equity-settled share awards and other welfare for our administrative employees. In 2022 and 2023, we recorded equity-settled share award expenses of RMB67.4 million and RMB22.2 million, respectively, under our administrative expenses.

Our administrative expenses decreased from RMB94.4 million in 2022 to RMB52.9 million in 2023. The decrease was primarily attributable to 1) a decrease of equity-settled share award expense of RMB45.2 million related to our key administrative employees with service periods requirements; 2) a decrease of professional service expenses of RMB3.8 million as a result of that the compliance service expenses and public relation services was not incurred during this year; 3) an increase of other expense of RMB7.1 million due to increased conference and travel costs incurred in 2023.

The following table sets forth a breakdown of our administrative expenses for the periods indicated:

	Year ended December 31,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Employee benefits expenses	28,565	72,979
Including: equity-settled share award expense	22,197	67,416
Depreciation expenses	8,226	8,125
Professional service expenses	5,981	9,772
Utilities and office expenses	1,398	1,865
Others	8,711	1,629

Research and Development Expenses

Our research and development expenses mainly consist of (i) third party contracting cost, (ii) employee benefits expenses for our research and development staff, (iii) costs of raw materials and consumables used, and (iv) depreciation and amortization expenses.

Employee benefits expenses under research and development expenses primarily include the salaries, welfare, and equity-settled share awards for our research and development employees. In 2022 and 2023, we recorded equity-settled share award expenses of RMB73.1 million and RMB25.4 million, respectively, under our research and development expenses. We have established incentive platforms for such purposes.

Our research and development expenses decreased from RMB157.8 million in 2022 to RMB111.7 million in 2023. The decrease was primarily attributable to the decrease of equity-settled share award expenses related to our research and development employees with service periods requirements.

The following table sets forth a breakdown of our research and development expenses for the periods indicated:

	Year ended December 31,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Third party contracting cost	50,540	49,547
Employee benefit expenses	36,660	84,805
Including: equity-settled share award expense	25,430	73,065
Costs of raw materials and consumables used	3,430	5,425
Depreciation and amortization expenses	13,129	12,732
Others	7,984	5,321

Other Expenses

Our other expenses increased from RMB0.1 million in 2022 to RMB30.6 million in 2023. The increase was due to the loss on disposal of items of property, plant and equipment resulting from the termination of the lease for one of our manufacturing plants during the Reporting Period.

Finance Costs

Our finance costs mainly consist of interest on lease liabilities relating to our lease of office premises. Our finance costs decreased from RMB1.0 million in 2022 to RMB0.6 million in 2023. The decrease was primarily attributable to the lease termination.

Income Tax Expense

No provision for Chinese Mainland income tax has been provided for at a rate of 25% pursuant to the Enterprise Income Tax Law of the PRC and the respective regulations, as the PRC entities of our Group have no estimated assessable profits.

No provision for Hong Kong income tax has been provided for at a rate of 16.5% as the Group's Hong Kong entity has no estimated assessable profits during the year.

We did not record any income tax expense during the Reporting Period.

Loss for the Year

Based on the factors described above, our net losses amounted to RMB188.8 million and RMB230.9 million in 2023 and 2022 respectively.

Liquidity and Financial Resources

Our primary uses of cash are to fund the development of our product candidates, our clinical trials, our payment for the purchase of plant and equipment, administrative expenses and other recurring expenses. Our net cash used in operating activities was RMB49.0 million for the year ended December 31, 2023, primarily due to the significant research and development expenses and administrative expenses we incurred during the Reporting Period. Our operating cash flow will continue to be affected by our research and development expenses. During the Reporting Period, we mainly relied on capital contributions by our shareholders and equity financing as the major sources of liquidity. Our management closely monitors uses of cash and cash balances and strives to maintain a healthy liquidity for our operations. Going forward, we believe our liquidity requirements will be satisfied by a combination of net proceeds from the Global Offering and cash generated from our operations.

