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)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2021

FINANCIAL HIGHLIGHTS

	Year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
Research and development expenses	**(214,228)**	(245,743)
Administrative expenses	**(195,424)**	(81,556)
Other expenses	**(6,647)**	(16,363)
Finance costs	**(685)**	(56)
Other income	**7,159**	3,424
Loss for the year	**(409,825)**	(340,294)

BUSINESS HIGHLIGHTS

On December 23, 2021, the Company was successfully listed on the Stock Exchange. As at the date of this announcement, we have made the following progress with respect to our product pipeline and business operation:

- The construction of the Company's new plant located at Zhangjiang Hi-Tech Park, Pudong New Area, Shanghai with a gross area of over 7,000 sq.m was completed in December 2021.
- 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.

The Board is pleased to announce the audited consolidated annual results of the Company and its subsidiaries for the year ended December 31, 2021, together with the comparative figures for the previous year.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

		Year ended December 31,	
		2021	2020
	Notes	***RMB'000***	*RMB'000*
Other income	*4*	**7,159**	3,424
Research and development expenses		**(214,228)**	(245,743)
Administrative expenses		**(195,424)**	(81,556)
Other expenses	*6*	**(6,647)**	(16,363)
Finance costs	*7*	**(685)**	(56)
LOSS BEFORE TAX	*5*	**(409,825)**	(340,294)
Income tax expense	*8*	**–**	–
LOSS FOR THE YEAR		**(409,825)**	(340,294)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		**(409,825)**	(340,294)
Attributable to:			
Owners of the parent		**(361,449)**	(325,523)
Non-controlling interests		**(48,376)**	(14,771)
		(409,825)	(340,294)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted *(RMB)*	*10*	**(1.64)**	(2.38)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Notes	As at December 31, 2021 RMB'000	2020 RMB'000
NON-CURRENT ASSETS			
Property, plant and equipment		**50,409**	18,696
Other intangible assets		**137,200**	137,200
Prepayments, other receivables and other assets	*11*	**4,301**	12,173
Right-of-use assets		**21,851**	1,578
Goodwill		**144,630**	144,630
Total non-current assets		**358,391**	314,277
CURRENT ASSETS			
Prepayments, other receivables and other assets	*11*	**47,997**	17,098
Cash and cash equivalents		**708,531**	453,667
Total current assets		**756,528**	470,765
CURRENT LIABILITIES			
Trade payables	*12*	**10**	10
Lease liabilities		**7,311**	1,236
Other payables and accruals	*13*	**28,510**	12,098
Deferred income		**981**	523
Total current liabilities		**36,812**	13,867
NET CURRENT ASSETS		**719,716**	456,898
TOTAL ASSETS LESS CURRENT LIABILITIES		**1,078,107**	771,175
NON-CURRENT LIABILITIES			
Lease liabilities		**15,135**	80
Deferred income		**7,517**	6,602
Deferred tax liabilities		**20,580**	20,580
Total non-current liabilities		**43,232**	27,262
Net assets		**1,034,875**	743,913
EQUITY			
Equity attributable to owners of the parent			
Share capital		**243,937**	220,000
Reserves		**751,750**	480,090
		995,687	700,090
Non-controlling interests		**39,188**	43,823
Total equity		**1,034,875**	743,913

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1 CORPORATE AND GROUP INFORMATION

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

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

The shares of the Company have been listed on the Main Board of the Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") effective from December 23, 2021.

2.1 BASIS OF PREPARATION

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

2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

Pursuant to the Accountants' Report of the Group in connection with the listing of the shares of the Company on the Stock Exchange, all IFRSs in issue as at June 30, 2021 and effective for annual periods beginning January 1, 2021, together with the relevant transitional provisions, had been early adopted by the Group in the preparation of the consolidated statements of profit or loss and other comprehensive income, statements of changes in equity and statements of cash flows of the Group for each of the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, and the consolidated statements of financial position of the Group and the statements of financial position of the Company as at December 31, 2019 and 2020 and June 30, 2021. Thus, the adoption of the below amendments had no impact on the Group's financial statements for the year ended December 31, 2021.

Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	*Interest Rate Benchmark Reform – Phase 2*

2.3 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

The Group has not applied the following new and revised IFRSs, that have been issued but are not yet effective, in the financial statements.

Amendment to IFRS 16	*Covid-19-Related Rent Concessions beyond June 30, 2021*[1]
Amendments to IFRS 3	*Reference to the Conceptual Framework*[2]
Amendments to IFRS 10 and IAS 28	*Sale or Contribution of Assets between an Investor and its Associate or Joint Venture*[4]
IFRS 17	*Insurance Contracts*[3]
Amendments to IFRS 17	*Insurance Contracts*[3, 5]
Amendments to IAS 1	*Classification of Liabilities as Current or Non-current*[3]
Amendments to IAS 1 and IFRS Practice Statement 2	*Disclosure of Accounting Policies*[3]
Amendments to IAS 8	*Definition of Accounting Estimates*[3]
Amendments to IFRS 17	*Initial Application of IFRS 17 and IFRS 9 – Comparative Information*[3]
Amendments to IAS 12	*Deferred Tax related to Assets and Liabilities arising from a Single Transaction*[3]
Amendments to IAS 16	*Property, Plant and Equipment: Proceeds before Intended Use*[2]
Amendments to IAS 37	*Onerous Contracts – Cost of Fulfilling a Contract*[2]
Annual Improvements to IFRS Standards 2018-2020	*Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41*[2]

1 Effective for annual periods beginning on or after April 1, 2021
2 Effective for annual periods beginning on or after January 1, 2022
3 Effective for annual periods beginning on or after January 1, 2023
4 No mandatory effective date yet determined but available for adoption
5 As a consequence of the amendments to IFRS 17 issued in June 2020, IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before January 1, 2023

The Group is in the process of making an assessment of the impact of these new and revised IFRSs upon initial application. So far, the Group considers that these new and revised IFRSs may result in changes in accounting policies and are unlikely to have a significant impact on the Group's results of operations and financial position.

3 OPERATING SEGMENT INFORMATION

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

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

4 OTHER INCOME

An analysis of other income is as follows:

	2021	2020
	RMB'000	*RMB'000*
Government grants*	**5,875**	3,031
Bank interest income	**972**	190
Consulting income	**–**	181
Others	**312**	22
	7,159	3,424

* The Group has received certain government grants related to assets. The grants related to assets were recorded in deferred income and recognized in profit or loss over the useful lives of the relevant assets after the relevant conditions are met. Government grants related to income that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future related costs are recognized in profit or loss in the period upon actual receipt.

5 LOSS BEFORE TAX

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

	2021	2020
	RMB'000	*RMB'000*
Depreciation of property, plant and equipment*	**8,770**	7,537
Depreciation of right-of-use assets*	**4,464**	1,106
Government grants	**(5,875)**	(3,031)
Bank interest income	**(972)**	(190)
Foreign exchange losses	**6,613**	16,353
Auditor's remuneration	**1,837**	602
Expense relating to leases of low-value assets	**17**	8
Listing expense	**19,400**	5,461
	34,254	27,846
Staff cost (excluding directors', supervisors' and chief executive's remuneration):		
– Wages and salaries	**8,859**	3,902
– Pension scheme contributions	**618**	19
– Equity-settled share award expense	**49,169**	56,987

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

6 OTHER EXPENSES

An analysis of other expenses is as follows:

	2021	2020
	RMB'000	*RMB'000*
Foreign exchange losses	**6,613**	16,353
Others	**34**	10
	6,647	16,363

7 FINANCE COSTS

An analysis of finance costs is as follows:

	2021	2020
	RMB'000	*RMB'000*
Interest on lease liabilities	**685**	56

8 INCOME TAX

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

(a) No provision for Mainland China income tax has been provided for at a rate of 25% pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "**CIT Law**"), as the Group's PRC entities have no estimated assessable profits during the year.

