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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, 2024;**

AND

CHANGE IN COMPOSITION OF THE NOMINATION COMMITTEE

FINANCIAL HIGHLIGHTS	Year ended December 31,	
	2024	2023
	RMB'000	RMB'000
Research and development expenses	(41,300)	(111,743)
Administrative expenses	(19,740)	(52,881)
Other expenses	(33,913)	(30,552)
Finance costs	(64)	(578)
Other income and gains	2,679	8,567
Share of loss of an associate	(986)	(1,633)
LOSS BEFORE TAX	<u>(93,324)</u>	<u>(188,820)</u>

BUSINESS HIGHLIGHTS

- Net loss of the Group for the year ended December 31, 2024 amounted to approximately RMB93.3 million, representing a decrease of 50.6% from approximately RMB188.8 million in 2023.
- Research and development expenses for the year ended December 31, 2024 amounted to approximately RMB41.3 million, representing a decrease of 63.0% from approximately RMB111.7 million recorded in 2023.
- As of December 31, 2024, cash and cash equivalents amounted to approximately RMB202.4 million, representing a decrease of 45.2% from appropriately RMB369.4 million as of December 31, 2023.
- Basic and diluted loss per Share for 2024 amounted to RMB0.36 (2023: RMB0.72).
- On February 26, 2025, Iberis® RDN system has been approved by the NMPA for the adjuvant treatment for resistant hypertension and hypertension patients with drug intolerance.
- In February 2025, Iberis® RDN system completed the first commercial procedure in Europe.

ANNUAL RESULTS

The Board is pleased to announce the audited consolidated annual results of the Group for the year ended December 31, 2024 together with the comparative figures for the year ended December 31, 2023 as follows:

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the year ended December 31, 2024

	<i>Notes</i>	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Other income and gains	4	2,679	8,567
Research and development expenses		(41,300)	(111,743)
Administrative expenses		(19,740)	(52,881)
Other expenses	6	(33,913)	(30,552)
Finance costs	7	(64)	(578)
Share of loss of an associate		(986)	(1,633)
		<hr/>	<hr/>
LOSS BEFORE TAX	5	(93,324)	(188,820)
Income tax expense	8	–	–
		<hr/>	<hr/>
LOSS FOR THE YEAR		(93,324)	(188,820)
		<hr/> <hr/>	<hr/> <hr/>
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		(93,324)	(188,820)
		<hr/>	<hr/>
Attributable to:			
Owners of the parent		(87,944)	(175,893)
Non-controlling interests		(5,380)	(12,927)
		<hr/>	<hr/>
		(93,324)	(188,820)
		<hr/>	<hr/>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (<i>RMB</i>)	10	(0.36)	(0.72)
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CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As of December 31, 2024

	<i>Notes</i>	2024 RMB'000	2023 RMB'000
NON-CURRENT ASSETS			
Property, plant and equipment		42,945	29,588
Other intangible assets		137,587	137,710
Investment in an associate		35,609	36,595
Financial assets at fair value through profit or loss (“FVTPL”)		18,296	50,469
Prepayments, other receivables and other assets	<i>11</i>	47,049	9,116
Right-of-use assets		8,633	1,318
Goodwill		144,630	144,630
		<hr/>	<hr/>
Total non-current assets		434,749	409,426
CURRENT ASSETS			
Inventories		18,327	3,980
Prepayments, other receivables and other assets	<i>11</i>	78,314	35,055
Cash and cash equivalents		202,386	369,438
		<hr/>	<hr/>
Total current assets		299,027	408,473
CURRENT LIABILITIES			
Trade payables	<i>12</i>	95	–
Lease liabilities		1,269	1,579
Other payables and accruals	<i>13</i>	17,813	14,627
Amounts due to related parties		472	472
Deferred income		–	3,391
		<hr/>	<hr/>
Total current liabilities		19,649	20,069

	2024	2023
<i>Notes</i>	<i>RMB'000</i>	<i>RMB'000</i>
NET CURRENT ASSETS	279,378	388,404
TOTAL ASSETS LESS CURRENT LIABILITIES	714,127	797,830
NON-CURRENT LIABILITIES		
Lease liabilities	7,014	183
Deferred income	6,000	3,210
Deferred tax liabilities	20,580	20,580
Total non-current liabilities	33,594	23,973
Net assets	680,533	773,857
EQUITY		
Equity attributable to owners of the parent		
Share capital	243,937	243,937
Treasury shares	(29,438)	(29,438)
Reserves	445,969	533,913
Non-controlling interests	660,468	748,412
	20,065	25,445
Total equity	680,533	773,857

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 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 are principally engaged in the research and development of BRS products and the RDN system.

