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 HeartCare Medical Technology Corporation Limited

# 上海心瑋醫療科技股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 6609)

# ANNOUNCEMENT OF ANNUAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2023

FINANCIAL HIGHLIGHTS			
	Year ended December 31, 2023 RMB'000	Year ended December 31, 2022 RMB'000	Period-to- period change
Revenue	232,344	183,032	26.9%
Gross profit	163,759	124,333	31.7%
Gross profit margin	70.5%	67.9%	2.6 percentage
			points
Selling & distribution and administrative expenses	153,882	167,993	-8.4%
Research and development costs	123,831	153,693	-19.4%
Loss before tax	(102,920)	(201,249)	-48.9%

#### **BUSINESS HIGHLIGHTS**

In the fiscal year 2023, the Company's revenue increased to RMB232.3 million, representing a year-on-year increase of 26.9%, and its loss before tax narrowed to RMB102.9 million, representing a year-on-year decrease of 48.9%. As the business scale expands and the effects of cost control and efficiency enhancement measures become evident, the Company's gross profit margin increased by 2.6 percentage points to 70.5%, and the expense rate of the selling and distribution expenses and administrative expenses decreased to 66.2% (2022: 91.8%).

In 2023, in order to adapt to the fast-changing market environment and the advancement of volume-base procurement, the company continuously promotes the upgrade of its neuro-intervention business toward the focus on treatment devices. Neuro-intervention treatment devices such as thrombectomy devices and aspiration catheters, dilatation balloons, embolization protection system and embolic coils etc. contributed 42.3% of the sales (2022: 33.0%), and the revenue increased by 62.9% to RMB98.2 million year-on-year. Neuro-intervention access devices and other products increased 9.3% year-on-year to RMB134.1 million.

In 2023, the Company's R&D costs stood at RMB123.8 million to support the diversified candidates of neuro-intervention treatment devices. In the following 24 months, the Company expects to launch at least five major neuro-interventional treatment devices, including **drug-eluting balloon** (NMPA innovative device qualification), **self-expanding drug stent** and **carotid artery stent** for the treatment of stenosis, **aneurysm embolization assisting stent** (NMPA innovative device qualification) and **flow diverter device** for the treatment of hemorrhagic stroke. Furthermore, the Company aims to enhance the competitiveness of key thrombectomy devices (**aspiration catheter** and **thrombectomy stent**) and one-stop medical device solutions for different subtypes of acute ischemic stroke, to meet the growing demand for stroke treatment in the aging Chinese market.

In the overseas market, the Company have obtained CE or FDA certification of the thrombectomy device, balloon guiding catheter, distal access catheter and microcatheter, as well as completed registration and booted the commercialization in Thailand and other countries or regions. Up to now, the Company has been working on product registrations in ten other countries or regions, expanding sales channels, and laying the foundation for achieving long-term goals in overseas sales.

The Board announces the audited consolidated annual results of the Group for the year ended December 31, 2023, together with the comparative figures for the year ended December 31, 2022 as follows:

# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the year ended December 31, 2023

	Notes	2023 RMB'000	2022 RMB'000
REVENUE	4	232,344	183,032
Cost of sales	-	(68,585)	(58,699)
Gross profit		163,759	124,333
Other income and gains	4	26,108	35,321
Other expenses		(12,916)	(2,268)
Research and development costs		(123,831)	(153,693)
Selling and distribution expenses		(79,246)	(96,527)
Administrative expenses		(74,636)	(71,466)
Finance costs	5	(2,158)	(2,149)
Share of loss of an associate	-		(34,800)
LOSS BEFORE TAX		(102,920)	(201,249)
Income tax credit	6	8,908	865
LOSS AND TOTAL COMPREHENSIVE LOSS FOR THE YEAR	:	(94,012)	(200,384)
Attributable to: Owners of the parent		(94,012)	(200,384)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (RMB)	8	(2.47)	(5. 24)

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at December 31, 2023

	Notes	As at December 31, 2023 RMB'000	As at December 31, 2022 RMB'000
NON-CURRENT ASSETS			
Plant and equipment		69,939	83,345
Right-of-use assets		68,572	34,886
Goodwill		9,711	9,711
Other intangible assets		37,708	39,243
Prepayments, other receivables and other assets, non-current		7,398	12,952
Financial assets at fair value through profit or loss,			
non-current		2,525	400
Investment in an associate			
Total non-current assets		195,853	180,537
CURRENT ASSETS			
Inventories		146,039	132,158
Trade receivables	9	76,913	25,350
Prepayments, other receivables and other assets, current		53,205	100,372
Financial assets at fair value through profit or loss		98,934	100,372
Cash and bank balances		622,205	870,122
Restricted cash		8,096	4,020
Total current assets		1,005,392	1,132,022
CURRENT LIABILITIES			
Trade and other payables	10	51,779	48,309
Interest-bearing bank borrowing		_	5,000
Lease liabilities, current		4,911	5,878
Government grants, current		_	1,467
Contract liabilities		3,092	6,852
Total current liabilities		59,782	67,506

	Notes	As at December 31, 2023 RMB'000	As at December 31, 2022 RMB'000
NET CURRENT ASSETS		945,610	1,064,516
TOTAL ASSETS LESS CURRENT LIABILITIES		1,141,463	1,245,053
NON-CURRENT LIABILITIES			
Lease liabilities, non-current		31,472	39,809
Government grants, non-current		33,895	30,407
Deferred tax liabilities		452	9,360
Total non-current liabilities		65,819	79,576
Net assets		1,075,644	1,165,477
EQUITY			
Share capital	11	38,834	38,834
Treasury shares	11	(48,999)	(42,563)
Reserves		1,085,809	1,169,206
Total equity		1,075,644	1,165,477

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### 1. CORPORATE AND GROUP INFORMATION

Shanghai HeartCare Medical Technology Corporation Limited (the "Company") was incorporated in the People's Republic of China ("PRC") on June 16, 2016 as a limited liability company. On December 3, 2020, the Company was converted into a joint stock company with limited liability under the Company Law of the PRC. The registered office and the principal place of the business of the Company is located at 1st and 3rd Floor, Building 38, No. 356, Zhengbo Road, Lingang New District, Pilot Free Trade Zone, Shanghai, the PRC.

