

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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, 2022**

FINANCIAL HIGHLIGHTS

	Six months ended June 30,	
	2022	2021
	RMB'000	RMB'000
	(unaudited)	(audited)
Research and development expenses	(71,391)	(120,486)
Administrative expenses	(53,853)	(104,535)
Other expenses	–	(3,226)
Finance costs	(510)	(227)
Other income and gains	10,178	964
Loss for the period	<u>(115,576)</u>	<u>(227,510)</u>

BUSINESS HIGHLIGHTS

During the Reporting Period, we have made the following progress with respect to our product pipeline and business operation:

- The Company completed the patient enrollment process for the clinical trial of Iberis® 2nd in January 2022.
- The Company completed the patient enrollment process for the clinical trial of Bioheart® in February 2022.
- At EuroPCR 2022, the Company finalized plans with clinical trial investigators on the European clinical trial on Renal Artery Denervation Using Radial Access in Uncontrolled Hypertension (RADIUS-HTN) to evaluate Iberis® 2nd RDN system in patients with uncontrolled hypertension.

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, 2022 together with the comparative figures for the corresponding period in 2021.

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

For the six months ended June 30, 2022

		Six months ended June 30,	
		2022	2021
	Notes	RMB'000	RMB'000
		(Unaudited)	(Audited)
Other income and gains	5	10,178	964
Research and development expenses		(71,391)	(120,486)
Administrative expenses		(53,853)	(104,535)
Other expenses	7	–	(3,226)
Finance costs	8	(510)	(227)
LOSS BEFORE TAX	6	(115,576)	(227,510)
Income tax expense	9	–	–
LOSS FOR THE PERIOD		(115,576)	(227,510)
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD		(115,576)	(227,510)
Attributable to:			
Owners of the parent		(101,439)	(199,789)
Non-controlling interests		(14,137)	(27,721)
		(115,576)	(227,510)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (RMB)	11	(0.42)	(0.91)

INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION
As at June 30, 2022

		As at 30 June 2022	As at 31 December 2021
	<i>Notes</i>	RMB'000 (Unaudited)	RMB'000 (Audited)
NON-CURRENT ASSETS			
Property, plant and equipment		52,057	50,409
Other intangible assets		137,562	137,200
Prepayments, other receivables and other assets		7,172	4,301
Right-of-use assets		18,855	21,851
Goodwill		144,630	144,630
Investment in an associate	<i>12</i>	24,658	–
		<hr/>	<hr/>
Total non-current assets		384,934	358,391
CURRENT ASSETS			
Prepayments, other receivables and other assets		43,460	47,997
Cash and cash equivalents		518,911	708,531
Time deposits		134,377	–
		<hr/>	<hr/>
Total current assets		696,748	756,528
CURRENT LIABILITIES			
Trade payables	<i>13</i>	10	10
Lease liabilities		8,091	7,311
Other payables and accruals		28,857	28,510
Deferred income		995	981
		<hr/>	<hr/>
Total current liabilities		37,953	36,812
NET CURRENT ASSETS		<hr/> 658,795	<hr/> 719,716
TOTAL ASSETS LESS CURRENT LIABILITIES		<hr/> 1,043,729	<hr/> 1,078,107

	As at 30 June 2022	As at 31 December 2021
<i>Notes</i>	RMB'000	RMB'000
	(Unaudited)	(Audited)
NON-CURRENT LIABILITIES		
Lease liabilities	13,216	15,135
Deferred income	7,013	7,517
Deferred tax liabilities	20,580	20,580
	<hr/>	<hr/>
Total non-current liabilities	40,809	43,232
	<hr/>	<hr/>
Net assets	1,002,920	1,034,875
	<hr/>	<hr/>
EQUITY		
Equity attributable to owners of the parent		
Share capital	243,937	243,937
Reserves	722,455	751,750
	<hr/>	<hr/>
	966,392	995,687
Non-controlling interests	36,528	39,188
	<hr/>	<hr/>
Total equity	1,002,920	1,034,875
	<hr/>	<hr/>

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the six months ended June 30, 2022

1 CORPORATE AND GROUP INFORMATION

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

During the 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 Company was listed on the Main Board of the Stock Exchange of Hong Kong Limited (the "Stock Exchange") on December 23, 2021.