Our net cash used in investing activities was RMB28.9 million for the year ended December 31, 2023, primarily due to the purchases of items of property, plant and equipment, payments for investment in an associate amounting to RMB17.7 million and RMB15.0 million, respectively.

Our net cash used in financing activities was RMB5.8 million for the year ended December 31, 2023, primarily due to the payment for leases.

As of December 31, 2023, we had cash and cash equivalents of RMB369.4 million, representing a decrease of 18.1% compared to RMB451.3 million as of December 31, 2022.

Our net current assets decreased from RMB512.7 million as of December 31, 2022 to RMB388.4 million as of December 31, 2023, primarily attributable to the decrease in cash and cash equivalents.

Capital Expenditure

Our capital expenditures primarily consist of expenditures on machinery, office equipment, motor vehicles as well as leasehold improvements.

Our capital expenditures decreased from RMB30.0 million in 2022 to RMB17.7 million in 2023. The decrease was primarily attributable to less purchase of machinery and leasehold improvements.

Indebtedness

As of December 31, 2023, we did not have any outstanding balance of borrowings.

As of the date of this announcement, we had no unutilized banking facilities.

Our lease liabilities decreased from RMB18.1 million as of December 31, 2022 to RMB1.8 million as of December 31, 2023, primarily because of increase of the lease payments made and leases termination during the year.

Gearing Ratio

The gearing ratio of the Group, which was calculated by using total liabilities divided by total assets and multiplied by 100%, was 5.4% as of December 31, 2023, decreased from 6.8% as of December 31, 2022. The decrease was primarily due to decrease of cash and cash equivalents.

Capital Commitments

As of December 31, 2023, we didn't have capital commitments contracted, but not yet provided for, which were related to the purchase of property, plant and equipment for the Group's production plant (2022: RMB7.6 million).

Pledge of Assets

As of December 31, 2023, the Group had no pledge of assets.

Contingent Liabilities

As of December 31, 2023, we did not have any material contingent liabilities.

Foreign Exchange Exposure

We are exposed to foreign currency risk mainly arising from cash at bank denominated in USD. We currently do not have a foreign currency hedging policy. However, our management monitors foreign exchange exposure and will consider appropriate hedging measures in the future should the need arises.

Future Plans for Material Investments or Capital Assets

Save as disclosed in this announcement, the Group has no other material capital expenditure plan as of the date of this announcement.

Human Resources

As of December 31, 2023, the Group had 32 full-time employees, who were all based in China. The total employee benefits expenses of our Group, which consist of (i) wages, salaries and bonuses, (ii) contributions to statutory employee benefit plans, (iii) employee welfare and (iv) equity-settled share award expenses, for the Reporting Period were approximately RMB65.2 million.

We recruit our employees based on a number of factors, including work experience, educational background and the requirements of a relevant vacancy. We invest in continuing education and training programs for our management staff and other employees to upgrade their skills and knowledge continuously. We provide our employees with regular feedback as well as internal and external training in various areas, such as product knowledge, project development and team building. We also assess our employees based on their performance to determine their salary, promotion and career development. In compliance with the relevant PRC labor laws, we enter into individual employment contracts with our employees covering matters such as duration,

wages, bonuses, employee benefits, workplace safety, confidentiality obligations, noncompetition and grounds for termination. The Group ensures that its remuneration packages are comprehensive and competitive from time to time. When determining the emolument payable to the Directors, we take into account the experience of the Directors, their level of responsibility and general market conditions. Any discretionary bonus and other merit payments of the Directors are linked to the profit performance of the Group and the individual performance of the Directors. Employees are remunerated with a fixed monthly income plus annual performance related bonus. In addition, we are required under PRC law to make contributions to statutory employee benefit plans (including pension plans, medical insurance, work-related injury insurance, unemployment insurance, maternity insurance and housing funds) at a certain percentage of our employees' salaries, including bonus and allowances, up to a maximum amount specified by the local government.

