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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, 2022
AND**

CHANGE OF USE OF PROCEEDS FROM THE GLOBAL OFFERING

FINANCIAL HIGHLIGHTS

	Year ended December 31,	
	2022	2021
	RMB'000	RMB'000
Research and development expenses	(157,830)	(214,228)
Administrative expenses	(94,370)	(195,424)
Other expenses	(55)	(6,647)
Finance costs	(959)	(685)
Other income and gains	23,776	7,159
Share of losses of an associate	(1,430)	–
	<hr/>	<hr/>
Loss for the year	<u>(230,868)</u>	<u>(409,825)</u>

BUSINESS HIGHLIGHTS

- Net loss of the Group for the year ended December 31, 2022 amounted to approximately RMB230.9 million, representing a decrease of 43.7% from approximately RMB409.8 million in 2021.
- Research and development expenses for the year ended December 31, 2022 amounted to approximately RMB157.8 million, representing a decrease of 26.3% from approximately RMB214.2 million recorded in 2021.

- As of December 31, 2022, cash and cash equivalents amounted to approximately RMB451.3 million, representing a decrease of 36.3% from approximately RMB708.5 million as of December 31, 2021.
- Basic and diluted loss per share for 2022 amounted to RMB0.84 (2021: RMB1.64).
- As of December 31, 2022, net gearing ratio was 6.8% (2021: 7.2%).

Our BRS and RDN completed the patient enrollment in February and January 2022, respectively, and have both completed clinical follow-up by now.

On August 16, 2022, we announced that the randomized controlled clinical trial of our Bioheart® BRS had achieved the primary clinical endpoint.

The Board is pleased to announce the audited consolidated annual results of the Group for the year ended December 31, 2022 (the “**Reporting Period**”), together with the comparative figures for the year ended December 31, 2021 as follows:

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the year ended December 31, 2022

	<i>Note</i>	2022 RMB'000	2021 <i>RMB'000</i>
Other income and gains	4	23,776	7,159
Research and development expenses		(157,830)	(214,228)
Administrative expenses		(94,370)	(195,424)
Other expenses	6	(55)	(6,647)
Finance costs	7	(959)	(685)
Share of losses of an associate		(1,430)	–
LOSS BEFORE TAX	5	(230,868)	(409,825)
Income tax expense	8	–	–
LOSS FOR THE YEAR		(230,868)	(409,825)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		(230,868)	(409,825)
Attributable to:			
Owners of the parent		(204,236)	(361,449)
Non-controlling interests		(26,632)	(48,376)
		(230,868)	(409,825)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (<i>RMB</i>)	10	(0.84)	(1.64)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at December 31, 2022

	<i>Note</i>	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
NON-CURRENT ASSETS			
Property, plant and equipment		59,561	50,409
Other intangible assets		137,542	137,200
Investment in an associate		23,228	–
Financial assets at fair value through profit or loss		50,000	–
Prepayments, other receivables and other assets	<i>11</i>	8,611	4,301
Right-of-use assets		16,419	21,851
Goodwill		144,630	144,630
Total non-current assets		439,991	358,391
CURRENT ASSETS			
Prepayments, other receivables and other assets	<i>11</i>	90,210	47,997
Cash and cash equivalents		451,318	708,531
Total current assets		541,528	756,528
CURRENT LIABILITIES			
Trade payables		–	10
Lease liabilities		7,616	7,311
Other payables and accruals	<i>12</i>	19,795	28,510
Amounts due to related parties		472	–
Deferred income		963	981
Total current liabilities		28,846	36,812
NET CURRENT ASSETS		512,682	719,716
TOTAL ASSETS LESS CURRENT LIABILITIES		952,673	1,078,107
NON-CURRENT LIABILITIES			
Lease liabilities		10,489	15,135
Deferred income		6,554	7,517
Deferred tax liabilities		20,580	20,580
Total non-current liabilities		37,623	43,232
Net assets		915,050	1,034,875
EQUITY			
Equity attributable to owners of the parent			
Share capital		243,937	243,937
Treasury shares		(29,438)	–
Reserves		668,715	751,750
Non-controlling interests		883,214	995,687
		31,836	39,188
Total equity		915,050	1,034,875

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, Block 4, No. 590, Ruiqing Road, Pudong District, 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 the second-generation renal denervation ("RDN") system.

