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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)

INTERIM RESULTS ANNOUNCEMENT
FOR THE SIX MONTHS ENDED JUNE 30, 2023

FINANCIAL HIGHLIGHTS

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
	(unaudited)	(unaudited)
Research and development expenses	(68,497)	(71,391)
Administrative expenses	(30,908)	(53,853)
Finance costs	(391)	(510)
Other income and gains	5,764	10,178
Share of losses of an associate	(1,085)	–
	<hr/>	<hr/>
Loss for the period	<u>(95,117)</u>	<u>(115,576)</u>

BUSINESS HIGHLIGHTS

- Our BRS and RDN completed the patient follow-up in February and January 2023 respectively.
- On March 27, 2023, the Company announced first patient enrollment in the RADIUS-HTN trial in Europe.
- On April 11, 2023, the Company announced that IBERIS-HTN study had achieved the primary clinical endpoint. Detailed data of the study has been presented at China Interventional Therapeutics 2023.

INTERIM RESULTS

The Board is pleased to announce the unaudited condensed consolidated interim results of the Company and its subsidiaries for the six months ended June 30, 2023 together with the comparative figures for the corresponding period in 2022.

INTERIM CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the six months ended June 30, 2023

		Six months ended June 30,	
		2023	2022
	Notes	RMB'000	RMB'000
		(Unaudited)	(Unaudited)
Other income and gains	5	5,764	10,178
Research and development expenses		(68,497)	(71,391)
Administrative expenses		(30,908)	(53,853)
Finance costs	7	(391)	(510)
Share of losses of an associate		(1,085)	—
		<u> </u>	<u> </u>
LOSS BEFORE TAX	6	(95,117)	(115,576)
Income tax expense	8	—	—
		<u> </u>	<u> </u>
LOSS FOR THE PERIOD		(95,117)	(115,576)
		<u> </u>	<u> </u>
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD		(95,117)	(115,576)
		<u> </u>	<u> </u>
Attributable to:			
Owners of the parent		(86,186)	(101,439)
Non-controlling interests		(8,931)	(14,137)
		<u> </u>	<u> </u>
		(95,117)	(115,576)
		<u> </u>	<u> </u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (RMB)	10	(0.35)	(0.42)
		<u> </u>	<u> </u>

INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION
As at June 30, 2023

	<i>Notes</i>	As at June 30, 2023 RMB'000 (Unaudited)	As at December 31, 2022 RMB'000 (Audited)
NON-CURRENT ASSETS			
Property, plant and equipment		53,934	59,561
Other intangible assets		137,771	137,542
Prepayments, other receivables and other assets		12,103	8,611
Right-of-use assets		13,449	16,419
Financial assets at fair value through profit or loss ("FVTPL")		50,000	50,000
Goodwill		144,630	144,630
Investment in an associate	<i>11</i>	37,143	23,228
Total non-current assets		449,030	439,991
CURRENT ASSETS			
Prepayments, other receivables and other assets		72,844	90,210
Cash and cash equivalents		389,334	451,318
Total current assets		462,178	541,528
CURRENT LIABILITIES			
Lease liabilities		7,877	7,616
Other payables and accruals		14,852	19,795
Amounts due to related parties		472	472
Deferred income		2,789	963
Total current liabilities		25,990	28,846
NET CURRENT ASSETS		436,188	512,682
TOTAL ASSETS LESS CURRENT LIABILITIES		885,218	952,673

	<i>Notes</i>	As at June 30, 2023 <i>RMB'000</i> (Unaudited)	As at December 31, 2022 <i>RMB'000</i> (Audited)
NON-CURRENT LIABILITIES			
Lease liabilities		7,504	10,489
Deferred income		4,227	6,554
Deferred tax liabilities		<u>20,580</u>	<u>20,580</u>
 Total non-current liabilities		 <u>32,311</u>	 <u>37,623</u>
 Net assets		 <u>852,907</u>	 <u>915,050</u>
EQUITY			
Equity attributable to owners of the parent			
Share capital		243,937	243,937
Treasury shares		(29,438)	(29,438)
Reserves		<u>610,978</u>	<u>668,715</u>
 Non-controlling interests		 <u>825,477</u> <u>27,430</u>	 883,214 <u>31,836</u>
 Total equity		 <u>852,907</u>	 <u>915,050</u>