In September 2020, the Board passed a resolution to grant up to 14,509,413 restricted shares of the Company to directors, employees and founders of the Company and AngioCare (the “**2020 Plan**”). The 2020 Plan was established in order to retain certain eligible employees for the continual operation and development of the Group. The subscription price paid by the shareholding platforms of the 2020 Plan was RMB1.0 per share of the Company.

On June 27, 2022, the annual general meeting approved the proposed adoption of the 2022 H Share Incentive Scheme (the “**Scheme**”). The Scheme aims to attract, motivate and retain highly skilled and experienced personnel to strive for the future development and expansion of the Group. The Scheme can also help the Company to modernize the remuneration practices and to improve the interests balancing mechanism among Shareholders, the operational and executive management by aligning their interests as a whole.

USE OF PROCEEDS

On December 23, 2021, the Company was successfully listed on the Stock Exchange. The net proceeds received by the Group from the Global Offering after deducting underwriting fee and relevant expenses amounted to approximately HK\$441.69 million.

The table below sets out the planned applications of the net proceeds from the Global Offering and actual usage as of December 31, 2023:

Use of proceeds	Percentage of total net proceeds	Allocation of net proceeds (HK\$ million)	Unutilized amount as of January 1, 2023 (HK\$ million)	Utilized amount during the Reporting Period (HK\$ million)	Unutilized amount as of December 31, 2023 ⁽¹⁾ (HK\$ million)	Expected timeline of full utilization of the unutilized proceeds ⁽²⁾
To fund the ongoing confirmatory clinical trial, preparation for registration filings, and planned commercial launch of our Core Product, Bioheart®	62.00%	273.85	195.49	18.89	176.60	December 2027
To fund the ongoing randomized controlled clinical trial in China for, and the continuous development of, our RDN product candidate, Iberis® 2nd	21.30%	94.08	84.83	23.04	61.79	December 2027
To fund the research and development, ongoing pre-clinical studies and planned clinical trials of other product candidates in our pipeline, including Bio-Leap™, Bioheart Ultra™, our Bioheart® balloon dilatation catheter, our Bioheart® non-compliant (high-pressure) balloon dilatation catheter and our Bioheart® impulse balloon dilatation catheters	2.79%	12.34	0.47	0.47	-	Fully utilized
General corporate and working capital purposes	10.00%	44.17	28.14	18.94	9.20	December 2027
To fund the research and development of DCB	3.91%	17.25	17.25	10.17	7.08	December 2027
	<u>100%</u>	<u>441.69</u>	<u>326.18</u>	<u>71.51</u>	<u>254.67</u>	

Notes:

- As of December 31, 2023, the unused net proceeds were deposited with certain licensed banks in Hong Kong or the PRC.
- The expected timeline to use the remaining proceeds is prepared based on the best estimate made by the Group, which is subject to change according to the current and future development of the market condition.

In February 2024, the Board has resolved to change the use of unutilized net proceeds from the Global Offering. For details, please refer to the section headed “SUBSEQUENT EVENTS AFTER THE REPORTING PERIOD” in this announcement.

SIGNIFICANT INVESTMENTS, MATERIAL ACQUISITIONS AND DISPOSALS

Please refer to the section headed “MANAGEMENT DISCUSSION AND ANALYSIS – I. BUSINESS REVIEW – Strategic Investments” for further details. Save as disclosed above, the Group did not hold any significant investment or made any significant acquisitions and disposals during the Reporting Period.

PRE-EMPTIVE RIGHTS

There are no provisions for pre-emptive rights under the articles of association of the Company, or the laws of the PRC, which would oblige the Company to offer new shares of the Company on a pro-rata basis to its existing Shareholders.

SUFFICIENCY OF PUBLIC FLOAT

According to the information that is publicly available to the Company and within the knowledge of the Board, as of the date of this announcement, the Company has maintained the public float as required under the Listing Rules.