The Company was listed on the Main Board of the Stock Exchange on December 23, 2021.

2.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with IFRS Accounting Standards (which include all IFRS Accounting Standards, International Accounting Standards (“IASs”) and interpretations) as issued by the IASB and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention, except for financial assets at fair value through profit or loss, derivative financial instruments and investment property which have been measured at fair value. 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 revised IFRS Accounting Standards for the first time for the current year’s financial statements.

Amendments to IFRS 16	<i>Lease Liability in a Sale and Leaseback</i>
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current</i> <i>(the “2020 Amendments”)</i>
Amendments to IAS 1	<i>Non-current Liabilities with Covenants</i> <i>(the “2022 Amendments”)</i>
Amendments to IAS 7 and IFRS 7	<i>Supplier Finance Arrangements</i>

The new or amended IFRS Accounting Standards that are effective from January 1, 2024 did not have any significant impact on the Group’s accounting policies.

2.3 ISSUED BUT NOT YET EFFECTIVE IFRS ACCOUNTING STANDARDS

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

IFRS 18	<i>Presentation and Disclosure in Financial Statements</i> ³
IFRS 19	<i>Subsidiaries without Public Accountability: Disclosures</i> ³
Amendments to IFRS 9 and IFRS 7	<i>Amendments to the Classification and Measurement of Financial Instruments</i> ²
Amendments to IFRS 9 and IFRS 7	<i>Contracts Referencing Nature-dependent Electricity</i> ²
Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ⁴
Amendments to IAS 21	<i>Lack of Exchangeability</i> ¹
Annual Improvements to IFRS Accounting Standards – Volume 11	<i>Amendments to IFRS 1, IFRS 7, IFRS 9, IFRS 10 and IAS 7</i> ²

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

² Effective for annual periods beginning on or after January 1, 2026

³ Effective for annual/reporting periods beginning on or after January 1, 2027

⁴ No mandatory effective date yet determined but available for adoption

These issued but not yet effective IFRS Accounting Standards 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 period 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:

	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
<u>Other income</u>		
Government grants*	625	948
Bank interest income	1,106	4,000
	<hr/>	<hr/>
Total other income	1,731	4,948
	<hr/>	<hr/>
<u>Gains</u>		
Foreign exchange differences, net	920	1,731
Gains on lease termination, net	–	1,419
Fair value gains on financial assets at FVTPL	–	469
Others	28	–
	<hr/>	<hr/>
Total gains	948	3,619
	<hr/>	<hr/>
Total other income and gains	2,679	8,567
	<hr/> <hr/>	<hr/> <hr/>

- * 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):

	<i>Notes</i>	2024 RMB'000	2023 <i>RMB'000</i>
Depreciation of property, plant and equipment*		6,789	16,411
Depreciation of right-of-use assets*		1,262	4,857
Amortisation of other intangible assets*		123	87
Government grants	4	(625)	(948)
Bank interest income	4	(1,106)	(4,000)
Foreign exchange differences, net	4	(920)	(1,731)
Auditor's remuneration		1,280	1,950
Expense relating to leases of low-value assets		11	17
Loss/(gains) on financial assets at FVTPL		32,173	(469)
Share of losses of an associate		986	1,633
Loss on disposal of items of property, plant and equipment	6	1,474	30,510
		41,447	48,317
Staff cost (excluding directors', supervisors' and chief executive's remuneration):			
– Wages and salaries		9,987	9,954
– Pension scheme contributions		1,149	1,119
– Equity-settled share award expense		–	5,231

* 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:

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Loss on disposal of items of property, plant and equipment	1,474	30,510
Fair value loss on financial assets at FVTPL	32,173	–
Others	266	42
	<u>33,913</u>	<u>30,552</u>

7. FINANCE COSTS

An analysis of finance costs is as follows:

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Interest on lease liabilities	64	578

8. INCOME TAX

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

- (a) No provision for Mainland China 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, as the Group's PRC entities have no estimated assessable profits during the year.