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

(c) A reconciliation of the tax expense applicable to loss before tax at the statutory rate to the tax expense at the effective tax rate is as follows:

	2021	2020
	RMB'000	*RMB'000*
Loss before tax	**(409,825)**	(340,294)
Tax at the statutory tax rate of 25%	**(102,456)**	(85,074)
Effect of different tax rate of a subsidiary operating in other jurisdictions and tax concession	**14,129**	3,997
Tax effect of income that is exempt from taxation	**(1,119)**	(351)
Expenses not deductible for tax	**67,542**	63,567
Additional deductible allowance for research and development costs	**(7,831)**	(3,711)
Tax effect of deductible temporary differences not recognised	**3,921**	2,037
Utilisation of deductible temporary differences previously not recognised	**(118)**	–
Tax losses not recognised	**25,932**	19,535
Tax charge at the Group's effective tax rate for the year	**–**	–

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

	2021	2020
	RMB'000	*RMB'000*
Tax losses	**356,393**	244,103
Deductible temporary differences	**26,847**	11,947
	383,240	256,050

The Group has tax losses arising of RMB356,393,000 and RMB244,103,000, as at December 31, 2021 and 2020. Deferred tax assets have not been recognised in respect of these losses as it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

9 DIVIDEND

No dividends have been paid or declared by the Company during the year (2020: Nil).

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

On November 24, 2020, the Company was converted to a joint stock limited liability company. A total of 220,000,000 shares of par value of RMB1.00 each were issued and allotted to the respective shareholders of the Company according to the paid-in capital registered under these shareholders on that day. The conversion of paid-in capital to share capital with par value of RMB1.00 each is applied retrospectively for the year ended December 31, 2020 for the purpose of computation of basic earnings per share.

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

The calculation of basic loss per share is based on:

	2021	2020
Loss		
Loss attributable to ordinary equity holders of the Company *(RMB'000)*	**(361,449)**	(325,523)
Ordinary shares		
Weighted average number of ordinary shares in issue during the year used in the basic loss per share calculation *(thousand)*	**220,590**	136,555
Loss per share *(RMB per share)*	**(1.64)**	(2.38)

11 PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	2021	2020
	RMB'000	*RMB'000*
Non-current:		
Prepayments for purchase of items of property, plant and equipment	**1,080**	2,496
Prepayments for purchase of intangible assets	**430**	–
Deferred listing expenses	**–**	8,273
Rental deposits	**1,871**	1,142
Value-added tax recoverable – non current	**607**	–
Other deposits	**313**	262
	4,301	12,173
Current:		
Prepayments	**39,084**	14,784
Value-added tax recoverable – current	**8,913**	2,314
	47,997	17,098

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

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

12 TRADE PAYABLES

	2021	2020
	RMB'000	*RMB'000*
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:

	2021	2020
	RMB'000	*RMB'000*
Over 12 months	**10**	10

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

13 OTHER PAYABLES AND ACCRUALS

	2021	2020
	RMB'000	*RMB'000*
Accruals for research and development	**3,324**	3,335
Payroll payable	**2,228**	1,360
Accrued listing expenses	**11,775**	7,146
Accrued other expenses	**3,591**	–
Payables for purchase of property, plant and equipment	**7,289**	–
Other payables	**303**	257
	28,510	12,098