The Company was listed on the Main Board of The Stock Exchange of Hong Kong Limited (the "Stock Exchange") on August 20, 2021.

During the year, the Company and its subsidiaries (the "Group") were principally engaged in the research, development, manufacturing and sale of innovative medical devices.

#### 2.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRSs") (which include all IFRSs, International Accounting Standards ("IASs") and Interpretations) issued by the International Accounting Standards Board (the "IASB") and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention, except for financial assets at fair value through profit or loss. These financial statements are presented in Renminbi ("RMB") and all values are rounded to the nearest thousand except when otherwise indicated.

#### 2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The Group has adopted the following new and revised IFRSs for the first time for the current year's financial statements.

IFRS 17 Insurance Contracts

Amendments to IAS 1 and Disclosure of Accounting Policies

Proceeds IFRS Practice

Statement 2

Amendments to IAS 8 Definition of Accounting Estimates

Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a

Single Transaction

Amendments to IAS 12 International Tax Reform — Pillar Two Model Rules

The nature and the impact of the new and revised IFRSs that are applicable to the Group are described below:

- (a) Amendments to IAS 1 require entities to disclose their material accounting policy information rather than their significant accounting policies. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. Amendments to IFRS Practice Statement 2 *Making Materiality Judgements* provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. The Group has disclosed the material accounting policy information in note 2 to the financial statements. The amendments did not have any impact on the measurement, recognition or presentation of any items in the Group's financial statements.
- (b) Amendments to IAS 8 clarify the distinction between changes in accounting estimates and changes in accounting policies. Accounting estimates are defined as monetary amounts in financial statements that are subject to measurement uncertainty. The amendments also clarify how entities use measurement techniques and inputs to develop accounting estimates. Since the Group's approach and policy align with the amendments, the amendments had no impact on the Group's financial statements.
- (c) Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction narrow the scope of the initial recognition exception in IAS 12 so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences, such as leases and decommissioning obligations. Therefore, entities are required to recognise a deferred tax asset (provided that sufficient taxable profit is available) and a deferred tax liability for temporary differences arising from these transactions.

Prior to the initial application of these amendments, the Group applied the initial recognition exception and did not recognise a deferred tax asset and a deferred tax liability for temporary differences for transactions related to leases. The Group has applied the amendments on temporary differences related to leases and decommissioning obligations as at January 1, 2022, with no financial effect recognised as an adjustment to the balance of accumulated losses or other component of equity as at that date. Upon initial application of these amendments, the Group recognised (i) a deferred tax asset amounting to RMB7,265,000 for all deductible temporary differences associated with lease liabilities (provided that sufficient taxable profit is available), and (ii) a deferred tax liability amounting to RMB7,265,000 for all taxable temporary differences associated with right-of-use assets as at January 1, 2022.

(d) Amendments to IAS 12 International Tax Reform — Pillar Two Model Rules introduce a mandatory temporary exception from the recognition and disclosure of deferred taxes arising from the implementation of the Pillar Two model rules published by the Organisation for Economic Co-operation and Development. The amendments also introduce disclosure requirements for the affected entities to help users of the financial statements better understand the entities' exposure to Pillar Two income taxes, including the disclosure of current tax related to Pillar Two income taxes separately in the periods when Pillar Two legislation is effective and the disclosure of known or reasonably estimable information of their exposure to Pillar Two income taxes in periods in which the legislation is enacted or substantively enacted but not yet in effect. The Group has applied the amendments retrospectively. Since the Group did not fall within the scope of the Pillar Two model rules, the amendments did not have any impact to the Group.

#### 2.3 ISSUED BUT NOT YET EFFECTIVE IFRSs

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

Amendments to IFRS 10 and Sale or Contribution of Assets between an Investor and

IAS 28 its Associate or Joint Venture<sup>3</sup>

Amendments to IFRS 16 Lease Liability in a Sale and Leaseback<sup>1</sup>

Amendments to IAS 1 Classification of Liabilities as Current or Non-current

(the "2020 Amendments")1

Amendments to IAS 1 Non-current Liabilities with Covenants (the "2022

Amendments")1

Amendments to IAS 7 and Supplier Finance Arrangements<sup>1</sup>

IFRS 7

Amendments to IAS 21 Lack of Exchangeability<sup>2</sup>

- Effective for annual periods beginning on or after January 1, 2024
- <sup>2</sup> Effective for annual periods beginning on or after January 1, 2025
- No mandatory effective date yet determined but available for adoption

These issued but not yet effective IFRSs are not expected to have any significant impact on the Group's financial statements.

#### 3. OPERATING SEGMENT INFORMATION

#### **Segment information**

For management purposes, the Group is not organised into business units based on their products and only has one reportable operating segment. Management monitors the operating results of the Group's operating segment as a whole for the purpose of making decisions about resource allocation and performance assessment.

# 4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2023 RMB'000	2022 RMB'000
Revenue from contracts with Sale of medical devices	th customers  232,344	183,032
Revenue from contracts w	vith customers	
(a) Disaggregated reven	nue information	
	2023 RMB'000	2022 RMB'000
Geographical mark Chinese Mainland Others	231,273 	182,909 123
Total	232,344	183,032
Timing of revenue r Goods transferred at	_	183,032

The following table shows the amounts of revenue recognised in the current reporting period that were included in the contract liabilities at the beginning of the reporting period:

	2023	2022
	RMB'000	RMB'000
Sale of medical devices	3,258	3,257

# (b) Performance obligations

Information about the Group's performance obligations is summarised below:

Sale of medical devices

The performance obligation is satisfied upon transfer of the products to the logistics companies or acceptance by the customer. Payment is made in advance or due within 45 to 120 days from delivery. Some contracts provide customers with volume rebates which give rise to variable consideration subject to constraint.