2 BASIS OF PREPARATION

The interim condensed consolidated financial information for the six months ended June 30, 2022 has been prepared in accordance with International Accounting Standard 34 Interim Financial Reporting ("IAS 34"). 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, 2021. The Interim 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, 2021, except for the adoption of the following revised International Financial Reporting Standards ("IFRSs") for the first time for the current period's financial information.

Amendment to IFRS 16	<i>Covid-19-Related Rent Concessions beyond June 30, 2021</i>
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>
Annual Improvements to IFRS Standards 2018-2020	<i>Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41</i>

The adoption of the revised standards 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,	
	2022 RMB'000 (Unaudited)	2021 RMB'000 (Audited)
Other income		
Government grants*	591	122
Bank interest income	1,737	821
Others	2	21
	<u> </u>	<u> </u>
Gains		
Foreign exchange gains	7,848	–
	<u> </u>	<u> </u>
	<u>10,178</u>	<u>964</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.

6 LOSS BEFORE TAX

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

	Six months ended June 30,	
	2022 RMB'000 (Unaudited)	2021 RMB'000 (Audited)
Depreciation of property, plant and equipment*	6,323	5,468
Depreciation of right-of-use assets*	2,996	1,725
Auditor's remuneration	400	301
Amortization of other intangible assets*	19	–
Expense relating to leases of low-value assets	7	–
Foreign exchange (gains)/losses	(7,848)	3,220
Bank interest income	(1,737)	(821)
Government grants	(591)	(122)
Listing expense	–	6,529
	<u>(431)</u>	<u>16,300</u>
Staff cost (excluding directors', supervisors' and chief executive's remuneration):		
– Wages and salaries	5,083	3,604
– Pension scheme contributions	379	286
– Equity-settled share award expense	12,266	28,995

* 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 OTHER EXPENSES

An analysis of other expenses is as follows:

	Six months ended June 30,	
	2022 RMB'000 (Unaudited)	2021 RMB'000 (Audited)
Foreign exchange losses	–	3,220
Others	–	6
	<u>–</u>	<u>3,226</u>

8 FINANCE COSTS

An analysis of finance costs is as follows:

	Six months ended June 30,	
	2022	2021
	RMB'000	RMB'000
	(Unaudited)	(Audited)
Interest on lease liabilities	510	227

9 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 recognised 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 Hong Kong income tax was provided for at a rate of 16.5% as there was no estimated assessable profit of the Group’s Hong Kong subsidiary during the period presented in the condensed consolidated financial statements.

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

10 DIVIDENDS

No dividends have been paid or declared by the Company during the six months ended June 30, 2022 (six months ended June 30, 2021: nil).

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

The calculation of the basic earnings per share amounts is based on the loss for the period attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 243,937,000 (2021: 220,000,000) in issue during the period, as adjusted to reflect the rights issue during the period.

The Company had no potentially dilutive ordinary shares in issue during the periods presented.

The calculation of basic loss per share is based on:

	Six months ended June 30,	
	2022	2021
	(Unaudited)	(Audited)
Loss		
Loss attributable to ordinary equity holders of the Company (RMB'000)	(101,439)	(199,789)
Ordinary shares		
Weighted average number of ordinary shares in issue during the period used in the basic loss per share calculation (thousand)	243,937	220,000
Loss per share (RMB per share)	(0.42)	(0.91)

12 INVESTMENT IN AN ASSOCIATE

In June 2022, the Group acquired an aggregate of 15.42% equity interest in Xinzhi Medical through (i) acquisition of 8.01% equity interest from one of the existing shareholders of Xinzhi Medical at the consideration of RMB8,658,000 which had been paid during the period and (ii) subscription of additional 7.41% equity interest of Xinzhi Medical at the consideration of RMB16,000,000.

The investment was then 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.

13 TRADE PAYABLES

	As at June 30, 2022 RMB'000 (Unaudited)	As at December 31, 2021 RMB'000 (Audited)
Trade payables	10	10

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

	As at June 30, 2022 RMB'000 (Unaudited)	As at December 31, 2021 RMB'000 (Audited)
Over 12 months	10	10

Trade payables are non-interest-bearing and are normally settled within one month.