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

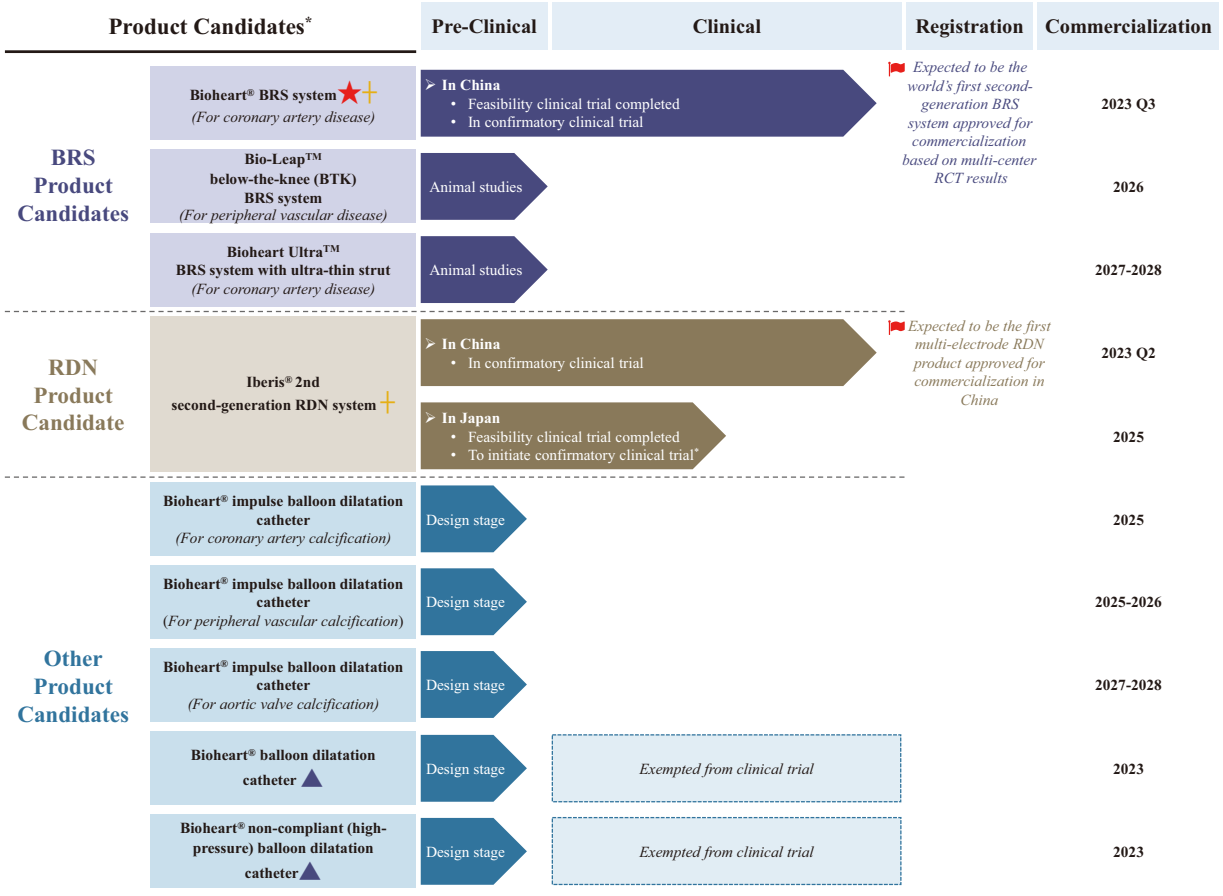
I. BUSINESS REVIEW

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 USA 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. The Company has contracted with the European Cardiovascular Research Center to conduct a European clinical trial evaluating Iberis® 2nd RDN system. 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.

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;
- 71 registered patents and 38 pending patent applications; and
- CE Marking and nine registration certificates for our first-generation RDN product commercialized in overseas markets.

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. However, the recent reported outbreak of COVID-19 in China may severely affect and restrict the general level of economic activity in Shanghai and other areas in China. 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.

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.

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

Our other income mainly consists of government grants, bank interest income, consulting income and others. Our government grants mainly include government subsidies for compensating our expenses relating to certain research and development projects. Our other income increased from RMB3.4 million in 2020 to RMB7.2 million in 2021. The increase was primarily attributable to (i) increase in governments grants due to more government grants received in 2021; (ii) increase in interest income due to increase in balance of cash at banks.

Administrative Expenses

Our administrative expenses mainly consist of (i) employee benefit expenses, (ii) depreciation expenses, (iii) listing expenses, (iv) professional services expenses, and (v) utilities and office expenses. Employee benefit expenses mainly include salaries, equity-settled share awards and other welfare for our administrative employees. In 2020 and 2021, we recorded equity-settled share award expenses of RMB50.0 million and RMB155.1 million respectively, under our administrative expenses.