The shares of the Company have been listed on the Main Board of The Stock Exchange of Hong Kong Limited (the "Stock Exchange") effective 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 revised IFRSs for the first time for the current year's financial statements.

Amendments to IFRS 3	<i>Reference to the Conceptual Framework</i>
Amendments to IAS 16	<i>Property, Plant and Equipment: Proceeds before Intended Use</i>
Amendments to IAS 37	<i>Onerous Contracts – Cost of Fulfilling a Contract</i>
<i>Annual Improvements to IFRS Standards 2018-2020</i>	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41

The new or amended IFRSs that are effective from January 1, 2022 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 new and revised IFRSs, that have been issued but are not yet effective, in the financial statements.

Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture¹</i>
Amendments to IFRS 16	<i>Lease Liability in a Sale and Leaseback⁴</i>
IFRS 17	<i>Insurance Contracts²</i>
Amendments to IFRS 17	<i>Insurance Contracts^{2, 3}</i>
Amendment to IFRS 17	<i>Initial Application of IFRS 17 and IFRS 9 – Comparative Information⁵</i>
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current (the “2020 Amendments”)^{4, 6}</i>
Amendments to IAS 1	<i>Non-current Liabilities with Covenants (the “2020 Amendments”)⁴</i>
Amendments to IAS 1 and IFRS Practice Statement 2	<i>Disclosure of Accounting Policies²</i>
Amendments to IAS 8	<i>Definition of Accounting Estimates²</i>
Amendments to IAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction²</i>

¹ No mandatory effective date yet determined but available for adoption

² Effective for annual periods beginning on or after January 1, 2023

³ As a consequence of the amendments to IFRS 17 issued in June 2020, IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before January 1, 2023

⁴ Effective for annual periods beginning on or after January 1, 2024

⁵ An entity that chooses to apply the transition option relating to the classification overlay set out in this amendment shall apply it on initial application of IFRS 17

⁶ As a consequence of the 2022 Amendments, the effective date of the 2020 Amendments was deferred to annual periods beginning on or after 1 January 2024

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 the purpose of 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:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Other income		
Government grants*	1,086	5,875
Bank interest income	4,010	972
Others	4	312
	<u>5,100</u>	<u>7,159</u>
Gains		
Foreign exchange differences, net	<u>18,676</u>	–
	<u>23,776</u>	<u>7,159</u>

* The Group has received certain government grants related to assets. The grants related to assets were recorded in deferred income and recognized 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 recognized 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):

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Depreciation of property, plant and equipment*	14,826	8,770
Depreciation of right-of-use assets*	5,992	4,464
Amortisation of other intangible assets	39	–
Government grants	(1,086)	(5,875)
Bank interest income	(4,010)	(972)
Foreign exchange differences, net	(18,676)	6,613
Auditor's remuneration	2,230	1,837
Expense relating to leases of low-value assets	12	17
Listing expense	–	19,400
Share of losses of an associate	1,430	–
	<u>757</u>	<u>34,254</u>
Staff cost (excluding directors', supervisors' and chief executive's remuneration):		
– Wages and salaries	10,198	8,860
– Pension scheme contributions	1,059	618
– Equity-settled share award expense	19,970	49,168

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

6 OTHER EXPENSES

An analysis of other expenses is as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Foreign exchange differences, net	–	6,613
Loss on disposal of property, plant and equipment	1	–
Others	54	34
	<hr/> 55	<hr/> 6,647

7 FINANCE COSTS

An analysis of finance costs is as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Interest on lease liabilities	959	685

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 (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 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:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Loss before tax	(230,868)	(409,825)
Tax at the statutory tax rate of 25%	(57,717)	(102,456)
Effect of different tax rate of a subsidiary operating in other jurisdictions and tax concession	(69)	14,129
Tax effect of income that is exempt from taxation	(398)	(1,119)
Expenses not deductible for tax	36,594	67,542
Additional deductible allowance for research and development costs	(16,280)	(7,831)
Tax effect of deductible temporary differences not recognised	72	3,921
Utilisation of deductible temporary differences previously not recognised	(2,083)	(118)
Tax losses not recognised	39,881	25,932
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:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Tax losses	515,920	356,393
Deductible temporary differences	18,803	26,847
	534,723	383,240

The Group had tax losses of RMB515,920,000 and RMB356,393,000, as at December 31, 2022 and 2021, 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 utilized.