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the six months ended June 30, 2023

1 CORPORATE AND GROUP INFORMATION

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

During the period, 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 BASIS OF PREPARATION

The interim condensed consolidated financial information for the six months ended June 30, 2023 has been prepared in accordance with International Accounting Standard (“IAS”) 34 Interim Financial Reporting. The interim condensed consolidated financial information does not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group’s annual consolidated financial statements for the year ended December 31, 2022. The interim condensed consolidated financial information is presented in Renminbi (“RMB”), and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

3 CHANGES IN ACCOUNTING POLICIES

The accounting policies adopted in the preparation of the interim condensed consolidated financial information are consistent with those applied in the preparation of the Group’s annual consolidated financial statements for the year ended December 31, 2022, except for the adoption of the following new and revised International Financial Reporting Standards (“IFRSs”) for the first time for the current period’s financial information.

IFRS 17	<i>Insurance Contracts</i>
Amendments to IFRS 17	<i>Insurance Contracts</i>
Amendment to IFRS 17	<i>Initial Application of IFRS 17 and IFRS 9 – Comparative Information</i>
Amendments to IAS 1 and IFRS Practice Statement 2	<i>Disclosure of Accounting Policies</i>
Amendments to IAS 8	<i>Definition of Accounting Estimates</i>
Amendments to IAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction</i>
Amendments to IAS 12	<i>International Tax Reform – Pillar Two Model Rules</i>

The adoption of the new and revised standards amendments has had no significant financial effect on the Group’s interim condensed consolidated financial information.

4 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 each of the periods presented and the Group's non-current assets are all located in the PRC, accordingly, no analysis of geographical segment is presented.

5 OTHER INCOME AND GAINS

An analysis of other income and gains is as follows:

	Six months ended June 30,	
	2023 RMB'000 (Unaudited)	2022 RMB'000 (Unaudited)
Other income		
Government grants*	501	591
Bank interest income	1,638	1,737
Others	32	2
	<u> </u>	<u> </u>
Gains		
Foreign exchange gains	3,593	7,848
	<u> </u>	<u> </u>
	<u>5,764</u>	<u>10,178</u>

* The Group received certain government grants related to long-term assets. The grants related to long-term 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.

6 LOSS BEFORE TAX

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

	Six months ended June 30,	
	2023 RMB'000 (Unaudited)	2022 RMB'000 (Unaudited)
Depreciation of property, plant and equipment*	9,458	6,323
Depreciation of right-of-use assets*	2,970	2,996
Share of losses of an associate	1,085	–
Auditor's remuneration	420	400
Amortization of other intangible assets*	26	19
Expense relating to leases of low-value assets	9	7
Foreign exchange gains	(3,593)	(7,848)
Bank interest income	(1,638)	(1,737)
Government grants	(501)	(591)
	<u>8,236</u>	<u>(431)</u>
Staff cost (excluding directors', supervisors' and chief executive's remuneration):		
– Wages and salaries	5,613	5,083
– Pension scheme contributions	520	379
– Equity-settled share award expense	4,091	12,266

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

7 FINANCE COSTS

An analysis of finance costs is as follows:

	Six months ended June 30,	
	2023 RMB'000 (Unaudited)	2022 RMB'000 (Unaudited)
Interest on lease liabilities	<u>391</u>	<u>510</u>

8 INCOME TAX

Mainland China

Under the Law of the PRC of Enterprise Income tax (the “EIT Law”) and Implementation Regulation of the EIT Law, the estimated tax rate of the Group is 25% during the period presented in the condensed consolidated financial statements. Preferential tax treatment is available to Shanghai AngioCare Medical Technology Co., Ltd. (上海安通醫療科技有限公司) (“AngioCare”) since it was recognized as a High and New Technology Enterprise on November 12, 2020 and was entitled to a preferential tax rate of 15% for a three-year period since then. No PRC Enterprise Income tax was provided for as there was no estimated assessable profit of the Group’s PRC subsidiaries during the period presented in the condensed consolidated financial statements.

Hong Kong

No provision for Hong Kong income tax was provided for at a rate of 16.5% as the Group’s Hong Kong entity had no estimated assessable profits during the period.