Our administrative expenses increased from RMB81.6 million in 2020 to RMB195.4 million in 2021. The increase was primarily attributable to 1) an increase of equity-settled share award expense of RMB105.1 million as we granted restricted shares to our key administrative employees in September 2020 with service periods requirements; 2) an increase in listing expenses of RMB13.9 million mainly in connection with our listing; 3) increase of depreciation expenses of RMB4.4 million as a result of our lease of a new plant in 2021.

The following table sets forth a breakdown of our administrative expenses in absolute amounts of the total administrative expenses for the years indicated:

	Year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
Employee benefits expenses	**160,667**	51,855
Including: equity-settled share award expense	**155,144**	49,993
Depreciation expenses	**5,020**	613
Listing expenses	**19,400**	5,461
Professional service expenses	**5,141**	21,350
Utilities and office expenses	**2,755**	841
Others	**2,441**	1,436

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. In 2020 and 2021, we recorded equity-settled share award expenses of RMB218.1 million and RMB163.6 million, respectively, under our research and development expenses. We have established incentive platforms for such purposes.

Our research and development expenses decreased from RMB245.7 million in 2020 to RMB214.2 million in 2021. The decrease was primarily due to our grant to Mr. Jay Qin, a former technology consultant of AngioCare with no service periods or performance target requirements in 2020 and incurred one-off significant equity-settled share award expense related to this issue in 2020 and partially offsetting by increase of equity-settled share award expense related to our research and development employees with service periods requirements in 2021.

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

	Year ended December 31,	
	2021	2020
	RMB'000	*RMB'000*
Testing fees	**19,889**	8,611
Employee benefit expenses	**173,928**	222,022
Including: equity-settled share award expense	**163,581**	218,122
Costs of raw materials and consumables used	**6,816**	3,034
Depreciation expenses	**8,214**	8,030
Others	**5,381**	4,046

Other Expenses

Our other expenses mainly consist of foreign exchange differences and others.

Our other expenses decreased from RMB16.4 million in 2020 to RMB6.6 million in 2021. The decrease was primarily attributable to the net foreign exchange loss of RMB6.6 million in 2021, as compared to the net foreign exchange gain of RMB16.4 million in 2020 due to the less fluctuation of the exchange rate of USD against RMB in 2021 compared with 2020.

Finance Costs

Our finance costs mainly consist of interest on lease liabilities relating to our lease of office premises. During the Reporting Period, we entered into certain long-term lease contracts for office premises, with lease terms from one year to five years in general.

Our finance costs increased from RMB0.06 million in 2020 to RMB0.7 million in 2021. The increase was primarily attributable to increase of lease liabilities in 2021 compared with 2020.

Income Tax Expense

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

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

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

Loss for the Year

Based on the factors described above, our net losses amounted to RMB409.8 million and RMB340.3 million in 2021 and 2020 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 RMB88.5 million as of December 31, 2021, primarily due to the significant research and development expenses and administrative expenses we incurred during the Reporting Period. Our operating cash flow will continue to be affected by our research and development expenses. During the Reporting Period, we mainly relied on capital contributions by our shareholders and equity financing as the major sources of liquidity. Our management closely monitors uses of cash and cash balances and strives to maintain a healthy liquidity for our operations. Going forward, we believe our liquidity requirements will be satisfied by a combination of net proceeds from the Global Offering and cash generated from our operations.

Our net cash used in investing activities was RMB33.7 million as of December 31, 2021, primarily due to the purchases of items of property, plant and equipment by us during the Reporting Period.

Our net cash from financing activities was RMB383.7 million as of December 31, 2021, primarily due to the net proceeds we received from our listing during the Reporting Period.

As of December 31, 2021, we had cash and cash equivalents of RMB708.5 million, representing an increase of 56.2% compared to RMB453.7 million as at December 31, 2020.

Our net current assets increased from RMB456.9 million as at December 31, 2020 to RMB719.7 million as at December 31, 2021, primarily because of increase in the cash of the Group as a result of the net proceeds we received from our listing in December 2021.

Capital Expenditure

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

Our capital expenditures increased from RMB5.7 million in 2020 to RMB34.3 million in 2021. The increase was primarily attributable to increase of machinery and leasehold improvements.

Indebtedness

As at December 31, 2021, we did not have any outstanding balance of borrowings.