An analysis of other income and gains is as follows:

	2023 RMB'000	2022 RMB'000
Other income		
Government grants (note)	11,211	11,876
Bank interest income	11,195	15,144
Others		3
Total other income	22,406	27,023
Gains		
Foreign exchange gains, net	1,403	8,298
Fair value gains on financial assets at FVTPL	934	_
Gain on disposal of items of property, plant and		
equipment	84	_
Gain on disposal of a subsidiary	1,281	
Total gains	3,702	8,298
Total other income and gains	26,108	35,321

#### Note:

The government grants mainly represent subsidies received from local government authorities for the purpose of compensation for expenditure arising from research and clinical trial activities, awards for new medical device development and capital expenditure incurred on certain projects.

#### 5. FINANCE COSTS

	2023 RMB'000	2022 RMB'000
Interest on lease liabilities Interest on bank loans	2,128	2,008 141
Total	2,158	2,149

#### 6. INCOME TAX

The provision for corporate income tax in Chinese Mainland is based on the statutory rate of 25% of the assessable profits as determined in accordance with the PRC Corporate Income Tax Law which was approved and became effective on January 1, 2008.

Weiming was accredited as a "Key industry enterprise in the Lingang New Area of China (Shanghai) Pilot Free Trade Zone" in January 2021 and has been entitled to a preferential income tax rate of 15% for a five-year period since 2020.

The Company was accredited as a "High and New Technology Enterprise" in November 2021 and therefore is entitled to a preferential tax rate of 15% for a three-year period since 2021. SealMed was accredited as a "High and New Technology Enterprise" in December 2023 and therefore is entitled to a preferential tax rate of 15% for a three-year period since 2023. The qualification as a High and New Technology Enterprise will be subject to review by the relevant tax authority in the PRC for every three years and the Company should self-evaluate whether it meets the criteria of High and New Technology Enterprise each year.

Pursuant to Caishui [2018] circular No. 76, the Company and its certain subsidiaries which were accredited as "Technology-based Small and Medium-sized Enterprises" can carry forward their unutilised tax losses for up to ten years. This extension of the expiration period applies to all the unutilised tax losses that were carried forward by the entities at the effective date of the tax circular.

Pursuant to the relevant EIT Law, the Company and its certain subsidiaries enjoyed a super deduction of 200% on qualifying research and development expenditures during the year ended December 31, 2023.

The income tax credit of the Group for the reporting period is analysed as follows:

	2023 RMB'000	2022 RMB'000
Current tax:		
Credit for the year	_	_
Deferred tax	(8,908)	(865)
	(8,908)	(865)

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:

	2023 RMB'000	2022 RMB'000
Loss before tax	(102,920)	(201,249)
Tax at the applicable tax rate of 25%	(25,730)	(50,312)
Lower tax rate enacted by local authority	6,621	12,791
Effect on opening deferred tax of decrease in rates	(3,744)	
Expenses not deductible for tax purpose	5,520	1,148
Additional deductible allowance for research and development		
expenses	(11,172)	(25,634)
Deductible temporary differences and tax losses not recognised	30,892	61,464
Utilization/recognition of deductible temporary differences		
and tax losses previously not recognized	(11,295)	(322)
Income tax expense credited to profit or loss	(8,908)	(865)

The Group has accumulated tax losses that are not recognised as deferred tax assets of RMB675,809,000 as at December 31, 2023 (2022: RMB624,117,000), that will expire in three to ten years for offsetting against future taxable profits of the entities in which the losses arose. The Group has deductible temporary differences of RMB70,875,000 as at December 31, 2023 (2022: RMB104,584,000), which are mainly related to government grants and share of loss of an associate.

#### 7. DIVIDENDS

No dividend has been paid or declared by the Company during the year (2022: Nil).

# 8. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amount is based on the loss for the year attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 38,077,150 (2022: 38,271,320) in issue during the year.

No adjustment has been made to the basic loss per share amounts presented for the years ended December 31, 2023 and 2022 in respect of a dilution as the impact of the share award schemes had an anti-dilutive effect on the basic loss per share amounts presented.

The calculations of basic and diluted loss per share are based on:

	2023	2022
Loss Loss attributable to ordinary equity holders of the parent, used in the basic loss per share calculation (RMB'000)	(94,012)	(200,384)
Shares Weighted average number of ordinary shares in issue during		
the year used in the basic loss per share calculation	38,077,150	38,271,320
Loss per share (basic and diluted) (RMB per share)	(2.47)	(5.24)

#### 9. TRADE RECEIVABLES

	2023 RMB'000	2022 RMB'000
Trade receivables Impairment	78,659 (1,746)	26,166 (816)
Net carrying amount	76,913	25,350

The Group's trading terms with its customers are payment in advance or on credit. The credit period is generally 45 to 120 days for major customers. Each customer has a maximum credit limit. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

An ageing of the trade receivables as at the end of each of the reporting period, based on the invoice date and net of loss allowance, is as follows:

	2023 RMB'000	2022 RMB'000
Within 6 months 6 to 12 months	76,913	25,303 47
Total	76,913	25,350

The movements in the loss allowance for impairment of trade receivables are as follows:

	2023 RMB'000	2022 RMB'000
At beginning of year Impairment losses	816 930	733 83
At end of year	1,746	816

Set out below is the information about the credit risk exposure on the Group's trade receivables using a provision matrix:

#### As at December 31, 2023

**10.** 

		Current
Expected credit loss rate		2.22%
Gross carrying amount (RMB'000)		78,659
Expected credit losses (RMB'000)		1,746
As at December 31, 2022		
		Current
Expected credit loss rate		3.12%
Gross carrying amount (RMB'000)		26,166
Expected credit losses (RMB'000)		816
TRADE AND OTHER PAYABLES		
	2023	2022
	RMB'000	RMB'000
Trade payables	3,667	4,132
Accrued expenses	6,872	6,523
Payroll payable	16,339	22,238
Other tax payables	7,431	1,369
Accrued listing expenses for A Share	_	2,409
Other payables	11,427	5,984
Advance payments received for subscription of share awards	,	,
(note)	6,043	5,654
	51,779	48,309

*Note:* The amount represented payments received from employees for subscribing share awards granted under the 2021 H Share Incentive Scheme.