In 2022, the Ministry of Finance and the State Administration of Taxation issued the Notice on the Further Implementation of Preferential Income Tax for Small and Micro Enterprises (Cai Shui [2022] No. 13), which provides that the portion of annual taxable income of small and micro enterprises shall be deducted to 25% of the taxable income and subject to income tax at a rate of 20% for the period from January 1, 2022 to December 31, 2024. AngioCare, Shanghai Xianjianyi Trading Co., Ltd. and Zhejiang Bioheart were recognised as small and micro enterprises and were entitled to a preferential tax rate of 20% 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:

	2024	2023
	RMB'000	<i>RMB'000</i>
Loss before tax	(93,324)	(188,820)
Tax at the statutory tax rate of 25%	(23,331)	(47,205)
Effect of different tax rate of the subsidiaries operating in other jurisdictions and tax concession	738	1,835
Tax effect of income that is exempt from taxation	(153)	(321)
Expenses not deductible for tax	887	12,106
Additional deductible allowance for research and development costs	(9,676)	(18,654)
Tax effect of deductible temporary differences not recognised	9,987	43
Utilization of deductible temporary differences previously not recognised	–	(1,218)
Tax losses not recognised	21,548	53,414
Tax charge at the Group's effective tax rate for the year	–	–

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

	2024	2023
	RMB'000	<i>RMB'000</i>
Tax losses	826,103	744,888
Deductible temporary differences	53,964	13,685
Total	880,067	758,573

The Group has accumulated tax losses that are not recognised as deferred tax assets of RMB826,103,000 as at December 31, 2024 (2023: RMB744,888,000), that will expire in one to ten years for offsetting against future taxable profits of the entities in which the losses arose. 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 utilized.

9. DIVIDEND

No dividend has been paid or declared by the Company during the year (2023: 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 shares purchased pursuant to the 2022 Scheme (as defined below).

The calculation of basic loss per share is based on:

	2024	2023
Loss		
Loss attributable to ordinary equity holders of the Company (RMB'000)	(87,944)	(175,893)
Ordinary shares		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation (<i>thousand</i>)	243,417	243,417
Loss per share (<i>RMB per share</i>)	(0.36)	(0.72)

11. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	2024 RMB'000	2023 RMB'000
Non-current:		
Prepayments for purchase of items of property, plant and equipment	26,023	503
Rental deposits	470	475
Value-added tax recoverable – non-current	20,352	7,756
Other deposits	204	382
	47,049	9,116
Current:		
Prepayments for research and development expenses and others	69,058	25,830
Prepayments for raw materials	9,256	1,807
Rental deposits	–	1,294
Value-added tax recoverable – current	–	6,124
Total	78,314	35,055

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 at the end of each of the reporting periods, the loss allowance was assessed to be minimal.

Value-added tax (“VAT”) 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 utilized 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. TRADE PAYABLES

An ageing analysis of the trade payables as at the end of the reporting period, based on the invoice date, is as follows:

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Within 1 month	95	–

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

13. OTHER PAYABLES AND ACCRUALS

	2024 <i>RMB'000</i>	2023 <i>RMB'000</i>
Accruals for research and development	9,726	6,596
Payroll payable	1,063	205
Accrued listing expenses	3,683	5,508
Accrued other expenses	2,979	1,798
Other payables	362	520
Total	17,813	14,627