Deferred taxation had not been recognized on the unused tax losses and deductible temporary differences due to the unpredictability of future profit streams.

9 DIVIDENDS

No dividends had been paid or declared by the Company during the six months ended June 30, 2023 (six months ended June 30, 2022: nil).

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

The Company had no potentially dilutive ordinary shares in issue during each of the periods presented. The calculation of the 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:

	Six months ended June 30,	
	2023	2022
	(Unaudited)	(Unaudited)
Loss		
Loss attributable to ordinary equity holders of the Company (RMB’000)	(86,186)	(101,439)
Ordinary shares		
Weighted average number of ordinary shares in issue during the period used in the basic loss per share calculation (thousand)	243,417	243,937
Loss per share (RMB per share)	(0.35)	(0.42)

11 INVESTMENT IN AN ASSOCIATE

	As at June 30, 2023 (Unaudited)	As at December 31, 2022 (Audited)
Cost of investment in joint ventures, unlisted	39,658	24,658
Share of post-acquisition losses	(2,515)	(1,430)
	37,143	23,228

In June 2022, the Group acquired an aggregate of 15.42% equity interests in Shanghai XinZhi Medical Technology Co., Ltd. (上海心至醫療科技有限公司) (“Xinzhi Medical”) through (i) the acquisition of 8.01% equity interest from one of the then shareholders of Xinzhi Medical at a consideration of approximately RMB8,658,000, and (ii) the subscription of an additional 7.41% equity interests of Xinzhi Medical at a consideration of RMB16,000,000.

In April 2023, the Group further agreed to make a capital increase of RMB15,000,000 into Xinzhi Medical, resulting in a total of 22.18% equity interests in Xinzhi Medical held by the Group as of June 30, 2023.

Xinzhi Medical is mainly engaged in research and development of Drug coated balloon (DCB) products.

The investment has been accounted for as an investment in an associate using the equity method because the Group had significant influence over the financial and operating policies of Xinzhi Medical as the Group has the power to appoint one out of the seven directors of Xinzhi Medical under the articles of association of Xinzhi Medical.

MANAGEMENT DISCUSSION AND ANALYSIS

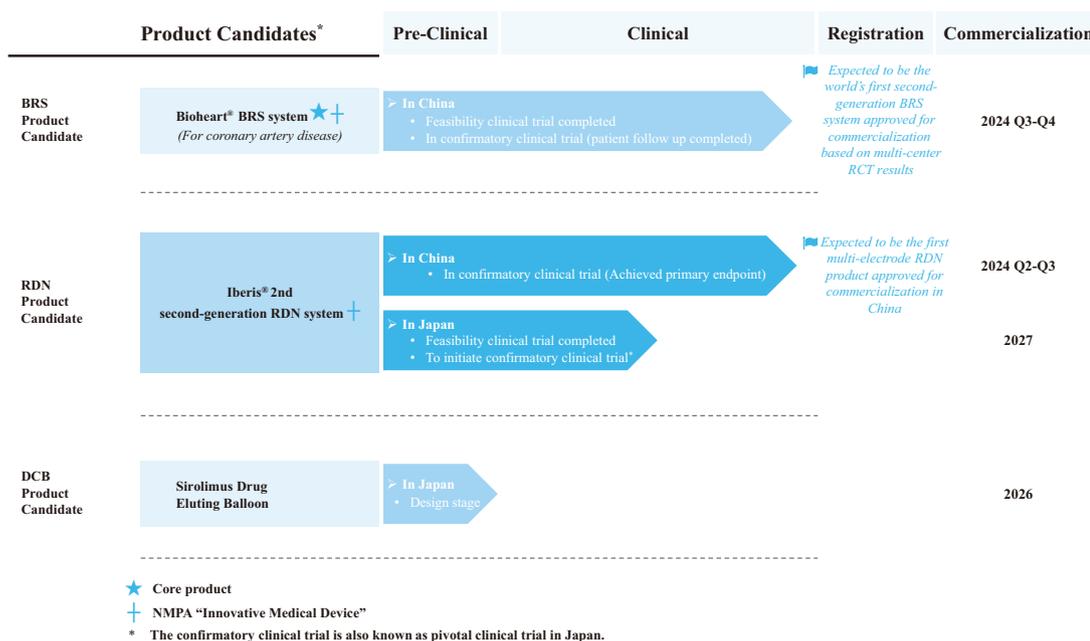
I. BUSINESS REVIEW

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 Candidates

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 43 registered patents (including 12 invention patents and 31 utility model patents) in relation to Bioheart[®], of which 41 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 obtain the approval from the NMPA in Q3-Q4 2024.