MANAGEMENT DISCUSSION AND ANALYSIS

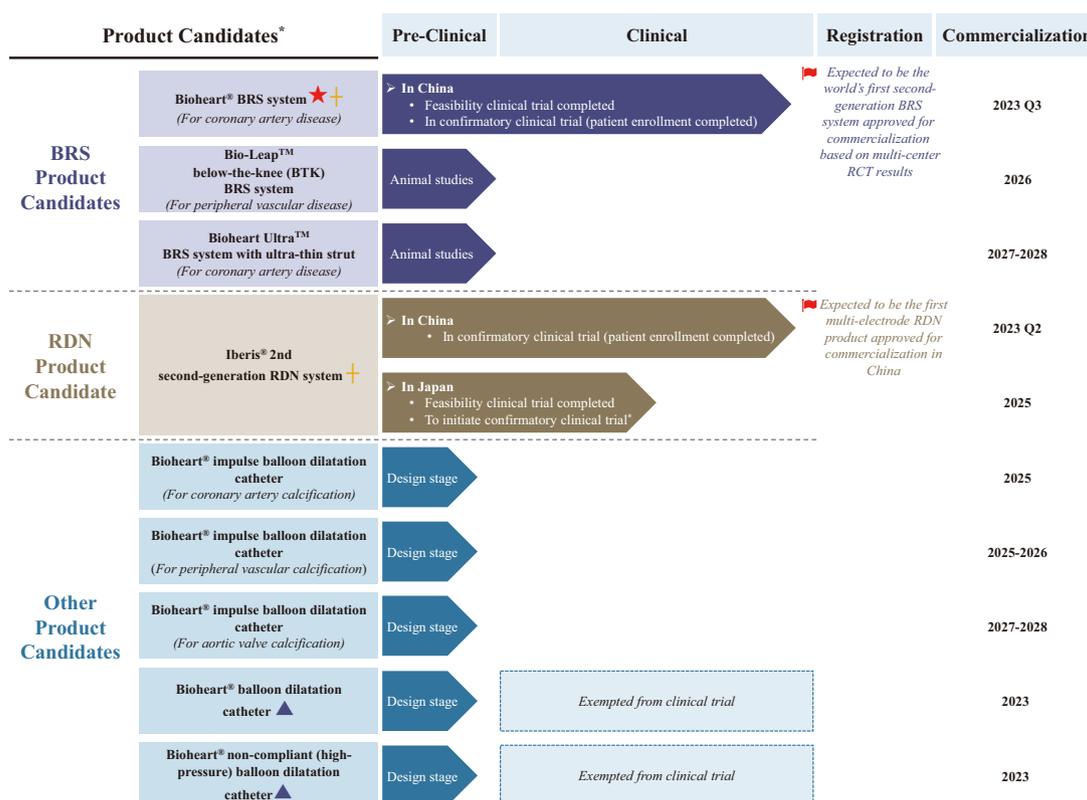
I. BUSINESS REVIEW

Overview

We are a leading innovative interventional cardiovascular device company in China with a current focus on two therapies: (i) bioresorbable scaffolds (BRS) addressing the unmet medical needs of Chinese patients for the treatment of coronary or peripheral artery diseases, and (ii) renal denervation (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 nine 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:



★ Core product

† NMPA "Innovative Medical Device"

▲ Among our product candidates, these devices are exempted from clinical trial requirements in accordance with the *Catalogue of Medical Devices Exempted from Clinical Trials* (《免於進行臨床試驗醫療器械目錄》) promulgated by the NMPA, as amended.

* The confirmatory clinical trial is also known as pivotal clinical trial in Japan.

Our Products and Product Candidates

BRS Product Candidates

Bioheart[®], our bioresorbable scaffold (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 35 registered patents (including 10 invention patents and 25 utility model patents) in relation to Bioheart[®], of which 33 were registered in China, one registered in the U.S. and one registered in Europe. We also have 14 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 complete the required follow-ups for the confirmatory clinical trial and submit our confirmatory clinical trial results to the NMPA for its approval in the first quarter of 2023.

Bio-Leap[™], a below-the-knee (BTK) BRS system, is our self-developed innovative BRS product candidate used in percutaneous transluminal angioplasty for the treatment of lower extremity peripheral artery disease. As of the date of this announcement, we had completed the design of Bio-Leap[™] and are currently in the process of conducting animal studies for Bio-Leap[™]. We currently expect to initiate the clinical trials for Bio-Leap[™] in 2023 and launch the product in or around 2026.

Bioheart Ultra[™], is our self-developed second-generation BRS system for the treatment of coronary artery disease featuring an estimated stent strut thickness less than 100 μm. As of the date of this announcement, we had completed the design of Bioheart Ultra[™] and are currently in the process of conducting animal studies for Bioheart Ultra[™]. We currently expect to initiate the clinical trials for Bioheart Ultra[™] in 2023 and launch the product in or around 2028.