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

MANAGEMENT DISCUSSION AND ANALYSIS

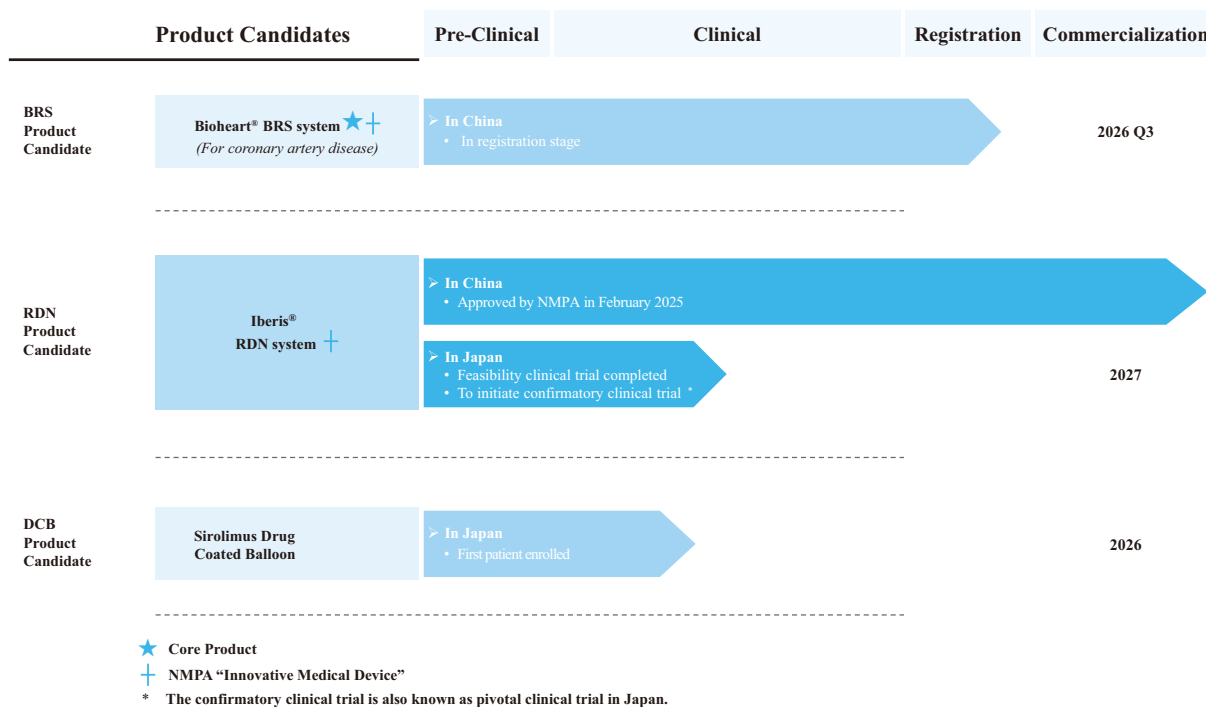
I. BUSINESS REVIEW

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 procedures for the treatment of coronary artery disease. As of the date of this announcement, we held over 40 patents in relation to Bioheart[®], with one registered in the U.S. and two 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[®]. The enrollment and follow-up progress of the clinical trial of BRS were delayed due to the COVID-19 pandemic, which led to a delay in the estimated commercialization time. We expect to obtain the approval from the NMPA in Q3 2026.

RDN Product Candidate

Iberis[®] is our self-developed 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[®] with one registered in Japan. Iberis[®] was recognized as an “innovative medical device” by the NMPA in November 2016. On April 11, 2023, the Company announced that the randomized controlled trial of Iberis[®] Multi-Electrode Renal Artery Radiofrequency Ablation Catheter System in patients with Essential Hypertension 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 and published in *Circulation* in 2024. For details, please refer to the Company’s announcements dated April 11, 2023 and November 28, 2024.

On February 26, 2025, Iberis[®] RDN system was approved by the NMPA for the adjuvant treatment for resistant hypertension and hypertension patients with drug intolerance. In February 2025, the first commercial procedure for Iberis[®] RDN system was completed in Europe. For further details, please refer to the Company’s announcements dated February 26, 2025 and March 3, 2025 respectively.

DCB Product Candidate

Our newly developed DCB is a sirolimus drug coated balloon catheter designed mainly for the treatment of in-stent restenosis. 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. By encapsulating sirolimus in biodegradable nanoparticles to form nano drug-loaded microspheres, this method achieves a long release of approximately 90 days in the target vessel tissue.

As of the date of this announcement, DCB products currently available in the Japan market all use paclitaxel-based drug coating. Compared with paclitaxel, sirolimus has anti-inflammatory effect and its unique cytostatic effect potentially allows it to have higher safety, wider therapeutic window and reduced restenosis.