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

	2023	2022
	RMB'000	RMB'000
Within 3 months	2,143	2,415
3 to 6 months	201	1,410
6 to 12 months	301	247
1 to 2 years	1,022	60
Total	3,667	4,132

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

#### 11. SHARE CAPITAL/TREASURY SHARES

**Shares** 

	2023 RMB'000	2022 RMB'000
Issued and fully paid:		
38,834,408 (2022: 38,834,408) ordinary shares of		
RMB1.00 each	38,834	38,834

#### **Treasury shares**

On November 1, 2021, shareholders of the Group approved the adoption of the 2021 H share incentive scheme (the "2021 H Share Incentive Scheme"). Pursuant to the 2021 H Share Incentive Scheme, 275,000 (2022: 418,250) shares were purchased on the Hong Kong Stock Exchange by the trustee under the scheme at a total consideration of RMB6,436,000 (2022: RMB21,378,000) before expenses during the year, of which RMB6,374,000 was settled as at 31 December 2023 and RMB62,000 was settled subsequently.

#### MANAGEMENT DISCUSSION AND ANALYSIS

# I. BUSINESS

#### Overview

We are an innovative medical device company committed to improving the accessibility of innovative medical technologies and protecting lives and health. We have established a pioneering leadership position in China's neuro-interventional market and successfully provided the first domestic one-stop solution for stroke treatment and prevention. Leveraging our advantage in R&D, manufacturing and commercialization, we strive to fulfill the unmet needs of clinicians and patients in the fields with tremendous opportunities, redefine the standard of care, reduce mortality rate, and improve prognosis by continuously launching innovative medical devices.

In the fiscal year 2023, the Company's revenue increased to RMB232.3 million, representing a year-on-year increase of 26.9%, and its loss before tax narrowed to RMB102.9 million, representing a year-on-year decrease of 48.9%. As the business scale expands and the effects of cost control and efficiency enhancement measures become evident, the Company's gross profit margin increased by 2.6 percentage points to 70.5%, and the expense rate of the selling and distribution expenses and administrative expenses decreased to 66.2% (2022: 91.8%).

In 2023, in order to adapt to the fast-changing market environment and the advancement of volume-base procurement, the company continuously promotes the upgrade of its neuro-intervention business toward the focus on treatment devices. Neuro-intervention treatment devices such as thrombectomy devices and aspiration catheters, dilatation balloons, embolization protection system and embolic coils etc. contributed 42.3% of the sales (2022: 33.0%), and the revenue increased by 62.9% to RMB98.2 million year-on-year. Neuro-intervention access devices and other products increased 9.3% year-on-year to RMB134.1 million.

In 2023, the Company's R&D costs stood at RMB123.8 million to support the diversified candidates of neuro-intervention treatment devices. In the following 24 months, the Company expects to launch at least five major neuro-interventional treatment devices, including **drug-eluting balloon** (NMPA innovative device qualification), **self-expanding drug stent** and **carotid artery stent** for the treatment of stenosis, **aneurysm embolization assisting stent** (NMPA innovative device qualification) and **flow diverter device** for the treatment of hemorrhagic stroke. Furthermore, the Company aims to enhance the competitiveness of key thrombectomy devices (**aspiration catheter** and **thrombectomy stent**) and one-stop medical device solutions for different subtypes of acute ischemic stroke, to meet the growing demand for stroke treatment in the aging Chinese market.

In the overseas market, the Company has obtained CE or FDA certification of the thrombectomy device, balloon guiding catheter, distal access catheter and microcatheter, as well as completed registration and booted the commercialization in Thailand and other countries or regions. Up to now, the Company has been working on product registrations in ten other countries or regions, expanding sales channels, and laying the foundation for achieving long-term goals in overseas sales.

# **Products and Pipeline**

As of the date of this announcement, we have 28 device products approved by NMPA, three device products approved by FDA and one product obtained CE Mark.

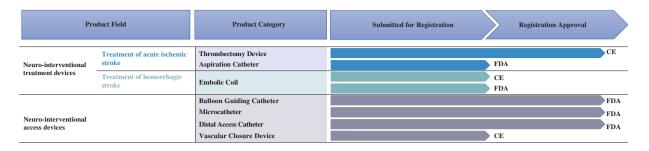
The following diagram summarizes the development status of our neuro-interventional pipeline including approved products and broad product pipelines in the late-stage of R&D covering acute ischemic stroke and neurovascular stenosis treatment, hemorrhagic stroke treatment, ischemic stroke prevention, and interventional access as of the date of this announcement:

# **NMPA Pipeline**

Product Field		Product Category	Desing Stage Clinical Registration and Evaluation Stage Evaluation Stage
	Treatment of acute ischemic stroke	Thrombectomy Device Aspiration Pump Aspiration Catheter	
Neuro-interventional treatment devices	Treatment of neurovascular stenosis	Drug-eluting Balloon Catheter* Intracranial Drug-eluting Stent Intracranial Balloon Dilatation Catheter	
		Intracranial Low Pressure Balloon Dilatation Catheter Carotid Artery Balloon Dilatation Catheter	
		Embolization Protection System Carotid Artery Stent Embolic Coil	
	Treatment of hemorrhagic stroke	Coil Embolization Assistant Stent* Embolization Assisting Balloon Flow Diverter Device	
	Prevention of ischemic stroke	Left Atrial Appendage (LAA) Occluder	
Neuro-interventional access devices		Balloon Guiding Catheter Distal Access Catheter Microcatheter	
		Microcatheter for Coiling Microcatheter for Flow Diverter Device Navigation Catheter	
		Vascular Closure Device Neuro-interventional Micro Guidewire	
		Support Catheter Neuro-interventional Microcatheter	

<sup>\*</sup> Eligible for NMPA Green Channel

# FDA and Conformité Européenne (CE) Pipeline



# Our Key Neuro-interventional Products and Product Candidates

Ischemic stroke thrombectomy devices

Core Product — Captor® Thrombectomy Device ("Captor") is the first domestic thrombectomy stent retriever with multi-markers approved by NMPA. Sales in China started in December 2020. As of the date of this announcement, we have upgraded Captor by adding more product models with stents of varying lengths and diameters. Depending on the occluded blood vessel diameter and thrombus size, physicians may choose the stent retriever with the proper length and size, out of a selection of nine product models. We are evaluating the opportunities for upgrading Captor for indication expansion. Further, we are evaluating the opportunities to market Captor overseas and may apply for its registration in the United States subject to the results of our evaluation. This product has obtained CE Mark during the Reporting Period.

# WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP NEW INDICATION AND SPECIFICATIONS AND EXPAND OVERSEAS MARKET FOR OUR CAPTOR SUCCESSFULLY.

**Aspiration Catheter** is used in the aspiration thrombectomy procedure to retrieve the thrombus and restore blood flow in occluded cerebral vessels for patients with acute ischemic stroke with large vessel occlusion ("**AIS-LVO**"). Aspiration thrombectomy can be performed not only on a stand-alone basis, but also together with stent retrieving thrombectomy in accordance with the patient's symptoms. We have obtained the NMPA approval for our aspiration catheter and sales commenced in 2022.

Besides Captor and Aspiration Catheter, our **Aspiration Pump** for the treatment of ischemic stroke has obtained NMPA approval, and we had a product portfolio covering stents and aspiration thrombectomy procedure for the emergency treatment of different subtypes of acute ischemic stroke.

Intracranial Drug-eluting Balloon Catheter ("Intracranial DEB") is designed to deliver an anti-proliferative drug to the lesion to prevent fibrosis and vessel occlusion. We initiated a registration clinical trial for intracranial DEB in May 2020. As of the date of this announcement, our intracranial DEB has completed the clinical trial, and was in NMPA registration stage. This product has obtained green channels for NMPA review.

**Embolization Protection System** is used in interventional procedures for peripheral, coronary artery and carotid artery to capture and remove debris that dislodges during the procedures. It can help prevent the debris from blocking smaller vessels, which may result in procedural complications. We have obtained the NMPA approval for our embolization protection system.

Hemorrhagic Stroke Treatment Devices

**Coil Embolization Assistant Stent** is used in aneurysm coiling procedures for patients with aneurysm. It is designed for bridging the neck of aneurysm to support the coils placed in the aneurysm. As of the date of this announcement, clinical trials of our coil embolization assistant stent was completed and we have submitted the application for NMPA registration. It has obtained green channels for NMPA review.

**Flow Diverter Device** is a neurovascular stent placed in the blood vessel of an aneurysm, which can divert blood flow away from the aneurysm. Over time, blood flow into the aneurysm may slow down and the aneurysm may shrink, thus healing the blood vessel. As at the date of this announcement, the patient enrollment for clinical trials of our flow diverter devices was completed.

Ischemic Stroke Prevention Devices

Core Product — LAA Occluder is a stroke prevention device designed to be permanently implanted at the opening of the LAA of patients with non-valvular atrial fibrillation (AF) to prevent thrombus escaping from the LAA, thus causing embolization. LAA Occlusion is a one-time surgical therapy with proven efficacy, in particular for the patient who is not suitable for long-term oral anticoagulation therapy and has a higher risk for bleeding complications. We have obtained the NMPA approval and commenced sales in 2022.

We are also developing various vascular access devices for use in interventional procedures. As of the date of this announcement, we have obtained NMPA approvals for Distal Access Catheter, Microcatheter, Balloon Guiding Catheter, Vascular Closure Device, Support Catheter, Neuro-Interventional Microcatheter, Micro Guidewire, Microcatheter for Coiling, Microcatheter for Flow Diverter Device and Navigation Catheter.

In addition, we have several other product candidates in the design stage, which further supplement our full-set product portfolio for the treatment and prevention of stroke. For details of our products and product candidates, please refer to the Prospectus.

#### **Research and Development**

The Company's product R&D aims to build a high-quality product portfolio with market competitiveness. Capitalizing on existing R&D platforms, certain products we developed are qualified for NMPA priority review. Meanwhile, we formed a multi-level product matrix through continuously iterating products approved for marketing, so as to meet the clinical needs.

As of the date of this announcement, we had 195 registered patents, including 87 invention patents, 96 utility models and 12 industrial design patents. As of the date of this announcement, we also had 135 pending patents applications, including 118 invention patents and 17 utility models.

#### **Manufacturing**

In terms of manufacturing, we continuously improve our product quality and competitive advantage based on a stable and efficient supply chain.

As of the date of this announcement, we have three production facilities in Shanghai Lingang New Area, Shanghai Zhangjiang and Nanjing Jiangbei New Area, which can ensure a sufficient supply of products.

#### Commercialization

As of the date of this announcement, we have established an extensive distribution network covering over 1,500 hospitals across all provinces nationwide other than Hong Kong, Macao and Taiwan.