9 DIVIDEND

No dividend have been paid or declared by the Company during the year (2021: Nil).

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

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

The calculation of basic loss per share is based on:

	2022	2021
Loss		
Loss attributable to owners of the Company (<i>RMB'000</i>)	(204,236)	(361,449)
Ordinary shares		
Weighted average number of ordinary shares in issue during the period used in the basic loss per share calculation (<i>thousand</i>)	243,745	220,590
Loss per share (<i>RMB per share</i>)	(0.84)	(1.64)

11 PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Non-current:		
Prepayments for purchase of items of property, plant and equipment	4,222	1,080
Prepayments for purchase of intangible assets	–	430
Rental deposits	1,754	1,871
Value-added tax recoverable – non-current	2,271	607
Other deposits	364	313
	8,611	4,301
Current:		
Prepayments for research and development expenses and others	84,412	39,084
Value-added tax recoverable – current	5,798	8,913
	90,210	47,997

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 is recorded as current assets, while those that are expected to be recovered after one year is recorded as non-current assets.

12 OTHER PAYABLES AND ACCRUALS

	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Accruals for research and development	4,819	3,324
Payroll payable	1,250	2,228
Accrued listing expenses	6,994	11,775
Accrued other expenses	1,952	3,591
Payables for purchase of property, plant and equipment	4,372	7,289
Other payables	408	303
	<hr/> 19,795 <hr/>	<hr/> 28,510 <hr/>

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.