On March 27, 2025, the Company's SAKURA-SCB trial for ischemic heart disease in Japan has successfully enrolled its first patient in Tokyo. The trial is a single-blind, multicenter comparative study to evaluate the efficacy and safety of the sirolimus DCB product candidate. The procedure was conducted at The Cardiovascular Institute located in Tokyo. For further details, please refer to the Company's announcement dated March 28, 2025.

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 70 registered patents and over 30 pending patent applications; and
- CE Marking and nine registration certificates for our first-generation RDN product commercialized in overseas markets.

Manufacturing

We have several manufacturing facilities located in Shanghai and a new manufacturing plant in construction in Jiaxing City, Zhejiang Province. Zhejiang Bioheart has rented a factory with a total gross area of around 10,000 square meters and is expected to finish decorating in 2025 and officially put into use in 2026.

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[®], 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, 2024 and 2023, we incurred net losses of RMB93.3 million and RMB188.8 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, foreign exchange gains 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 by RMB5.9 million from RMB8.6 million in 2023 to RMB2.7 million in 2024. The decrease was primarily attributable to the decrease of foreign exchange gains of RMB0.8 million and bank interest income of RMB2.9 million during the Reporting Period.

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 2023 and 2024, we recorded equity-settled share award expenses of RMB22.2 million and nil, respectively, under our administrative expenses.

Our administrative expenses decreased by RMB33.2 million from RMB52.9 million in 2023 to RMB19.7 million in 2024. The decrease was primarily attributable to (i) the decrease of equity-settled share award expense for administrative employees amounting to RMB22.2 million due to service periods requirements; (ii) the decrease of professional service expenses by RMB2.0 million due to the decrease of compliance service expenses; and (iii) the decrease of depreciation expenses by RMB7.1 million as a result from the disposal of long-term assets during the second half of 2023.

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 2023 and 2024, we recorded equity-settled share award expenses of RMB25.4 million and nil, respectively, under our research and development expenses.

Our research and development expenses decreased by RMB70.4 million from RMB111.7 million in 2023 to RMB41.3 million in 2024. The decrease was primarily attributable to (i) the decrease of equity-settled share award expenses for research and development employees amounting to RMB25.4 million due to service periods requirements; (ii) the decrease of third party contracting cost by RMB30.1 million resulted from part of the research and development pipelines had reached important clinical milestones in 2023; and (iii) the decrease of depreciation and amortization expenses by RMB7.2 million as a result from the disposal of long-term assets in the second half of 2023.

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

	Year ended December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Third party contracting cost	20,462	50,540
Employee benefit expenses	8,494	36,660
Including: equity-settled share award expense	–	25,430
Costs of raw materials and consumables used	1,404	3,430
Depreciation and amortization expenses	5,899	13,129
Others	5,041	7,984
	<hr/>	<hr/>
Total	41,300	111,743
	<hr/> <hr/>	<hr/> <hr/>

Other Expenses

Our other expenses increased from RMB30.6 million in 2023 to RMB33.9 million in 2024. The increase was due to the fair value loss on financial assets at FVTPL, which is an equity investment in an unlisted company that is in research and development phase, of RMB32.2 million incurred by the Group during the Reporting Period (2023: Nil).

Finance Costs

Our finance costs mainly consist of interest on lease liabilities relating to our lease of office premises. Our finance costs decreased from RMB0.6 million in 2023 to RMB0.1 million in 2024. The decrease was primarily attributable to lease termination in 2023.

Income Tax Expense

No provision for PRC income tax has been provided for at a rate of 25% or 20% 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 RMB93.3 million and RMB188.8 million in 2024 and 2023 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. Going forward, we may also use some of our cash for the acquisition of property for constructing our own manufacturing facility. Our net cash used in operating activities was RMB119.6 million for the year ended December 31, 2024, primarily due to the research and development expenses and administrative expenses incurred by the Group 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 bank balances 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 RMB46.0 million for the year ended December 31, 2024, primarily due to the payments for construction of a new manufacturing plant in Jiaxing City, Zhejiang Province and the acquisition of manufacturing facility for the Group's RDN product candidate, Iberis® 2nd during the Reporting Period.