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 33 registered patents (including nine invention patents, 20 utility model patents and four design patents) and 19 pending invention patent applications in relation to Iberis[®] 2nd. Of the 33 registered patents, 32 were registered or applied in China, and one registered in Japan. Iberis[®] 2nd was recognized as an “innovative medical device” by the NMPA in November 2016 and is therefore eligible for an expedited approval process. On January 26, 2022, the Company completed the patient enrollment process for the clinical trial of Iberis[®] 2nd. We expect to complete the required follow-ups for the clinical trial and submit our randomized controlled clinical trial results to the NMPA for its approval in the fourth quarter of 2022.

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 European clinical trial on Renal Artery Denervation Using Radial Access in Uncontrolled Hypertension (RADIUS-HTN). 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 shortens the duration of hospital stay with a reduction in procedural costs and increased patient gratification. Clinical trials for Iberis® 2nd are conducted in collaboration with Terumo, our strategic business collaborator.

Other Product Candidates

We have five balloon catheter product candidates.

Bioheart® balloon dilatation catheter and Bioheart® non-compliant (high-pressure) balloon dilatation catheter are designed to be used in the pre- and post-dilatation procedure for stent deployment, which, together with our Core Product, will provide full suite solutions to physicians for BRS implantation. Since these two product candidates are exempted from clinical trial requirements in China, we expect to launch them shortly after their respective development stage concludes in the second quarter of 2023.

Bioheart® impulse balloon dilatation catheters consist of three product candidates designed to remove coronary artery calcification, peripheral vascular calcification and aortic valve calcification, respectively. We expect to initiate clinical trials for Bioheart® impulse balloon dilatation catheters in the second quarter of 2023. As of the date of this announcement, we held three registered patents (including one utility patent) and five pending invention patent (including one PCT application) applications in relation to Bioheart® impulse balloon dilatation catheters, all of which were registered or applied in China.

For details of our products and product candidates, please refer to our Prospectus.

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 and peripheral 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 seven other product candidates in various stages of development;
- 72 registered patents and 40 pending patent applications; and
- CE Marking and nine registration certificates for our first-generation RDN product commercialized in overseas markets.

Strategic Investment

On June 21, 2022, our Group acquired 15.42% equity interest of 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.

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.

Impact of the COVID-19 Outbreak

The outbreak of COVID-19 since December 2019 did not have long-term material and adverse impact on our clinical trials or overall clinical development plans, operations, supply chains, and financial condition. With effective quarantine measures taken by the Chinese government to reduce confirmed COVID-19 cases in China, as well as the various precautionary measures implemented by us to adjust our employees’ work arrangements in accordance with the relevant regulations and policies, we were able to maintain a sufficient number of personnel to work on-site and continue our research and development activities. While the sporadic outbreak of COVID-19 in China in March 2022 to May 2022 has affected and restricted the general level of economic activity in China, economic activities have resumed since June 2022.

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 pandemic 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 may result in potential delay with the progress of our clinical trials and our operations.

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

Other Income and Gains

During the six months ended June 30, 2022 and 2021, our other income and gains mainly consisted of government grants, bank interest income, foreign exchange differences and others. Other income and gains increased by RMB9.2 million from RMB1.0 million for the six months ended June 30, 2021 to RMB10.2 million for the six months ended June 30, 2022. The increase was primarily attributable to the increase of foreign exchange gains of RMB7.8 million, which was due to the increase of exchange rate of USD against RMB and the increase of bank interest income of RMB0.9 million.

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 awards and other welfare for our administrative employees. During the six months ended June 30, 2022 and 2021, we recorded equity-settled share award expenses of RMB40.3 million and RMB90.7 million, respectively, under our administrative expenses.

Our administrative expenses decreased by RMB50.6 million from RMB104.5 million for the six months ended June 30, 2021 to RMB53.9 million for the six months ended June 30, 2022. The decrease was primarily attributable to 1) a decrease of equity-settled share award expense of RMB50.4 million related to our key administrative employees with service periods requirements; 2) a decrease of listing expenses of RMB6.5 million as the Company became listed on December 23, 2021; 3) an increase of depreciation expenses of RMB2.0 million as a result of our lease of a new plant during the second half of year 2021; 4) an increase of professional service expenses of RMB4.2 million as a result of that compliance service expenses, interim financial information review services and public relations services that were incurred in the first half of year 2022.