Meanwhile, academic exchange platforms elaborately built by us contribute to our brand image and influence in the market through diversified channels and digital media, laying the foundation for long-term and stable revenue growth.

#### **Future and Outlook**

We aim to become the leader in the neuro-interventional medical device market in China, and to develop into a competitive domestic device company in several innovative medical device markets within China.

We plan to implement the following strategies to achieve this goal:

- improve our brand recognition as a comprehensive neuro-interventional device solution provider in the market, expand sales of our commercialized neuro-interventional devices and rapidly advance our product candidates into commercialization;
- further enhance our manufacturing capabilities to ensure reliability of our product supply; and
- promote the development of innovative medical devices in emerging therapeutic fields with high potential growth market to form a second business unit with a competitive commercialized product portfolio in addition to our neuro-interventional business.

The Company also proposed to apply to the relevant PRC authorities for the issuance of A shares to be listed on the Science and Technology Innovation Board of the Shanghai Stock Exchange, please refer to the Company's announcements dated October 10, 2022, November 9, 2022 and October 16, 2023 and circulars dated October 24, 2022 and October 20, 2023 for further details.

#### II. FINANCIAL REVIEW

#### Overview

The following discussion is based on, and should be read in conjunction with, the financial information and the notes included elsewhere in this announcement.

#### Revenue

For the year ended December 31, 2023, all our revenue was generated from the sales of our commercialized neuro-interventional devices.

Revenue increased by 26.9% from RMB183.0 million for the year ended December 31, 2022 to RMB232.3 million for the year ended December 31, 2023. The increase in revenue was mostly attributable to sales growth of treatment devices mainly including thrombectomy devices, dilatation balloons and embolic coils. Meanwhile, we boosted overseas revenue after a number of product registrations approved by local bureau.

#### **Cost of Sales**

Cost of sales increased from RMB58.7 million for the year ended December 31, 2022 to RMB68.6 million for the year ended December 31, 2023, which was in line with the increase in our revenue.

# **Gross Profit and Gross Profit Margin**

As a result of the foregoing, our gross profit increased from RMB124.3 million for the year ended December 31, 2022 to RMB163.8 million for the year ended December 31, 2023. Gross profit margin is calculated as gross profit divided by revenue. Our gross profit margin increased from 67.9% for the year ended December 31, 2022 to 70.5% for the year ended December 31, 2023, primarily attributed to increased manufacture scale, and the increasingly mature manufacturing techniques.

#### Other Income and Gains

Other income and gains decreased from RMB35.3 million for the year ended December 31, 2022, to RMB26.1 million for the year ended December 31, 2023, primarily attributable to (i) the decrease in bank interest income and (ii) the decrease in foreign exchange gains, net.

# **Research and Development Costs**

Research and development costs decreased from RMB153.7 million for the year ended December 31, 2022, to RMB123.8 million for the year ended December 31, 2023, primarily due to the decrease in the number of our pipeline candidates and the reduction of R&D team.

The following table sets forth a breakdown of our research and development costs:

	Year ended December 31, 2023		Year ended December 31, 2022	
	RMB million	%	RMB million	
Staff Costs	43.9	35.5	51.9	33.8
Depreciation	8.2	6.6	9.4	6.1
Third party contracting costs	35.9	29.0	51.7	33.6
Raw materials and consumables	28.0	22.6	29.9	19.5
Other	7.8	6.3	10.8	7.0
	123.8	100.0	153.7	100.0

# **Administrative Expenses**

Administrative expenses increased from RMB71.5 million for the year ended December 31, 2022 to RMB74.6 million for the year ended December 31, 2023, primarily attributed to an increase in staff costs.

# **Selling and Distribution Expenses**

Selling and distribution expenses decreased from RMB96.5 million for the year ended December 31, 2022 to RMB79.2 million for the year ended December 31, 2023, primarily attributed to reducing in staff costs and market development costs.

# **Other Expenses**

For the year ended December 31, 2023, we incurred other expenses of RMB12.9 million, which was primarily in relation to the impairment of inventories.

#### **Finance Costs**

Finance costs increased from RMB2.1 million for the year ended December 31, 2022, to RMB2.2 million for the year ended December 31, 2023.

# **Borrowings and Gearing Ratio**

The Group has not incurred any outstanding borrowing as at December 31, 2023, compared to RMB5 million as at December 31, 2022. The gearing ratio (calculated by dividing the sum of borrowings and lease liabilities by total equity) of the Group as at December 31, 2023 was 3.4%, compared to 4.3% for the year ended December 31, 2022.

# **Liquidity and Financial Resources**

We primarily rely on capital contributions by our shareholders, equity financing as the major sources of liquidity as well as cash generated from our sales revenue of existing commercialized medical device products. As part of our treasury policy, our management monitors and maintains a level of cash and bank balances deemed adequate to finance our operations and mitigate the effects of fluctuations in cash flows. As our business develops and expands, we expect to generate more cash from our operating activities, through increasing sales revenue of the existing commercialized products and by launching new products.

Our cash and bank balances as of December 31, 2023 were RMB622.2 million, representing a decrease of RMB247.9 million compared to RMB870.1 million as of December 31, 2022.

Our net current assets as of December 31, 2023 were RMB945.6 million, as compared to RMB1,064.5 million as of December 31, 2022.

#### Capital Expenditure

For the year ended December 31, 2023, our total capital expenditure amounted to approximately RMB49.3 million as compared to a capital expenditure of RMB37.2 million for the year ended December 31, 2022. The capital expenditure was primarily used in the acquisition of a land-use-right.

# **Contingent Liabilities**

As of December 31, 2023, the Group did not have any material contingent liabilities.