Our net cash used in financing activities was RMB2.4 million for the year ended December 31, 2024, primarily due to the lease payments amounting to RMB2.1 million.

As of December 31, 2024, we had cash and cash equivalents of RMB202.4 million, representing a decrease of 45.2% compared to RMB369.4 million as of December 31, 2023.

Our net current assets decreased from RMB388.4 million as of December 31, 2023 to RMB279.4 million as of December 31, 2024, primarily attributable to the decrease of 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 increased from RMB17.7 million in 2023 to RMB47.1 million in 2024. The increase was primarily due to the acquisition of manufacturing facility for the Group's RDN product candidate, Iberis® 2nd amounting to RMB20.2 million during the Reporting Period.

Indebtedness

As of December 31, 2024, we did not have any outstanding balance of borrowings nor any unutilized banking facilities.

Our lease liabilities increased from RMB1.8 million as of December 31, 2023 to RMB8.3 million as of December 31, 2024, primarily attributable to additions of new lease in 2024.

Gearing Ratio

The gearing ratio of the Group, which was calculated by using total liabilities divided by total assets and multiplied by 100%, increased from 5.4% as of December 31, 2023 to 7.3% as of December 31, 2024. The increase was primarily due to decrease of cash and cash equivalents.

Capital Commitments

As of December 31, 2024, our capital commitments increased from nil in 2023 to RMB71.8 million in 2024, due to the purchase of leasehold improvements and the capital contributions for investment.

Pledge of Assets

As of December 31, 2024, the Group had no pledge of assets.

Contingent Liabilities

As of December 31, 2024, 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 above and 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, 2024, the Group had 63 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, and (iii) employee welfare, were approximately RMB16.7 million for the Reporting Period.

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 “**2022 Scheme**”). The 2022 Scheme aims to attract, motivate and retain highly skilled and experienced personnel to strive for the future development and expansion of the Group. The 2022 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.

On March 31, 2023, the Board has reallocated the unutilized proceeds originally for “To fund the research and development, ongoing preclinical studies and planned clinical trials of other product candidates in our pipeline, including Bio-Leap™, Bioheart Ultra™, our Bioheart® ballon dilatation catheter, our Bioheart® non-compliant (high-pressure) balloon dilatation catheter and our Bioheart® impulse balloon dilatation catheters” to “To fund the research and development of DCB”. For details, please refer to the announcement of the Company dated March 31, 2023.

On February 8, 2024, the Board resolved to change the use of unutilized net proceeds from the Global Offering 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, please refer to the announcement of the Company dated February 8, 2024.

On October 30, 2024, the Board resolved to further change the use of unutilized net proceeds from the Global Offering as follows:

- (i) reallocating approximately HK\$51.48 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 construction of manufacturing facility and sales center and the subsequent commercial operation”;
- (ii) reallocating approximately HK\$10 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 ongoing randomized controlled clinical trial in China for, and the continuous development of, the Group’s RDN product candidate, Iberis® 2nd”; and
- (iii) reallocating approximately HK\$8 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 “general corporate and working capital purposes”.

For details, please refer to the announcement of the Company dated October 30, 2024.

The table below sets out the planned applications of the net proceeds from the Global Offering (after taking into account the revised allocation of the net proceeds on March 31, 2023, February 8, 2024 and October 30, 2024) and actual usage as of December 31, 2024:

Use of Net Proceeds	Revised allocation of the Net Proceeds <i>(HK\$ million)</i>	Utilized amount as of December 31, 2024 <i>(HK\$ million)</i>	Unutilized amount as of December 31, 2024⁽¹⁾ <i>(HK\$ million)</i>	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 the Company's Core Product, Bioheart®	134.37	115.02	19.35	December 2027
To fund the ongoing randomized controlled clinical trial in China for, and the continuous development of, the Group's RDN product candidate, Iberis® 2nd	77.71	66.21	11.50	December 2027
To fund the acquisition of manufacturing facility for the Group's RDN product candidate, Iberis® 2nd	26.37	26.37	–	N/A
To fund the construction of manufacturing facility and sales center and the subsequent commercial operation	51.48	32.43	19.05	December 2027
To fund the research and development, ongoing preclinical studies and planned clinical trials of other product candidates in the Group's 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	12.34	12.34	–	N/A