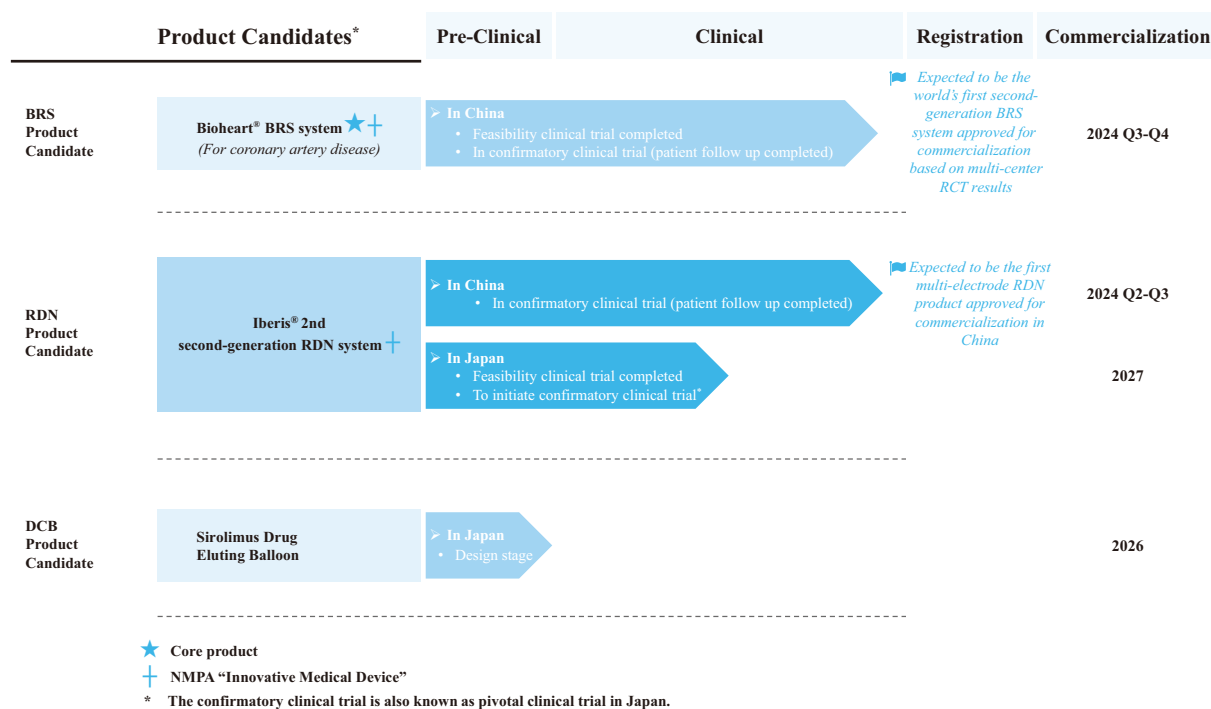
Products and Pipeline

In the past, the clinical enrollment and follow-up progress of BRS and RDN projects were delayed due to the COVID-19 pandemic. Our team has concentrated on promoting the clinical study of BRS and RDN to reduce the delay caused by the pandemic to the project progress. BRS and RDN completed the clinical enrollment in February and January 2022, respectively. We have announced that the randomized controlled clinical trial of BRS has achieved the pre-set primary clinical endpoint. Both BRS single-arm clinical trial and RDN clinical trial have completed clinical follow-up, and our clinical team is conducting data analysis to obtain the clinical research report as soon as possible for product registration application submission. However, due to the delay of clinical enrollment and follow-up, and the fact that Medtronic, which is the pioneer in the field of RDN, announced that its On-Med clinical trial did not meet the primary clinical end point at the 2022 American Heart Association (AHA) meeting. The result has raised discussion regarding RDN therapy among the industry and the academic communities worldwide, which could impact the expected timeline for the approval of RDN by the health authorities globally. According to the latest situation, we have revised the expected time for the future commercialization of our BRS product and RDN product.

During the Reporting Period, we have newly developed a sirolimus drug eluting balloon with high technical barriers. We have been actively communicating with the Japan Pharmaceuticals and Medical Devices Agency (“PMDA”) and has initiated the preclinical research in Japan, accelerating the preparation of clinical research in Japan.

In addition, according to our expectation of the future market and in order to concentrate our existing resources to push forward the development and commercialization of our core products, we have followed the characteristics of “large market scale, easy to promote, high technical barriers” to prioritize and adjust our existing pipelines. According to the assessment of the future market and the plan of our existing funds, we have suspended the research and development of Bioheart Ultra™. It is expected that after the launch of Bioheart®, we will continue to promote clinical development in a timely manner with the development strategy of iterative products. Bioheart Ultra™ has now completed the pre-clinical animal experiment evaluation, which will facilitate the rapid iteration of BRS products in the later stage. Considering the difficulty of clinical enrollment in the research and development phase of Bio-Leap™ and that the potential market for Bio-Leap™ in the peripheral intervention field is smaller compared

to BRS, we have terminated the research and development of Bio-Leap™ project, and we will focus on promoting the commercialization of coronary BRS products in the future. Additionally, considering that the technical barriers of our other balloon projects including Bioheart® balloon dilatation catheter, Bioheart® non-compliant (high-pressure) balloon dilatation catheter and Bioheart® impulse balloon dilatation catheters are lower than our core product candidates, the competition of these products in the future is expected to be fierce and the impact of the centralized procurement policy on the relevant market scale, we have decided to terminate the research and development of relevant projects and invest the relevant resources in the development of other products with better market potential. 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 41 registered patents (including 10 invention patents and 31 utility model patents) in relation to Bioheart[®], of which 39 were registered in China, one was registered in the U.S. and one was registered in Europe. We also have 10 pending patent applications in relation to Bioheart[®]. 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 submit our confirmatory clinical trial results to the NMPA for its approval before the end of 2023.

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 34 registered patents (including nine invention patents, 21 utility model patents and four design patents) and 20 pending invention patent applications in relation to Iberis[®] 2nd. Of the 34 registered patents, 33 were registered or applied in China, and one was 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. We expect to submit our randomized controlled clinical trial results to the NMPA for its approval in the third quarter of 2023.

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 renal denervation 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;
- 79 registered patents and 53 pending patent applications; and
- CE Marking and nine registration certificates for our first-generation RDN product commercialized in overseas markets.

Strategic Investments

On June 21, 2022, our Group agreed to acquire 15.42% equity interest of Shanghai Xinzhi Medical Technology Co., Ltd.* (上海心至醫療科技有限公司) (“**Xinzhi Medical**”) through acquisition and capital injection. Xinzhi Medical has four DCB products at clinical stage in its pipeline, with the registration application for paclitaxel coronary DCB submitted to the NMPA for approval, and the patient enrollment process for the clinical trial of rapamycin coronary DCB 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.

