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## Peijia Medical Limited

### 沛嘉醫療有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9996)

## ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2022

The Board is pleased to announce the audited consolidated results of the Group for the year ended December 31, 2022, together with the audited comparative figures for the year ended December 31, 2021.

### FINANCIAL HIGHLIGHTS

	Year ended December 31,		Year-on-year change
	2022	2021	
	RMB'000	RMB'000	
Revenue	250,833	136,534	83.7%
Gross profit	176,201	95,654	84.2%
Loss before income tax	(398,235)	(574,216)	-30.6%
Loss for the period and attributable to the owners of the Company	(407,809)	(574,216)	-29.0%
Cash, cash equivalents and term deposits	1,839,665	2,296,112	-19.9%
Research and development expenses	(373,127)	(445,879)	-16.3%
Including: One-time BD expenses*	(226,111)	(314,575)	-28.1%

\* This item is not required by, or presented in consolidated financial statements in accordance with, IFRS.

## **BUSINESS HIGHLIGHTS**

- 1. THE TRANSCATHETER VALVE THERAPEUTIC BUSINESS HAS EXPERIENCED MEANINGFUL ACCELERATION AS A RESULT OF OUTSTANDING PRODUCT PERFORMANCE AND PROFESSIONAL MARKET EDUCATION AND PROMOTION. WE HAVE SEEN AN INCREASE IN ADOPTION RATE IN NEW HOSPITALS AND UTILIZATION RATE IN ADOPTED HOSPITALS OF OUR PRODUCTS THROUGHOUT THE YEAR.**

We have consistently met our guidance in 2022 and have made significant progress with product adoption in hospitals. As of December 31, 2022, our products have been placed in 290 hospitals, representing an increase of 195 hospitals as compared to the year end of December 31, 2021.

Although the overall market has been affected by the COVID-19 pandemic, the sales and implantation of our TaurusOne® and TaurusElite® products have made steady progress, repeatedly setting new monthly highs in implantation volume. For the Reporting Period, the revenue of the Transcatheter Valve Therapeutic Business increased by 155.9% as compared to the same period of 2021, and the total implantation volume for the year is around four times of 2021.

The Transcatheter Valve Therapeutic Business has progressed rapidly since its commercial launch, as a result of our cross functional teams comprised of marketing, sales and medical professionals. The well rounded support includes academic promotion, collaboration on new technologies, patient identification, physician training, preoperative, intraoperative and postoperative clinical support and diligent sales service. The product adoption by new hospitals and the utilization rate in the adopted hospitals, especially in core hospitals, continued rising. The rapid advancement of commercialization has laid a solid cash foundation for the long-term development of the Company.

**2. WITH THE SUCCESSIVE LAUNCH OF FOUR ISCHEMIC PRODUCTS IN OUR NEUROINTERVENTIONAL BUSINESS IN 2022, THE ISCHEMIC PRODUCT PORTFOLIO IS WELL ESTABLISHED FOR MARKET ADOPTION. THE CONTINUOUS DEVELOPMENT OF THE ISCHEMIC PRODUCT LINE, COUPLED WITH THE FIRST MOVER ADVANTAGE OF OUR HEMORRHAGIC PRODUCT LINE, ENABLE US TO FURTHER DIVERSIFY THE REVENUE COMPOSITION OF THE NEUROINTERVENTIONAL BUSINESS.**

During the Reporting Period, the registration applications of four of our products have been approved by the NMPA, namely, Syphonet<sup>®</sup> Stent Retriever, Tethys AS<sup>®</sup> Aspiration Catheter, Fastunnel<sup>®</sup> Delivery Balloon Dilatation Catheter and Fluxcap<sup>®</sup> Balloon Guide Catheter. The product portfolio of our ischemic product line has been preliminarily established, with all major devices readily in place.

The newly approved Syphonet<sup>®</sup> Stent Retriever, Tethys AS<sup>®</sup> Aspiration Catheter and Fluxcap<sup>®</sup> Balloon Guide Catheter, together with the existing products including Tethys<sup>®</sup> Intermediate Catheter and Presgo<sup>®</sup> Microcatheter, form a complete solution for AIS patients. The unique “zero exchange” technology of Fastunnel<sup>®</sup> Delivery Balloon Dilatation Catheter is poised to disrupt the standard of care in ICAD treatment. Together with SacSpeed<sup>®</sup> Balloon Dilatation Catheter, we aim to provide better treatment solutions to more patients with ICAD.