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

	Six months ended June 30,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Employee benefits expenses	43,210	94,212
Including: equity-settled share award expenses	40,322	90,716
Depreciation expenses	3,399	1,432
Listing expenses	–	6,529
Professional service expenses	5,019	786
Utilities and office expenses	695	985
Others	1,530	591
	<u>53,853</u>	<u>104,535</u>

Research and Development Expenses

Our research and development expenses mainly consist of (i) testing fees, (ii) employee benefits expenses, (iii) costs of raw materials and consumables used, and (iv) depreciation expenses.

Employee benefits expenses under research and development expenses primarily include the salaries, welfare, and equity-settled share awards for our research and development employees. During the six months ended June 30, 2022 and 2021, we recorded equity-settled share award expenses of RMB43.3 million and RMB95.3 million, respectively, under our research and development expenses.

Our research and development expenses decreased by RMB49.1 million from RMB120.5 million for the six months ended June 30, 2021 to RMB71.4 million for the six months ended June 30, 2022, primarily attributable to the decrease of equity-settled share award expenses related to our research and development employees with service periods requirements.

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

	Six months ended June 30,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Testing fees	11,956	9,505
Employee benefit expenses	49,044	99,744
Including: equity-settled share award expenses	43,299	95,250
Costs of raw materials and consumables used	2,313	3,125
Depreciation and amortization expenses	5,939	5,761
Others	2,139	2,351
	<u>71,391</u>	<u>120,486</u>

Other Expenses

During the six months ended June 30, 2022 and 2021, our other expenses mainly consisted of foreign exchange losses and others. We did not record any other expenses during the six months ended June 30, 2022, primarily attributable to the increase of exchange rate of USD against RMB in the first half of year 2022.

Finance Costs

During the six months ended June 30, 2022 and 2021, our finance costs mainly consisted of interest on lease liabilities relating to our lease of office premises. Finance costs increased by RMB0.3 million from RMB0.2 million for the six months ended June 30, 2021 to RMB0.5 million for the six months ended June 30, 2022, primarily attributable to the addition of lease liabilities during the second half of year 2021.

Income Tax Expense

We did not record any income tax expense during the six months ended June 30, 2022 and 2021.

Loss for the Period

Based on the factors described above, our net losses amounted to RMB115.6 million and RMB227.5 million for the six months ended June 30, 2022 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 and other recurring expenses. Our net cash used in operating activities was RMB35.0 million for the six months ended June 30, 2022, 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 capital contributions by our shareholders and equity financing as the major sources of liquidity. Our management closely monitors uses of cash and cash balances and strives to maintain a healthy liquidity for our operations. Going forward, we believe our liquidity requirements will be satisfied by a combination of net proceeds from the Global Offering and cash generated from our operations.

Our net cash used in investing activities was RMB152.3 million for the six months ended June 30, 2022, primarily attributable to the purchases of items of property, plant and equipment, payments for investment in an associate and increase in time deposits with initial terms of over three months when acquired amounting to RMB17.7 million, RMB8.7 million and RMB127.5 million, respectively.

Our net cash used in financing activities was RMB3.8 million for the six months ended June 30, 2022, primarily attributable to the payment of listing expenses and lease payments amounting to RMB2.1 million and RMB1.6 million, respectively.

As at June 30, 2022, we had cash and cash equivalents of RMB518.9 million, representing a decrease of 26.8% 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 RMB658.8 million as at June 30, 2022, 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 increased from RMB10.1 million for the six months ended June 30, 2021 to RMB17.7 million for the six months ended June 30, 2022. The increase was primarily attributable to addition of machinery and construction in progress.

Indebtedness

As at June 30, 2022, we did not have any outstanding balance of borrowings nor any unutilized banking facilities.

Our lease liabilities decreased from RMB22.4 million as at December 31, 2021 to RMB21.3 million as at June 30, 2022, primarily attributable to the lease payments.

Gearing Ratio

Our gearing ratio, which was calculated by using total liabilities divided by total assets and multiplied by 100%, increased from 7.2% as at December 31, 2021 to 7.3% as at June 30, 2022. The increase was primarily attributable to the decrease of right-of-use assets and cash and cash equivalents.

Capital Commitments

As at June 30, 2022, we had capital commitments contracted, but not yet provided for, of RMB3.6 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, 2022, the Group had no pledge of assets.