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

Our lease liabilities increased from RMB1.3 million as at December 31, 2020 to RMB22.4 million as at December 31, 2021, primarily because of increase of right-of-use assets.

Gearing Ratio

The gearing ratio of the Group, which was calculated by using total liabilities divided by total assets and multiplied by 100%, was 7.2% as of December 31, 2021, increased from 5.2% as of December 31, 2020. The increase was primarily due to increase of lease liabilities and other payables and accruals.

Capital Commitments

The capital commitments of the Group as at December 31, 2021 were RMB0.9 million, representing a decrease of RMB2.0 million as compared with that of RMB2.9 million as at December 31, 2020, primarily attributable to change of capital expenditures contracted for at year end, but not yet incurred, with respect to our purchase of property, plant and equipment.

Pledge of Assets

As at December 31, 2021, the Group had no pledge of assets.

Contingent Liabilities

As of December 31, 2021, we did not have any material contingent liabilities.

Significant Investments, Material Acquisitions and Disposals

As of December 31, 2021, 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 December 31, 2021, the Group had 50 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 year ended December 31, 2021 were approximately RMB334.6 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, non-competition and grounds for termination. In addition, we are required under PRC law to make contributions to statutory employee benefit plans (including pension plans, medical insurance, work-related injury insurance, unemployment insurance, maternity insurance and housing funds) at a certain percentage of our employees' salaries, including bonus and allowances, up to a maximum amount specified by the local government.

USE OF NET PROCEEDS FROM LISTING

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 up to the date of this announcement:

Use of proceeds	Percentage of total net proceeds	Allocation of net proceeds *(HK$ million)*	Utilized amount as at the date of this announcement *(HK$ million)*	Unutilized amount as at the date of this announcement[(1)] *(HK$ million)*	Expected timeline of full utilization of the unutilized proceeds[(2)]
To fund the ongoing confirmatory clinical trial, preparation for registration filings, and planned commercial launch of our Core Product, Bioheart®	62.0%	273.85	–	273.85	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 to fund the research and development, ongoing pre-clinical studies and planned clinical trials of other product candidates in our pipeline, including Bio-Leap™, Bioheart Ultra™, our Bioheart® balloon dilatation catheter, our Bioheart® non-compliant (high-pressure) balloon dilatation catheter and our Bioheart® impulse balloon dilatation catheters	6.7%	29.59	–	29.59	December 2026
General corporate and working capital purposes	10.0%	44.17	0.16	44.01	December 2026
Total	100%	441.7	0.16	441.53	

Notes:

1. As at the date of this announcement, the unused net proceeds were deposited with certain licensed banks in Hong Kong or the PRC.

2. The expected timeline to use the remaining proceeds is prepared based on the best estimate made by the Group, which is subject to change according to the current and future development of the market condition.

SUBSEQUENT EVENT AFTER THE REPORTING PERIOD

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.

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.

FINAL DIVIDEND

The Board did not recommend the payment of a final dividend for the year ended December 31, 2021.

ANNUAL GENERAL MEETING

The Company will hold the AGM on Thursday, June 2, 2022. The notice of AGM will be published on the Company's website (www.bio-heart.com) and the Stock Exchange (www.hkexnews.hk) and despatched to the Shareholders in the manner as required by the Listing Rules in due course.

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

The register of members of H Shares of the Company will be closed from Tuesday, May 3, 2022 to Thursday, June 2, 2022, both days inclusive, during which no transfer of H Shares will be registered, in order to determine the holders of the H Shares who are entitled to attend and vote at the forthcoming AGM.

To be eligible to attend and vote at the AGM, all properly completed transfer documents, accompanied by relevant share certificate, must be lodged with the Company's H Share registrar, Computershare Hong Kong Investor Services Limited at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong no later than 4:30 p.m. on Friday, April 29, 2022 for registration.

SUFFICIENCY OF PUBLIC FLOAT

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

CORPORATE GOVERNANCE PRACTICES

The Group is committed to maintaining high standards of corporate governance to safeguard the interests of the Shareholders and to enhance corporate value and accountability.