RDN Product Candidate

Iberis[®] **2nd** is our self-developed second-generation RDN system. RDN is one of the few device therapies with proven clinical efficacy to treat uncontrolled hypertension and resistant hypertension and is considered by many industry experts as having the potential to transform the treatment paradigm of hypertension. As of the date of this announcement, we held 38 registered patents (including 13 invention patents, 21 utility model patents and four design patents) and 19 pending invention patent applications in relation to Iberis[®] 2nd. Of the 38 registered patents, 37 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. On April 11, 2023, the Company announced that the RCT of Iberis[®] 2nd Multi-Electrode Renal Artery Radiofrequency Ablation Catheter System in patients with Essential Hypertension (“Iberis-HTN”) has achieved its primary clinical endpoint according to the Statistical Report that the Company received. Detailed data has been presented at China Interventional Therapeutics 2023. We expect to obtain the approval from the NMPA in Q2-Q3 2024.

We have contracted with the European Cardiovascular Research Center to conduct a European clinical trial evaluating Iberis[®] 2nd RDN system. At EuroPCR 2022, we finalized plans with clinical trial investigators on the RADIUS-HTN Trial. The European Cardiovascular Research Center will conduct the RADIUS-HTN Trial comparing the effectiveness of RDN performed via transradial arterial access (“TRA”) and transfemoral arterial access (“TFA”). We are the only company in the world to have CE Marking for catheters that can be used for both TRA and TFA to treat high blood pressure. The TRA approach to vascular interventions is preferred by physicians and patients. Compared to TFA, TRA interventions reduce access site complications and shorten the duration of hospital stay with a reduction in procedural costs and increased patient gratification. Clinical trials in Japan for Iberis[®] 2nd are conducted in collaboration with Terumo, our strategic business collaborator. On March 27, 2023, the first patient under the RADIUS-HTN Trial was enrolled, and the procedure was performed at the Centre Hospitalier Universitaire de Bordeaux.

DCB Product Candidate

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

As of the date of this announcement, current DCB products available in Japan market all use paclitaxel-based drug coating. Compared with paclitaxel, sirolimus’ 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 for the preparation of 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;
- 91 registered patents and 74 pending patent applications; and
- CE Marking and nine registration certificates for our first-generation RDN product commercialized in overseas markets.

Strategic Investment

On April 14, 2023, our Group agreed to make a capital increase of RMB15,000,000 into Shanghai Xinzhi Medical Technology Co., Ltd.* (上海心至醫療科技有限公司) (“Xinzhi Medical”). The Group holds an aggregate of approximately 22.18% interest in Xinzhi Medical after the completion of the capital increase. Xinzhi Medical’s paclitaxel coronary DCB has been approved by the NMPA in May 2023. Additionally, Xinzhi Medical has three DCB products at clinical stage in its pipeline and the patient enrollment process for the clinical trial of rapamycin coronary DCB has been completed. Compared to the commonly used stents in clinical practice, DCB, as the complementary product of BRS, is able to offer treatment without implanting foreign objects into human bodies, thereby achieving the concept of “intervention without implantation”. By investing in Xinzhi Medical, we expect to enrich our portfolio in cardiovascular device through cooperation and achieving synergy between Xinzhi’s Medical DCB products and our pipeline. For details of the capital increase in Xinzhi Medical, please refer to the Company’s announcement dated April 14, 2023.

Manufacturing

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.

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.

* For identification purposes only

II. FINANCIAL REVIEW

Other Income and Gains

During the six months ended June 30, 2023 and 2022, our other income and gains mainly consisted of government grants, bank interest income, foreign exchange gains and others. Other income and gains decreased by RMB4.4 million from RMB10.2 million for the six months ended June 30, 2022 to RMB5.8 million for the six months ended June 30, 2023. The decrease was primarily attributable to the decrease of foreign exchange gains of RMB4.3 million.