# Significant Investments, Material Acquisitions and Disposals

On December 11, 2023, the Company and Mr. Xing Tingyu, Mr. Li Meng, Value Magnet Limited and Shanghai Shenji Zhixin Enterprise Management Consulting Partnership (Limited Partnership) (collectively, the "Purchasers") entered into an equity transfer agreement pursuant to which the Company conditionally agreed to sell its entire equity interest in Shanghai Shenji Medical Technology Co., Ltd. (上海神璣醫療科技有限公司, "Shenji Medical") to the Purchasers for an aggregate consideration of RMB9.0 million. Upon completion, the Company will cease to have any interest in Shenji Medical and it will cease to be a subsidiary of the Company. Value Magnet Limited is controlled by Mr. Ding Kui (a director of the Company) and Ms. Li Jun (the spouse of Mr. Ding Kui) and therefore an associate of a connected person.

Since its inception, Shenji Medical has initiated research and development on potential robotics medical devices. As of the date of the equity transfer agreement, none of the medical devices under development has advanced to late stage due to various unforeseen or unexpected difficulties that were encounter during the development process. The Group would have to commit significant resources to bring these medical devices into commercialization and there is no assurance that these products could be successfully developed and commercialized. Continued investment into Shenji Medical and its research and development effort would also further divert resources away from the Group's core business of neuro-intervention medical devices. Therefore the Board considers that it is suitable to dispose of Shenji Medical by way of a management buy-out by existing employees backed by experienced investor in the biotechnology sector.

The Company will continue to enable internal resource allocated to the core business of the Group, focusing on the development and commercialization of medical devices in the field of neuro-intervention. The Group will continue to work on the pipeline products set out in this announcement, and does not expect that the disposal of Shenji Medical will have a material adverse impact on the business operations and financial position of the Group.

For further details, please refer to the Company's announcement dated December 11, 2023.

Saved as disclosed above, the Group did not have material acquisitions and disposals of subsidiaries, associates and joint ventures, or have any significant investment accounting for more than 5% of the Group's total assets for the year ended December 31, 2023.

# **Pledge of Assets**

As of December 31, 2023, the Group had no pledge of assets.

# Foreign Exchange Exposure

We are exposed to foreign currency risk mainly arising from cash at bank denominated in USD and HKD. 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**

We had not authorized any plan for the material investments or acquisition of capital assets as of the date of this announcement.

#### **HUMAN RESOURCES**

As of December 31, 2023, we had 368 full-time employees in total.

The remuneration policy for the Directors and senior management is based on their responsibility and general market conditions. Any discretionary and performance bonus are linked to the general performance of the Group and the individual performances of the Directors and senior management.

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 and grounds for termination.

To remain competitive in the labor market, we provide various incentives and benefits to our employees. We invest in continuing education and training programs, including internal and external training, for our management staff and other employees to upgrade their skills and knowledge. We also provide competitive salaries and stock incentive plans to our employees especially key employees. We believe our benefits, working environment and development opportunities for our employees have contributed to good employee relations and employee retention.

# SUBSEQUENT EVENTS 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.

# 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.

# PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES OF THE COMPANY

Neither the Company nor any of its subsidiaries have purchased, sold or redeemed any of the Company's listed securities during the Reporting Period.

#### **USE OF PROCEEDS FROM LISTING**

The H Shares of the Company were first listed on the Main Board of the Stock Exchange on August 20, 2021. Net proceeds received from our Global Offering aggregated approximately HK\$1,014.8 million. Reference is made to the Company's Prospectus dated August 10, 2021.

Details of the planned applications of net proceeds from the Listing were disclosed in the Prospectus. As at December 31, 2023, the utilisation of the net proceeds from the Global Offering are as follows:

Use of proceeds	Planned applications (HK\$ million)	31, 2022	O	31, 2023	at December 31, 2023	Expected timeline for full utilisation of the unutilised net proceeds
R&D, manufacturing and						December 31,
marketing of our core products	459.7	187.7	79.6	267.3	192.4	2025
R&D, product registration, manufacturing and marketing of other product candidates in our pipeline	404.9	160.3	62.8	223.1	181.8	December 31, 2025
Improvements to our R&D capacities and our continued expansion of product portfolio						
through internal research Working capital and general	48.7	48.7	_	48.7	_	_
corporate purposes	101.5	101.5		101.5		_
Total	1,014.8	498.2	142.4	640.6	374.2	

# FINAL DIVIDEND

The Board does not recommend the payment of a final dividend for the Reporting Period (2022: Nil).

#### ANNUAL GENERAL MEETING

The Company will hold the annual general meeting (the "AGM") on Monday, May 20, 2024. A notice of convening the AGM will be published on the websites of the Stock Exchange at www.hkexnews.hk and the Company at www.heartcare.com.cn, and dispatched to the Shareholders in the manner as required by the Listing Rules in due course.

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

The register of members of H Shares of the Company will be closed from Saturday, April 20, 2024 to Monday, May 20, 2024 (both days inclusive), during which period no transfer of H Shares will be registered. In order to qualify for attending and voting at the AGM, all transfer documents accompanied by the relevant share certificate(s) must be lodged with the Company's H Share registrar, Computershare Hong Kong Investor Services Limited at Shops 1712–1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong no later than 4:30 p.m. on Friday, April 19, 2024.

#### CORPORATE GOVERNANCE PRACTICES

The Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the shareholders of the Company as a whole. The Company has adopted the code provisions as set out in the Corporate Governance Code as its own code to govern its corporate governance practices. Except for code provision C.2.1 set out below, in the opinion of the Directors, the Company has complied with all the code provisions as set out in Part 2 of the CG Code during the Reporting Period.