Use of Net Proceeds	Revised allocation of the Net Proceeds <i>(HK\$ million)</i>	Utilized amount as of December 31, 2024 <i>(HK\$ million)</i>	Unutilized amount as of December 31, 2024⁽¹⁾ <i>(HK\$ million)</i>	Expected timeline of full utilization of the unutilized proceeds⁽²⁾
General corporate and working capital purposes	52.17	45.33	6.84	December 2027
To fund the research and development of DCB	87.25	84.90	2.35	December 2027
	441.69	382.60	59.09	

Notes:

1. As of December 31, 2024, the unused net proceeds were deposited with certain licensed banks in Hong Kong or the PRC.
2. 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.

SIGNIFICANT INVESTMENTS, MATERIAL ACQUISITIONS AND DISPOSALS

Save as disclosed in this announcement, 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 SCHEME

In the annual general meeting held on June 27, 2022, the 2022 Scheme has been duly approved by the Shareholders. Since the adoption of the 2022 Scheme and up to the date of this announcement, the Company has purchased an aggregate of 519,900 H Shares. Since the adoption of the 2022 Scheme and up to the end of the Reporting Period, no restricted share units had been granted.

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 (including sale of treasury shares, if any) during the Reporting Period. The Company did not have any treasury shares as defined under the Listing Rules as at December 31, 2024.

FINAL DIVIDEND

The Board does not recommend the payment of a final dividend for the Reporting Period (2023: Nil).

SUBSEQUENT EVENTS AFTER THE REPORTING PERIOD

Reference is made to the circular of the Company dated January 24, 2025 in relation to the investment agreement dated December 31, 2024 (the “**Investment Agreement**”) entered into between Zhejiang Bioheart and Jiaying Guojian Baixin Equity Investment Partnership Enterprise (Limited Partnership)* (嘉興國健百心股權投資合夥企業(有限合夥)) (the “**Investor**”). As at the date of this announcement, all conditions precedent of the Investment Agreement have been fulfilled and the consideration of the subscription by the Investor (the “**Capital Injection**”) has been paid into Zhejiang Bioheart's designated bank account. The Capital Injection is expected to be completed by April 2025. Immediately after completion of the Capital Injection, the Investor is interested in approximately 45.32% of the enlarged registered capital of Zhejiang Bioheart, and the Group's interest in Zhejiang Bioheart will be diluted from 100% to approximately 54.68%.

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.

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, and designation of a lead independent non-executive Director 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 currently consists of three independent non-executive Directors, namely Mr. Yiqing CHEN, Mr. Xubo LU and Mr. Yifei JIANG. Mr. Yiqing CHEN serves as the chairman 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 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 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 2024 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 published on the respective websites of the Stock Exchange and the Company in due course.

CHANGE IN COMPOSITION OF THE NOMINATION COMMITTEE

The Board also hereby announces in light of the proposed amendments to the CG Code to be effective from July 1, 2025 and with regard to the circumstances of the Company, the following changes in the composition of the Nomination Committee with effect from March 28, 2025:

- Mr. Philip Li WANG, an executive Director, ceased to be a member of the Nomination Committee; and
- Ms. Peili WANG, an executive Director, was appointed as a member of the Nomination Committee.

Mr. Wang will remain as an executive Director, the chairman of the Board, the chief executive officer and the general manager of the Company. Mr. Wang has confirmed that he has no disagreement with the Board and is not aware of other matters about his cessation as a member of the Nomination Committee that need to be brought to the attention of the Shareholders and the Stock Exchange.

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 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:

“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
“Global Offering”	the global offering of the H Shares, details of which are set forth in the Prospectus
“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
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“HK dollars” or “HK\$”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
“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 the Board, our general manager and an executive Director of the 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)

“Nomination Committee”	the nomination committee of the Company
“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
“RDN”	renal denervation
“Reporting Period”	the year ended December 31, 2024
“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

“Zhejiang Bioheart”

Zhejiang Bioheart Medical Device Co., Ltd.* (浙江百心安醫療器械有限公司), a non-wholly owned subsidiary of the Company established in the PRC with limited liability on October 15, 2024

%

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 28, 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.

* *For identification purposes only*