Administrative Expenses

Our administrative expenses mainly consist of (i) employee benefit expenses, (ii) depreciation expenses, (iii) professional services expenses, and (iv) utilities and office expenses.

Employee benefit expenses mainly include salaries, equity-settled share awards and other welfare for our administrative employees. During the six months ended June 30, 2023 and 2022, we recorded equity-settled share award expenses of RMB15.7 million and RMB40.3 million, respectively, under our administrative expenses.

Our administrative expenses decreased by RMB23.0 million from RMB53.9 million for the six months ended June 30, 2022 to RMB30.9 million for the six months ended June 30, 2023. The decrease was primarily attributable to the decrease of (i) equity-settled share award expense of RMB24.7 million related to our administrative employees with service periods requirements and (ii) professional service expenses of RMB1.4 million as a result of that compliance service expenses and public relations services were incurred in 2022, partially offset by depreciation expenses of RMB2.2 million due to the beginning of depreciation of long-term assets completed in 2023.

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

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
Employee benefits expenses	18,554	43,210
Including: equity-settled share award expenses	15,652	40,322
Depreciation expenses	5,588	3,399
Professional service expenses	3,577	5,019
Utilities and office expenses	912	695
Others	2,277	1,530
	<u>30,908</u>	<u>53,853</u>

Research and Development Expenses

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

Employee benefits expenses under research and development expenses primarily included the salaries, welfare, and equity-settled share awards for our research and development employees. During the six months ended June 30, 2023 and 2022, we recorded equity-settled share award expenses of RMB17.3 million and RMB43.3 million, respectively, under our research and development expenses.

Our research and development expenses decreased by RMB2.9 million from RMB71.4 million for the six months ended June 30, 2022 to RMB68.5 million for the six months ended June 30, 2023, primarily attributable to the decrease of equity-settled share award expenses related to our research and development employees with service periods requirements but partially offset by increase of third party contracting cost and depreciation and amortization expenses.

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

	Six months ended June 30,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Third party contracting cost	25,028	11,956
Employee benefit expenses	23,692	49,044
Including: equity-settled share award expenses	17,322	43,299
Costs of raw materials and consumables used	4,622	2,313
Depreciation and amortization expenses	6,866	5,939
Others	8,289	2,139
	68,497	71,391

Finance Costs

During the six months ended June 30, 2023 and 2022, our finance costs mainly consisted of interest on lease liabilities relating to our lease of office premises. Finance costs decreased by RMB0.1 million from RMB0.5 million for the six months ended June 30, 2022 to RMB0.4 million for the six months ended June 30, 2023.

Income Tax Expense

We did not record any income tax expense during the six months ended June 30, 2023 and 2022.

Loss for the Period

Based on the factors described above, our net losses amounted to RMB95.1 million and RMB115.6 million for the six months ended June 30, 2023 and 2022, respectively.

Liquidity and Financial Resources

Our primary uses of cash are to fund the development of our product candidates, our clinical trials, our payment for the purchase of plant and equipment, administrative expenses and other recurring expenses. Our net cash used in operating activities was RMB38.1 million for the six months ended June 30, 2023, primarily attributable to the significant research and development expenses and administrative expenses we incurred during the Reporting Period. Our operating cash flow will continue to be affected by our research and development expenses. During the Reporting Period, we mainly relied on 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 RMB23.9 million for the six months ended June 30, 2023, primarily attributable to the purchases of items of property, plant and equipment and payments for investment in an associate when acquired amounting to RMB10.2 million and RMB15.0 million, respectively.

Our net cash used in financing activities was RMB3.7 million for the six months ended June 30, 2023, primarily attributable to the payment of listing expenses and lease payments amounting to RMB0.6 million and RMB3.1 million, respectively.

As at June 30, 2023, we had cash and cash equivalents of RMB389.3 million, representing a decrease of 13.7% compared to RMB451.3 million as at December 31, 2022.

Our net current assets decreased from RMB512.7 million as at December 31, 2022 to RMB436.2 million as at June 30, 2023, 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 and leasehold improvements.

Our capital expenditures decreased from RMB17.7 million for the six months ended June 30, 2022 to RMB10.5 million for the six months ended June 30, 2023. The decrease was primarily attributable to a reduction in purchases of machinery and construction in progress.