On September 5, 2022, our Group agreed to acquire 9.09% equity interest of Cardioteck (Beijing) Medical Technology Co., Ltd.* (康迪泰科(北京)醫療科技有限公司) (“**Cardioteck**”) through capital injection. Cardioteck is a pre-revenue medical device developer dedicated to the research and development of minimally invasive interventional cardiovascular devices. Its core product is the transcatheter aortic valve replacement product (“**TAVR**”) which is balloon-expandable. Compared with the common self-expanding products available in the current market in the PRC, balloon-expandable TAVR enjoys obvious advantages such as easy operation, more accurate implantation, lower risk of coronary intervention, less paravalvular leakage, and lower usage rate of permanent pacing. Following the excellent results of the six months follow up animal experiment completed in June 2022, which shows no calcification in the valves, Cardioteck balloon expandable TAVR has been sent for registration inspection. Cardioteck expects to start clinical trials for its TAVR in 2023. Multi-center clinical trials will be launched in domestic first-line medical centers. By investing in Cardioteck, we expect to broaden our portfolio in innovative medical devices with high technical barriers.

Manufacturing

In preparation for the launch of our pipeline products and with an aim to capture the growing market demand to the extent possible, we have built a new plant located at Zhangjiang Hi-Tech Park, Pudong New Area, Shanghai with a gross area of over 7,000 sq.m. The production site, which is located at the second and third floor with a total gross area of 3,600 sq.m (including a class 10,000 cleanroom production area with a gross area of over 2,000 sq.m), has passed the relevant inspections, completed the relevant filings and has been officially put into use in December 2021.

* For identification purposes only

Impact of the COVID-19

Our Directors have carried out a holistic review of the impact of the COVID-19 on our operations and confirmed that as of the date of this announcement, COVID-19 has not had any long-term material adverse impact on our operations. We are closely monitoring the development of the COVID-19 and continuously evaluating any potential impact the pandemic may have on our business, results of operations and financial condition. We note that any travel restrictions or quarantine as a result of the outbreak of COVID-19 in the past may result in potential delay with the progress of our clinical trials and our operations. With great effort of our employees, we have minimized the potential risk caused to our R&D. The impact of travel restrictions or quarantine has fundamentally improved after COVID-19 came under Category B management in January 2023 in China.

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, 2022 and 2021, we incurred net losses of RMB230.9 million and RMB409.8 million, respectively. It is highly possible 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 gains of about RMB18.6 million is due to foreign exchange transaction differences. Our other income and gains increased from RMB7.2 million in 2021 to RMB23.8 million in 2022. The increase was primarily attributable to (i) the favorable exchange rate gains in the foreign currency held by the Company; (ii) increase in interest income due to increase in balance of cash at banks.

Administrative Expenses

Our administrative expenses mainly consist of (i) employee benefit expenses; (ii) depreciation expenses; (iii) listing expenses; (iv) professional services expenses; and (v) utilities and office expenses. Employee benefit expenses mainly include salaries, equity-settled share award expenses and other welfare for our administrative employees. In 2021 and 2022, we recorded equity-settled share award expenses of RMB155.1 million and RMB67.4 million, respectively, under our administrative expenses.

Our administrative expenses decreased from RMB195.4 million in 2021 to RMB94.4 million in 2022. The decrease was primarily attributable to (i) a decrease of equity-settled share award expenses of RMB87.7 million related to our administrative employees with service periods requirements; (ii) a decrease in listing expenses of RMB19.4 million as the Company became listed on December 23, 2021; (iii) an increase of depreciation expenses of RMB3.1 million as a result of our lease of a new plant during the second half of year 2021; and (iv) an increase of professional service expenses of RMB4.6 million as a result of that compliance service expenses, financial statements audit and review services and public relations services incurred in 2022.

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

	Year ended December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Employee benefits expenses	72,979	160,667
Including: equity-settled share award expense	67,416	155,144
Depreciation expenses	8,125	5,020
Listing expenses	–	19,400
Professional service expenses	9,772	5,141
Utilities and office expenses	1,865	2,755
Others	1,629	2,441

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 amortisation expenses.

Employee benefits expenses under research and development expenses primarily include the salaries, welfare, and equity-settled share award expenses for our research and development employees. In 2021 and 2022, we recorded equity-settled share award expenses of RMB163.6 million and RMB73.1 million, respectively, under our research and development expenses. We have established incentive platforms for such purposes.

Our research and development expenses decreased from RMB214.2 million in 2021 to RMB157.8 million in 2022. 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 and partially offset by increase of third party contracting cost and depreciation and amortisation expenses.