THE 2022 H SHARE INCENTIVE SCHEME

In the Shareholders’ annual general meeting held on June 27, 2022, the 2022 H Share Incentive Scheme has been duly approved by the Shareholders. Since the adoption of the Scheme, the Company has purchased an aggregate of 519,900 H Shares. Since the adoption of the Scheme and up to the end of the Reporting Period, no restricted share units (“RSU”) had been granted. As of the end of the Reporting Period, and as of the date of this announcement, there is no change in the number of H Shares held by the trustee of the Scheme.

PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES OF THE COMPANY

Neither the Company nor any of its subsidiaries have purchased, sold or redeemed any of the Company’s listed securities during the Reporting Period.

FINAL DIVIDEND

The Board does not recommend the payment of a final dividend for the Reporting Period (2022: Nil).

FULL CIRCULATION

On January 13, 2023, the conversion of 100,107,425 Domestic Shares and 74,509,781 Unlisted Foreign Shares into H Shares, and the Full Circulation of Domestic Shares and certain Unlisted Foreign Shares were completed on January 13, 2023. For further details of the share capital structure of the Company immediately after the completion of the Full Circulation, please refer to the announcement on the same date.

SUBSEQUENT EVENTS AFTER THE REPORTING PERIOD

On February 8, 2024, the Board resolved to change the use of the unutilized net proceeds from the Global Offering, totaling approximately HK\$247.10 million as of February 8, 2024, as follows:

- (i) reallocating approximately HK\$26.37 million, which was originally allocated for funding the ongoing randomized controlled clinical trial in China for, and the continuous development of, the Group's RDN product candidate, Iberis[®] 2nd, to funding the acquisition of the Property, which was completed in March 2024; and
- (ii) reallocating approximately HK\$70 million, which was originally allocated for funding the ongoing confirmatory clinical trial, preparation for registration filings, and planned commercial launch of the Company's Core Product, Bioheart[®], to funding the research and development of DCB.

For details of the above change, please refer to the announcement of the Company dated February 8, 2024.

Save as disclosed above, there is no material subsequent event undertaken by the Company or by the Group after the Reporting Period and up to the date of this announcement.

ANNUAL GENERAL MEETING

The Company will hold the AGM on Friday, June 21, 2024. A notice of convening the AGM will be published on the websites of the Stock Exchange at www.hkexnews.hk and the Company at www.bio-heart.com, and dispatched to the Shareholders in the manner as required by the Listing Rules in due course.

CLOSURE OF REGISTER OF MEMBERS OF H SHARES AND ASCERTAINING OF ELIGIBILITY FOR ATTENDING THE AGM

The register of members of H Shares the Company will be closed from Wednesday, May 22, 2024 to Friday, June 21, 2024 (both days inclusive), during which period no transfer of H Shares will be registered. In order to qualify for attending and voting at the AGM, all transfer documents accompanied by the relevant share certificate(s) must be lodged with the Company's H Share registrar, Computershare Hong Kong Investor Services Limited at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong no later than 4:30 p.m. on Tuesday, May 21, 2024.

CORPORATE GOVERNANCE PRACTICES

The Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the shareholders of the Company as a whole. The Company has adopted the code provisions of the CG Code as its own code of corporate governance. During the Reporting Period, the Company has complied with all applicable code provisions set out in Part 2 of the CG Code, except for the following deviation from code provision C.2.1 of the CG Code.

Under code provision C.2.1 of Part 2 of the CG Code, the roles of chairman and chief executive should be separate and should not be performed by the same individual. Mr. Wang is our chairman of the Board and the general manager of our Company. Mr. Wang has extensive experience in the pharmaceutical industry and has served in the Company since its establishment. Mr. Wang is in charge of overall management, business, strategic development and scientific R&D of the Group. Despite the fact that the roles of our chairman of the Board and our general manager are both performed by Mr. Wang which constitutes a deviation from code provision C.2.1 of Part 2 of the CG Code, the Board considers that vesting the roles of the chairman of the Board and the chief executive officer in the same person is beneficial to the management of the Group. The Board also believes that the combined role of the chairman of the Board and the chief executive officer of the Company can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board.