Indebtedness

As at June 30, 2023, we did not have any outstanding balance of borrowings nor any unutilized banking facilities.

Our lease liabilities decreased from RMB18.1 million as at December 31, 2022 to RMB15.4 million as at June 30, 2023, primarily attributable to the lease payments made during the Reporting Period.

Gearing Ratio

Our gearing ratio, which was calculated by using total liabilities divided by total assets and multiplied by 100%, decreased from 6.8% as at December 31, 2022 to 6.4% as at June 30, 2023. The decrease was primarily attributable to the decrease of other payables and accruals and lease liabilities.

Capital Commitments

As at June 30, 2023, we had capital commitments contracted, but not yet provided for, of RMB8.2 million, which were related to the purchase of property, plant and equipment for the Group's production plant.

Pledge of Assets

As at June 30, 2023, the Group had no pledge of assets.

Contingent Liabilities

As of June 30, 2023, we did not have any material contingent liabilities.

Significant Investments, Material Acquisitions and Disposals

Please refer to the strategic investment as disclosed in this announcement and note 11 of the section headed "NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS" for further details.

Saved as disclose above, as of June 30, 2023, we did not hold any significant investments, nor did we conduct any material acquisitions and disposals of subsidiaries.

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 arise.

Future Plans for Material Investments or Capital Assets

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

Human Resources

As of June 30, 2023, the Group had 58 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 awards expenses, for the Reporting Period were approximately RMB42.2 million.

We recruit our employees based on a number of factors, including work experience, educational background and the requirements of a relevant vacancy. We invest in continuing education and training programs for our management staff and other employees to upgrade their skills and knowledge continuously. We provide our employees with regular feedback as well as internal and external training in various areas, such as product knowledge, project development and team building. We also assess our employees based on their performance to determine their salary, promotion and career development. In compliance with the relevant PRC labor laws, we enter into individual employment contracts with our employees covering matters such as duration, wages, bonuses, employee benefits, workplace safety, confidentiality obligations, non-competition and grounds for termination. The Group ensures that its remuneration packages are comprehensive and competitive from time to time. When determining the emolument payable to the Directors, we take into account the experience of the Directors, their level of responsibility and general market conditions. Any discretionary bonus and other merit payments of the Directors are linked to the profit performance of the Group and the individual performance of the Directors. Employees are remunerated with a fixed monthly income plus annual performance related bonus. In addition, we are required under PRC law to make contributions to statutory employee benefit plans (including pension plans, medical insurance, work-related injury insurance, unemployment insurance, maternity insurance and housing funds) at a certain percentage of our employees' salaries, including bonus and allowances, up to a maximum amount specified by the local government.

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

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

USE OF PROCEEDS

On December 23, 2021, the Company was successfully listed on the Stock Exchange. The net proceeds received by the Group from the Global Offering after deducting underwriting fee and relevant expenses amounted to approximately HK\$441.69 million. After due and careful consideration of the business environment and the development needs of the Group, 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® balloon 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”. The table below sets out the planned applications of the net proceeds from the Global Offering and actual usage as of June 30, 2023:

Use of proceeds as disclosed in the Prospectus/2022 Annual Report	Original allocation of net proceeds (HK\$ million)	Change of allocation of net proceeds (HK\$ million)	Revised allocation of net proceeds (HK\$ million)	Unutilized amount as of January 1, 2023/ immediately after change of allocation of net proceeds (HK\$ million)	Utilized amount during the Reporting Period (HK\$ million)	Unutilized amount as of June 30, 2023 ⁽¹⁾ (HK\$ million)	Expected timeline of full utilization of the unutilized proceeds ⁽²⁾
To fund the ongoing confirmatory clinical trial, preparation for registration filings, and planned commercial launch of our Core Product, Bioheart®	273.85	–	273.85	195.49	13.19	182.30	December 2027
To fund the ongoing randomized controlled clinical trial in China for, and the continuous development of, our RDN product candidate, Iberis® 2nd	94.08	–	94.08	84.83	10.13	74.7	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	29.59	(17.25)	12.34	0.47	0.47	–	N/A
General corporate and working capital purposes	44.17	–	44.17	28.14	9.91	18.23	December 2027
To fund the research and development of DCB	–	17.25	17.25	17.25	1.80	15.45	December 2027
	<u>441.69</u>	<u>–</u>	<u>441.69</u>	<u>326.18</u>	<u>35.50</u>	<u>290.68</u>	

Notes:

1. As of June 30, 2023, the unutilized 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.

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.

PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES

During the Reporting Period, neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities.

INTERIM DIVIDEND

The Board did not recommend the payment of an interim dividend for the six months ended June 30, 2023 (six months ended June 30, 2022: Nil).

FULL CIRCULATION

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

SUBSEQUENT EVENT AFTER THE REPORTING PERIOD

On July 10, 2023, the Group set up BIO-HEART BIOLOGICAL PTE. LTD. in Singapore, a new wholly-owned subsidiary of the Company. BIO-HEART BIOLOGICAL PTE. LTD. has not commenced any business operation as at the date of this announcement and is expected to be principally engaged in the overseas R&D and sales activities for the Group.

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.

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.

CORPORATE GOVERNANCE CODE

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) 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.

REVIEW OF INTERIM RESULTS

The Board has established the Audit Committee which comprises three independent non-executive Directors, namely Mr. Charles Sheung Wai CHAN, Mr. Xubo LU and Mr. Wing Yiu DJEN. Mr. Charles Sheung Wai CHAN 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 and internal controls.

The Audit Committee, together with the management of the Company, have considered and reviewed the Group's interim results for the Reporting Period and the accounting principles and policies adopted by the Group and discussed internal control, risk management and financial reporting matters, and is of the view that the interim results of the Group is prepared in accordance with applicable accounting standards, rules and regulations and appropriate disclosures have been duly made.

The independent auditor of the Company, Ernst & Young, has also reviewed the Group's interim financial information for the six months ended June 30, 2023 in accordance with Hong Kong Standard on Review Engagements 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Hong Kong Institute of Certified Public Accountants.

PUBLICATION OF THE 2023 CONDENSED CONSOLIDATED INTERIM RESULTS AND INTERIM REPORT

This interim results announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.bio-heart.com). The 2023 interim report of the Company containing all the information required by the Listing Rules will be dispatched to the shareholders of the Company and made available on the above websites in due course.

DEFINITIONS

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

"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
“DCB”	drug coated balloon
“Director(s)”	the director(s) of the Company or any one of them
“Domestic Share(s)”	ordinary share(s) in the share capital of our Company, with a nominal value of RMB1.00 each, which are subscribed for and paid up in RMB and are unlisted Shares which are currently not listed or traded in any stock exchange
“EuroPCR 2022”	an official annual meeting of the European Association of Percutaneous Cardiovascular Interventions
“Full Circulation”	the conversion of the Domestic Shares and certain Unlisted Foreign Shares into H Shares and their listing on the Stock Exchange, of which the Company received the approval from official approval from the China Securities Regulatory Commission and was completed on January 13, 2023
“Global Offering”	the global offering of the H Shares, details of which are set forth in the Prospectus
“Group”, “the Group”, “our Group”, “our”, “we”, or “us”	the Company and all of its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
“H Shares”	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”, “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 (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)
“PMDA”	the Pharmaceuticals and Medical Devices Agency of Japan
“Prospectus”	the prospectus of the Company dated December 13, 2021
“R&D”	research and development
“RDN”	renal denervation
“Reporting Period”	for the six months ended June 30, 2023
“RMB”	Renminbi, the lawful currency of the PRC
“Share(s)”	ordinary share(s) in the capital of our Company with a nominal value of RMB1.00 each, comprising, Unlisted Foreign Shares and H Shares
“Shareholder(s)”	holder(s) of the Share(s)
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“Supervisor(s)”	the supervisor(s) of the Company
“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“USD”	United States dollars, the lawful currency of the United States

“Unlisted Foreign Shares” ordinary shares issued by our company with a nominal value of RMB1.00 each and are held by foreign investors and are not listed on any stock exchange

“%” 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, August 11, 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 and Mr. Charles Sheung Wai CHAN, Mr. Xubo LU and Mr. Wing Yiu DJEN as independent non-executive Directors.