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

	Year ended December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Third party contracting cost	49,547	19,889
Employee benefit expenses	84,805	173,928
Including: equity-settled share award expense	73,065	163,580
Costs of raw materials and consumables used	5,425	6,816
Depreciation and amortisation expenses	12,732	8,214
Others	5,321	5,381

Other Expenses

Our other expenses mainly consisted of foreign exchange differences, loss on disposal of property, plant and equipment and others.

Our other expenses decreased from RMB6.6 million in 2021 to RMB0.06 million in 2022. The decrease was primarily attributable to the net foreign exchange loss of RMB6.6 million in 2021, as compared to the net foreign exchange gain of RMB18.7 million recorded in other income and gains in 2022 due to the gains fluctuation of the exchange rate of USD against RMB in 2022 compared with 2021.

Finance Costs

Our finance costs mainly consisted of interest on lease liabilities relating to our lease of office premises. Our finance costs increased from RMB0.7 million in 2021 to RMB1.0 million in 2022. The increase was primarily attributable to the addition of lease liabilities during the second half of year 2022.

Income Tax Expense

No provision for Mainland China income tax has been provided for 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 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 RMB230.9 million and RMB409.8 in the Reporting Period and 2021 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, investment activities and other recurring expenses. Our net cash used in operating activities was RMB140.6 million as of December 31, 2022, primarily due to the significant research and development expenses and administrative expenses which 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 proceeds from the Global Offering as the major sources of liquidity. Our management closely monitors the 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 RMB100.7 million as of December 31, 2022, primarily due to the purchases of other financial asset and items of property, plant and equipment of RMB30.0 million, payments for financial assets at fair value through profit or loss of RMB50.0 million and payments for investment in an associate of RMB24.7 million.

Our net cash used in financing activities was RMB35.2 million as of December 31, 2022, primarily due to the payment to the trustee to purchase H Shares on the market pursuant to the Scheme (as defined below) during the Reporting Period.

As of December 31, 2022, we had cash and cash equivalents of RMB451.3 million, representing an decrease of 36.3% compared to RMB708.5 million as at December 31, 2021.

Our net current assets decreased from RMB719.7 million as at December 31, 2021 to RMB512.7 million as at December 31, 2022, which was primarily attributable to the decrease in cash and cash equivalents.

Capital Expenditures

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

Our capital expenditures decreased from RMB34.3 million in 2021 to RMB30.0 million in 2022. The decrease was primarily attributable to decrease of machinery and leasehold improvements.

Indebtedness

As at December 31, 2022, 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 RMB22.4 million as at December 31, 2021 to RMB18.1 million as at December 31, 2022, primarily because of the lease payments made and COVID-19-related rent concessions from lessors 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 6.8% as of December 31, 2022, decreased from 7.2% as of December 31, 2021. The decrease was primarily due to decrease of lease liabilities.

Capital Commitments

The capital commitments of the Group as at December 31, 2022 were RMB7.6 million, representing an increase of RMB6.7 million as compared with that of RMB0.9 million as at December 31, 2021, primarily attributable to change of capital expenditures contracted for at year end, but not yet incurred, with respect to our purchase of property, plant and equipment.

Pledge of Assets

As at December 31, 2022, we had no pledge of assets.

Contingent Liabilities

As of December 31, 2022, 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

The Group has no other material capital expenditure plan as of the date of this announcement.

Human Resources

As of December 31, 2022, the Group had 54 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 RMB157.8 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, non-competition and grounds for termination. 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.

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 Company intends to apply such net proceeds in accordance with the purposes as set out in the Prospectus, as modified pursuant to the reasons provided below.

The table below sets out the planned applications of the net proceeds from the Global Offering and actual usage as at December 31, 2022:

Use of proceeds as disclosed in the Prospectus	Percentage of total net proceeds	Allocation of net proceeds (HK\$ million)	Unutilized amount as at January 1, 2022 (HK\$ million)	Utilized amount during the Reporting Period (HK\$ million)	Unutilized amount as at December 31, 2022 ⁽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®	62.0%	273.85	273.85	78.36	195.49	December 2027
To fund the ongoing randomized controlled clinical trial in China for, and the continuous development of, our RDN product candidate, Iberis® 2nd	21.3%	94.08	94.08	9.25	84.83	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	6.7%	29.59	29.59	11.87	17.72	December 2027
General corporate and working capital purposes	10.0%	44.17	44.17	16.03	28.14	December 2027
	<u>100%</u>	<u>441.69</u>	<u>441.69</u>	<u>115.51</u>	<u>326.18</u>	

Notes:

- As at December 31, 2022, 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.