The Company has adopted the CG Code (version up to December 31, 2021) contained in Appendix 14 to the Listing Rules as its own code of corporate governance. The Company will adopt the new CG Code (version with effect from January 1, 2022), the requirement under which shall apply to the Company's corporate governance report in the forthcoming financial year ending December 31, 2022. During the period from the Listing Date to December 31, 2021, the Company has complied with all applicable code provisions of the CG Code save and except for the following deviation from code provision A.2.1 of the CG Code.

Under code provision A.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 paragraph A.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), four 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.

COMPLIANCE WITH THE 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's securities. Having made specific enquiries with all Directors and Supervisors, each of them has confirmed that he/she has complied with the Model Code from the Listing Date to December 31, 2021. 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.

PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES

The shares of the Company were listed on the Main Board of the Stock Exchange on December 23, 2021. During the period from the Listing Date to December 31, 2021, neither the Company nor any of its subsidiaries has purchased, sold or redeemed any of the Company's listed securities.

AUDIT COMMITTEE

The Board has established the Audit Committee which comprises three independent non-executive Directors, namely Mr. Charles Sheung Wai Chan, Mr. George Chien Cheng Lin, and Mr. Xubo Lu. Mr. Charles Sheung Wai Chan serves as the chairperson of the Audit Committee, who has the professional qualification and experience in financial matters in compliance with the requirements of the Listing Rules. The primary duties of the Audit Committee are to review and supervise the Company's financial reporting process and internal controls.

The Audit Committee, together with the management and external auditor of the Company of the Company, has reviewed the accounting principles and policies adopted by the Company and discussed internal control and financial reporting matters (including the review of the audited consolidated financial statements of the Group for the year ended December 31, 2021) of the Group, and is of the view that the annual results of the Group is prepared in accordance with applicable accounting standards, rules and regulations and appropriate disclosures have been duly made.

SCOPE OF WORK OF ERNST & YOUNG

The figures in respect of the Group's consolidated statement of financial position, consolidated statements of profit or loss and other comprehensive loss income the related notes thereto for the year ended December 31, 2021 as set out in this announcement have been agreed by the Group's auditor, Ernst & Young, to the amounts set out in the Group's audited consolidated financial statements for the Reporting Period. The work performed by Ernst & Young in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards on Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by Ernst & Young in this announcement.

PUBLICATION OF THE ANNUAL RESULTS AND 2021 ANNUAL REPORT

This annual results announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.bio-heart.com). The annual report of the Company for the year ended December 31, 2021 containing all the information required by the Listing Rules will be dispatched to the Shareholders and will be published on the respective websites of the Stock Exchange and the Company in due course.

APPRECIATION

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

DEFINITIONS

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

"AGM"	the 2021 annual general meeting of the Company to be held on June 2, 2022
"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 "Corporate Governance Code" as contained 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
"CRO(s)"	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
"Director(s)"	the director(s) of the Company or any one of them
"Domestic Share(s)"	ordinary share(s) in the share capital of our Company, with a nominal value of RMB1.00 each, which are subscribed for and paid up in RMB and are unlisted Shares which are currently not listed or traded in any stock exchange

"Global Offering"	the global offering of the H Shares, details of which are set forth in the Prospectus
"Group", "our Group", "our", "we", or "us"	the Company and all of its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
"H 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
"IPO"	the initial public offering of the H Shares on the Main Board of the Stock Exchange on December 23, 2021
"Listing"	the listing of the H Shares on the Main Board of the Stock Exchange
"Listing Date"	December 23, 2021, on which the H Shares were listed and from which dealings therein were permitted to take place on 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
"NDA"	new drug application

"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"	the year ended December 31, 2021
"RMB"	Renminbi, the lawful currency of the PRC
"SFO"	the Securities and Futures Ordinance, Chapter 571 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)
"Share(s)"	ordinary share(s) in the capital of our Company with a nominal value of RMB1.00 each, comprising 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
"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
"%"	per cent

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

Shanghai, the People's Republic of China, March 18, 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, Mr. Ji CHEN and Mr. Jie YIN 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*