The balance of power and authority is ensured by the operation of the Board, which comprises experienced and diverse individuals. The Board currently comprises three executive Directors (including Mr. Wang) and three independent non-executive Directors, and therefore has a strong independent element in its composition. The Board will continue to review the effectiveness of the corporate governance structure of the Group in order to assess whether separation of the roles of chairman and the chief executive officer is necessary.

MODEL CODE FOR SECURITIES TRANSACTIONS

The Company has adopted the Model Code as its own code of conduct regarding securities transactions by the Directors, Supervisors and the Company's senior management who, because of his/her office or employment, is likely to possess inside information in relation to Company or its securities. Having made specific enquiries with all Directors and Supervisors, each of them has confirmed that he/she has complied with the Model Code during the Reporting Period. No incident of non-compliance of the Model Code by the employees who are likely to be in possession of inside information of the Company was noted by the Company.

REVIEW OF ANNUAL RESULTS AND THE AUDITED CONSOLIDATED FINANCIAL STATEMENTS

The Board has established the Audit Committee with terms of reference in compliance with the Listing Rules. The Audit Committee consists of three independent non – executive Directors, being Mr. Charles Sheung Wai CHAN, Mr. Xubo LU and Mr. Wing Yiu DJEN. Mr. Charles Sheung Wai CHAN serves as the chairperson of the Audit Committee, who has the professional qualification and experience in financial matters in compliance with the requirements of the Listing Rules.

The primary duties of the Audit Committee are to review and supervise the Company’s financial reporting process, internal control and risk management system, overseeing the audit process and performing other duties and responsibilities as assigned by the Board.

The Audit Committee, together with the management team and external auditor of the Company, Ernst & Young, have reviewed the accounting principles and policies adopted by the Group and discussed internal control, risk management and financial reporting matters, including a review of the audited consolidated financial statements and the annual report of the Group for the Reporting Period, and is of the view that the annual results of the Group is prepared in accordance with applicable accounting standards, rules and regulations and appropriate disclosures have been duly made.

SCOPE OF WORK OF ERNST & YOUNG

The figures in respect of the Group’s consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the Reporting Period as set out in this results announcement have been agreed by the Group’s auditor, Ernst & Young, to the amounts set out in the Group’s consolidated financial statements for the Reporting Period. The work performed by Ernst & Young in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards in Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by Ernst & Young on this results announcement.

PUBLICATION OF ANNUAL RESULTS AND 2023 ANNUAL REPORT

This announcement is published on the websites of the Stock Exchange at www.hkexnews.hk and the Company at www.bio-heart.com. The annual report of the Company for the Reporting Period containing all the information required by the Listing Rules will be dispatched to the Shareholders and will be published on the respective websites of the Stock Exchange and the Company in due course.

APPRECIATION

On behalf of the Board, I would like to thank all our colleagues for their diligence, dedication, loyalty and integrity. I would also like to thank all our Shareholders, customers, bankers and other business associates for their trust and support.