Contingent Liabilities

As of June 30, 2022, we did not have any material contingent liabilities.

Significant Investments, Material Acquisitions and Disposals

Apart from the strategic investment as disclosed in this announcement, as of June 30, 2022, 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, 2022, the Group had 52 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) social security costs, (iii) employee welfare and (iv) equity-settled share awards, for the Reporting Period were approximately RMB92.3 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 terms, wages, bonuses, employee benefits, workplace safety, confidentiality obligations, noncompetition 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 the annual general meeting held by the Company on June 27, 2022, the Company approved the adoption of the 2022 H Share Incentive 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 modernize the remuneration practices and improve the interests balance mechanism among the Shareholders, and the operational and executive management by aligning their interests.

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\$441.7 million. The Company intends to apply such net proceeds in accordance with the purposes as set out in the Prospectus.

The table below sets out the planned applications of the net proceeds from the Global Offering and actual usage as at June 30, 2022:

Use of proceeds	Percentage of total net proceeds	Allocation of net proceeds (HK\$ million)	Utilized amount as at June 30, 2022 (HK\$ million)	Unutilized amount as at June 30, 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	2.13	271.72	December 2026
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	December 2026
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	10.18	19.41	December 2026
General corporate and working capital purposes	10.0%	44.17	14.45	29.72	December 2026
	100%	441.69	26.76	414.93	

Notes:

- As at June 30, 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.

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, 2022.

SUBSEQUENT EVENT AFTER THE REPORTING PERIOD

On July 27, 2022, the Company announced that the board lot size for trading in the H Shares on the Stock Exchange will be changed from 500 H Shares to 100 H Shares with effect from 9:00 a.m. on Wednesday, August 17, 2022. For details of the change in board lot size, please refer to the Company's announcement dated July 27, 2022.

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.

COMPLIANCE WITH MODEL CODE FOR SECURITIES TRANSACTIONS

The Company has adopted the Model Code as its own code of conduct regarding securities transactions by the Directors and Supervisors. 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.

COMPLIANCE WITH CORPORATE GOVERNANCE CODE

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 two executive Directors (including Mr. Wang), three 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.

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. 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 of the Company, has considered and reviewed the Group's interim results for the Reporting Period and the accounting principles and policies adopted by the Company and discussed internal control 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 30 June 2022 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 2022 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 2022 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.

“AngioCare”	Shanghai AngioCare Medical Technology Co., Ltd.* (上海安通醫療科技有限公司), a subsidiary of our Company
“Audit Committee”	the audit committee of the Board
“Board of Directors” or “Board”	the board of Directors
“CG Code”	the code provisions of the “Corporate Governance Code” as 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”, “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
“Global Offering”	the global offering of the H Shares, details of which are set forth in the Prospectus
“Group”, “our Group”, “our”, “we”, or “us”	the Company and all of its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
“H 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” 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”	the listing of the H Shares on the Main Board of the Stock Exchange
“Listing Rules”	the Rules Governing the Listing of Securities on 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)
“Prospectus”	the prospectus of the Company dated December 13, 2021
“R&D”	Research and development

“Reporting Period”	For the six months ended June 30, 2022
“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 Domestic Shares, Unlisted Foreign Shares and H Shares
“Shareholder(s)”	holder(s) of the Share(s)
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“Terumo”	Terumo (China) Investment Co., Ltd. (泰爾茂(中國)投資有限公司), a limited liability company incorporated in the PRC on August 2, 2011 and is a wholly-owned subsidiary of Terumo Corporation (泰爾茂株式會社), a company listed on the Tokyo Stock Exchange (TSE: 4543). Terumo refers to Terumo (China) Investment Co., Ltd. (泰爾茂(中國)投資有限公司) or Terumo Corporation (泰爾茂株式會社), where the context requires
“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“Unlisted Foreign Shares”	ordinary shares issued by our company with a nominal value of RMB1.00 each and are held by foreign investors and are not listed on any stock exchange
“Xinzhi Medical”	Shanghai Xinzhi Medical Technology Co., Ltd.* (上海心至醫療科技有限公司), a company established in the PRC with limited liability
%	per cent

By order of the Board
Shanghai Bio-heart Biological Technology Co., Ltd.
Philip Li WANG
Chairman and executive Director

Shanghai, the People’s Republic of China, August 5, 2022

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

* For identification purpose only