Under code provision C.2.1 of Part 2 of the CG Code, the roles of chairman and chief executive officer should be separate and should not be performed by the same individual. Mr. Wang Guohui is the chairman of the Board and chief executive officer of the Company. With extensive experience in the medical devices industry and having served in the Company as the general manager since the very early stage of our Company, Mr. Wang is in charge of overall management of the Company. Despite the fact that the roles of our chairman of the Board and our chief executive officer are both performed by Mr. Wang which constitutes a deviation from code provision C.2.1 of Part 2 of the CG Code, the Board considers that vesting the roles of both chairman of the Board and chief executive officer all in Mr. Wang has the benefit of ensuring consistent leadership and more effective and efficient overall strategic planning of the Company. The balance of power and authority is ensured by the operation of our Board, which comprises experienced and diverse individuals. The Board currently comprises three non-executive Directors and three independent non-executive Directors as compared to three executive Directors. Therefore, the Board possesses a strong independent element in its composition. The Board will continue to review and monitor the practices of the Company with an aim of maintaining a high standard of corporate governance.

#### MODEL CODE FOR SECURITIES TRANSACTIONS

The Company has adopted the Model Code as its own code of conduct regarding dealings in the securities of the Company by the Directors, Supervisors and the Company's senior management who, because of their office or employment, are likely to possess inside information in relation to Company or its securities.

Upon specific enquiry, all Directors and Supervisors confirmed that they have complied with the Model Code during the Reporting Period. In addition, the Company is not aware of any non-compliance with the Model Code by the senior management of the Group during the Reporting Period.

# REVIEW OF ANNUAL RESULTS AND ANNUAL REPORT

The Audit Committee has three members comprising two independent non-executive Directors, being Mr. Gong Ping (chairman) and Mr. Feng Xiangqian, and one non-executive Director, being Mr. Ding Kui, with terms of reference in compliance with Rule 3.21 of the Listing Rules. The Audit Committee has considered and reviewed the accounting principles and practices adopted by the Group and has discussed matters in relation to internal controls, risk management and financial reporting with the management, including the review of the audited consolidated financial statement and the annual report of the Group for the Reporting Period.

The Audit Committee, together with the management and external auditor of the Company, considers that the audited consolidated financial statements of the Group for the Reporting Period are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

# Scope of Work of Ernst & Young

The figures in respect of the Group's consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the Reporting Period as set out in this announcement have been agreed by the Company's auditors, Ernst & Young (the "Auditors"), to the amounts set out in the Group's audited consolidated financial statements for the Reporting Period.

The work performed by the Auditors 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 the Auditors on this announcement.

# PUBLICATION OF ANNUAL RESULTS AND 2023 ANNUAL REPORT

This announcement is published on the websites of the Stock Exchange at www.hkexnews.hk and the Company at www.heartcare.com.cn. The annual report of the Company for the Reporting Period containing all the information required by the Listing Rules will be published on the respective websites of the Stock Exchange and the Company and will be dispatched to the Shareholders (if necessary) in due course.

#### **DEFINITIONS**

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

"AGM" The forthcoming annual general meeting of the Company to be

held on Monday, May 20, 2024

"Audit Committee" the audit committee of the Board

"Board" or "Board of the boa

Directors"

the board of directors of the Company

"CG Code" or "Corporate the C

Governance Code"

the Corporate Governance Code set out in Appendix C1 to the

Listing Rules

"China" or "PRC" the People's Republic of China, but for the purpose of this

announcement and for geographical reference only and except where the context requires, excluding Hong Kong, Macau

Special Administrative Region and Taiwan

"Company" or "our

Company"

Shanghai HeartCare Medical Technology Corporation Limited (上海心瑋醫療科技股份有限公司), a joint stock limited

liability company incorporated in the PRC, whose H Shares are

listed on the Stock Exchange (Stock Code: 6609)

"Director(s)" the director(s) of the Company or any one of them

"FDA" the U.S. Food and Drug Administration

"Global Offering" has the meaning as ascribed to it under the Prospectus

"Group", "the Group",

"our Group", "our",

"we" or "us"

the Company and its subsidiaries

"H Share(s)" the overseas listed foreign shares with a nominal value of

RMB1.00 each in the share capital of the Company, which are listed on the Hong Kong Stock Exchange and subscribed for

and traded in Hong Kong dollars

"Hong Kong" or "HK" the Hong Kong Special Administrative Region of the PRC

"Hong Kong dollars", Hong Kong dollars and cents respectively, the lawful currency "HKD" or "HK\$" 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 Shares on the Main Board of the Stock Exchange "Listing Rules" the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time "Model Code" the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix C3 to the Listing Rules "NMPA" the National Medical Products Administration (國家藥品 監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局) or the CFDA "Prospectus" the prospectus of the Company dated August 10, 2021, in relation to the Global Offering "R&D" research and development "Reporting Period" the year ended December 31, 2023 "RMB" or "Renminbi" Renminbi, the lawful currency of the PRC "Share(s)" share(s) in the share capital of the Company, with a nominal value of RMB1.00 each, comprising the Unlisted Shares and H Shares "Shareholder(s)" holder(s) of the Share(s) "Stock Exchange" The Stock Exchange of Hong Kong Limited "Subsidiary" has the meaning ascribed thereto under the Listing Rules

the supervisor(s) of the Company

"Supervisor(s)"

"Unlisted Share(s)" the ordinary shares in the share capital of the Company, with a nominal value of RMB1.00 each, which are subscribed and credited as fully paid up in Renminbi

"United States" or "U.S." the United States of America, its territories, its possessions and all areas subject to its jurisdiction

"U.S. dollars", "US\$" or "Usb" United States dollars, the lawful currency of the United States "USD"

"%" per cent

# By Order of the Board Shanghai HeartCare Medical Technology Corporation Limited Wang Guohui

Chairman of the Board

Shanghai, March 28, 2024

As at the date of this announcement, the executive Directors are Mr. Wang Guohui, Ms. Zhang Kun and Mr. Wei Jiawei; the non-executive Directors are Mr. Ding Kui, Mr. Chen Shaoxiong and Mr. Chen Gang; and the independent non-executive Directors are Mr. Guo Shaomu, Mr. Feng Xianggian and Mr. Gong Ping.