DEFINITIONS

In this announcement, unless the context otherwise requires, the following expressions shall have the following meanings:

“AGM”	The forthcoming annual general meeting of the Company to be held on Friday, June 21, 2024
“AngioCare”	Shanghai AngioCare Medical Technology Co., Ltd.* (上海安通醫療科技有限公司), a subsidiary of our Company
“Audit Committee”	the audit committee of the Board
“Board”	the board of directors of the Company
“BRS”	Bioheart® bioresorbable scaffold
“CG Code”	the Corporate Governance Code set out in Appendix C1 to the Listing Rules
“China” or “PRC”	the People’s Republic of China, which, for the purpose of this announcement and for geographical reference only, excludes Hong Kong, Macau and Taiwan
“Company” or “our Company”	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 PRC with limited liability on December 8, 2020, or, where the context requires (as the case may be), its predecessor with the same English name (上海百心安生物技術有限公司), a limited liability company established in the PRC on July 18, 2014
“Core Product”	Bioheart®, the designated “core product” as defined under Chapter 18A of the Listing Rules
“DCB”	drug coated balloon
“Director(s)”	the director(s) of the Company or any one of them
“Domestic Share(s)”	ordinary share(s) in the share capital of our Company, with a nominal value of RMB1.00 each, which are subscribed for and paid up in RMB and are unlisted Shares which are currently not listed or traded in any stock exchange
“EuroPCR 2022”	an official annual meeting of the European Association of Percutaneous Cardiovascular Interventions

“Full Circulation”	the conversion of the Domestic Shares and certain Unlisted Foreign Shares into H Shares and their listing on the Stock Exchange, of which the Company received the approval from official approval from the China Securities Regulatory Commission and was completed on January 13, 2023
“Global Offering”	the global offering of the H Shares, details of which are set forth in the Prospectus
“Group”, “the Group”, “our Group”, “our”, “we”, or “us”	the Company and all of its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
“H Share(s)”	overseas listed foreign invested ordinary share(s) in the ordinary share capital of our Company, with a nominal value of RMB1.00 each, which are listed on the Stock Exchange
“HK Bio-heart”	Hong Kong Bio-heart Biological Technology Co., Limited (香港百心安生物技術有限公司), a company incorporated in Hong Kong on April 7, 2021, a wholly-owned subsidiary of the Company
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong dollars” or “HK dollars” or “HK\$”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
“IFRS”	International Financial Reporting Standards, as issued from time to time by the International Accounting Standards Board
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (as amended, supplemented or otherwise modified from time to time)
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix C3 to the Listing Rules
“Mr. Wang”	Mr. Philip Li Wang (汪立), our Founder, Controlling Shareholder, the chairman of our Board, our general manager and an executive Director of our Company

“NMPA”	the National Medical Product Administration of the PRC (國家藥品監督管理局), successor to the China Food and Drug Administration or CFDA (國家食品藥品監督管理總局)
“PMDA”	the Pharmaceuticals and Medical Devices Agency of Japan
“Property”	the manufacturing facility for the Group’s RDN product candidate located at Room 401, Building 6, 590, Ruiqing Road, Zhangjiang Hi-Tech, Industrial Park, Shanghai, the PRC
“Prospectus”	the prospectus of the Company dated December 13, 2021
“R&D”	research and development
“RADIUS-HTN Trial”	the European clinical trial on Renal Artery Denervation Using Radial Access in Uncontrolled Hypertension
“RDN”	renal denervation
“Reporting Period”	for the year ended December 31, 2023
“RMB”	Renminbi, the lawful currency of the PRC
“Share(s)”	ordinary share(s) in the capital of our Company with a nominal value of RMB1.00 each, comprising Unlisted Foreign Shares and H Shares
“Shareholder(s)”	holder(s) of the Share(s)
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“Supervisor(s)”	the supervisor(s) of the Company
“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“USD”	United States dollars, the lawful currency of the United States
“Unlisted Foreign Shares”	ordinary shares issued by our company with a nominal value of RMB1.00 each and are held by foreign investors and are not listed on any stock exchange

“Xinzhi Medical”

Shanghai Xinzhi Medical Technology Co., Ltd.* (上海心至醫療科技有限公司), a company established in the PRC with limited liability

%

per cent

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 25, 2024

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. Charles Sheung Wai CHAN, Mr. Xubo LU and Mr. Wing Yiu DJEN as independent non-executive directors.

* *For identification purposes only*