Proposed Change of Use of Proceeds

As stated in the section headed “MANAGEMENT DISCUSSION AND ANALYSIS – I. BUSINESS REVIEW” of this announcement, we have suspended the research and development of Bioheart Ultra™ and terminated the research and development of Bio-Leap™ and Bioheart® balloon dilatation catheter, Bioheart® non-compliant (high-pressure) balloon dilatation catheter and Bioheart® impulse balloon dilatation catheters. Consequently, the unutilized net proceeds, allocated to “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® balloon dilatation catheter, our Bioheart® non-compliant (high-pressure) balloon dilatation catheter and our Bioheart® impulse balloon dilatation catheters” amounted to HK\$17.72 million as at December 31, 2022 and HK\$17.25 million as at the date of this announcement, and the Board has resolved to reallocate the unutilized amount (HK\$17.25 million) for the above planned application to our continuing research and development of DCB, which is a sirolimus drug-eluting balloon catheter designed for in-stent restenosis and one of our newly develop product candidate as described earlier in this announcement. As disclosed in the announcement of the Company dated November 18, 2022, in-stent restenosis is a common complication after Percutaneous Coronary Intervention (PCI) procedures, with over 240,000 PCI procedures per year reported in Japan according to literature reports, and the incidence rate of in-stent restenosis is approximately 10%, and the Drug coated balloon (DCB) market is expected to be broad due to the increase in the number of PCI procedures and the expansion of indications. According to the consensus of Asia-Pacific experts, DCB is currently recommended as the first-line treatment for in-stent restenosis, and the indications are gradually expanded to small vessel disease, bifurcation lesions, etc. Based on the public information available to date, no sirolimus drug-coated balloon products are currently available in Japan market. The Company’s DCB product is expected to become the first sirolimus drug-coated balloon approved in Japan. In light of the above, the Board considered that such reallocated proceeds would facilitate an effective use of the financial resources of the Group and the research and development of our DCB product and accelerate its development execution to achieve commercialization, and is in the best interest of the Company and its shareholders as a whole. It is expected that such reallocated proceeds will be utilized by the end of 2027. The Board will continue to assess the plans for the use of net proceeds and may revise or amend such plans where necessary to respond to the changing market conditions. Further, due to the potential delay of the expected commercialization of our products, we have amended the expected timeline of full utilization of the unused proceeds.

SIGNIFICANT INVESTMENTS, ACQUISITIONS AND DISPOSALS

Please also 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 at 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 at the end of the Reporting Period, and as at the date of this announcement, the trustee of the Scheme held a total of 519,900 H Shares.

PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES OF THE COMPANY

Save for the purchases made under the Scheme as stated in the section headed "THE 2022 H SHARE INCENTIVE SCHEME" of this announcement, 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 (2021: Nil).

SUBSEQUENT EVENTS AFTER THE REPORTING PERIOD

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.

On March 27, 2023, the company announced that the first patient under the RADIUS-HTN Trial was enrolled, and the procedure was performed at the Centre Hospitalier Universitaire de Bordeaux. For details of this event, please refer to the Company's announcement dated March 27, 2023.

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 Monday, June 26, 2023. 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 Saturday, May 27, 2023 to Monday, June 26, 2023 (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 Thursday, May 25, 2023.

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 CG Code contained in Appendix 14 to the Listing Rules as its own code of corporate governance. During the Reporting Period, the Company has complied with all applicable code provisions of the CG Code save and except for the following deviation from code provision C.2.1 of the CG Code.

Under code provision C.2.1 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 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), two non-executive Directors 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 which comprises three independent non-executive Directors, namely Mr. Charles Sheung Wai CHAN, Mr. George Chien Cheng LIN, and Mr. Xubo LU. 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 and internal controls.

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 the Audit Committee 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 2022 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 Monday, June 26, 2023
“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 14 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

“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
“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 10 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)
“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, 2022
“RMB”	Renminbi, the lawful currency of the PRC
“SFO”	the Securities and Futures Ordinance, Chapter 571 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)
“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
%	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 31, 2023

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