In 2022, we continued increasing sales and capturing market share in the sizable hemorrhagic market. As a result of our continued efforts in product upgrades and long-established sales relationships, the revenue generated from the Neurointerventional Business for the Reporting Period increased by 51.7% as compared to the same period of 2021. Our revenue from hemorrhagic products, ischemic products and vascular access products accounted for 39.4%, 27.6% and 32.9% of the revenue from the Neurointerventional Business, respectively. With increasing sales from hemorrhagic products and upcoming commercialization of recently approved ischemic products, the revenue composition of our Neurointerventional Business will further diversify. This will not only create stability for the Company in this market, but also enhance the attractiveness and synergy of our product portfolio among physicians and distributors.

**3. PIONEERING IN THE NEXT-GENERATION TECHNOLOGIES OF TRANSCATHETER VALVE THERAPIES, WE HAVE DEVELOPED A COMPETITIVE AND COMPREHENSIVE PIPELINE WITH INNOVATIVE TECHNOLOGIES TO MEET LARGE UNMET NEEDS IN THE MARKET. MAJOR PRODUCT CANDIDATES OF THE TRANSCATHETER VALVE THERAPEUTIC BUSINESS ARE PROGRESSED TO HUMAN TRIAL STAGE. THE NEUROINTERVENTIONAL BUSINESS FOCUSES ON INNOVATIVE PRODUCTS SUITABLE FOR CHINESE PATIENTS AND PHYSICIANS, THROUGH THE COOPERATION BETWEEN MEDICAL AND ENGINEERING PROFESSIONALS.**

We have developed a strong product pipeline in the Transcatheter Valve Therapeutic Business with a wide range of innovative product candidates through external acquisitions and internal development, covering Transcatheter Aortic Valve Replacement (AR and AS), Transcatheter Mitral Valve and Transcatheter Tricuspid Valve Replacement and Repair. During the Reporting Period, we facilitated the technology transfer of Trilogy™ Heart Valve System, successfully launched the registration clinical trial of HighLife® TSMVR system and GeminiOne® TEER system and completed the first human implant of MonarQ™ TTVR system in Denmark.

- 1) As of the date of this announcement, Trilogy™ Heart Valve System of JenaValve Technology Inc. (“**JenaValve**”) is the first and the only transfemoral aortic valve replacement device of its kind to receive CE Mark approval for the treatment of symptomatic severe AR or symptomatic severe AS. We entered into a series of agreements with JenaValve in December 2021, for an exclusive license regarding Trilogy™ Heart Valve System in the Greater China region. The transaction will enable us to have the most comprehensive TAVR pipeline covering major aortic valve diseases, as compared to other players in China. As of the date of this announcement, the technology transfer of the product is progressing smoothly. We plan to launch the registration clinical trial in 2023. Since the product has obtained CE Mark, we are preparing the implantation of Trilogy™ in Hong Kong and Macau or the rest of the Greater Bay Area within the Greater China region.
- 2) HighLife® TSMVR system is a leading product candidate in the field of mitral valve replacement in terms of product design and clinical progress in the world. HighLife® TSMVR system adopted the unique “Valve-in-Ring” concept, allowing the system to self-center and self-align. We entered into an exclusive license agreement with HighLife SAS (“**HighLife**”) in 2020 and completed the technology transfer in 2021. We completed the first patient enrollment of HighLife® multi-center registration clinical trial successfully in November 2022.

- 3) GeminiOne® is our internally developed TEER device. The product has a unique design, which enables a longer coaptation length while still maintaining smaller implant size and delivery system. Other innovations include its independent leaflet grasp that reduces the complexity of the procedure, auto-locking mechanism that avoids repeatedly locking and unlocking during the procedure, as well as multi-angular detachment that copes with a wider range of anatomy. We completed the first patient enrollment of GeminiOne® multi-center registration clinical trial successfully in November 2022.
- 4) MonarQ™ TTVR system developed by inQB8 Medical Technologies, LLC (“inQB8”) is one of the most important product candidates for the Company, being an innovative option for treating TR. The Company entered into a strategic partnership with inQB8 and agreed to acquire the MonarQ TTVR technology, which inQB8 continues to develop on the Company’s behalf. The Company owns the global right of the MonarQ TTVR technology and the product developed on the basis of it. We completed the first patient implant of the FIM clinical trial in Demark in November 2022.

The registration applications of four ischemic products in our Neurointerventional Business were approved by the NMPA during the Reporting Period which enables us to provide one-stop treatment solutions for ICAD and AIS patients:

- 1) Fastunnel® Delivery Balloon Dilatation Catheter is the first medical device in China which can realize balloon dilatation and stent delivery in one device. The innovative design can reduce the number of device exchanges as required in a traditional ICAD procedure, shorten procedure time and improve the safety of the procedure.
- 2) Syphonet® Stent Retriever is an internally developed product based on clinical feedback. The product has various specifications, all compatible with 0.017-inch microcatheter. The stent is designed with optimized radial force to maintain the integrity of the lumen, even in tortuous vessels, ensuring a smooth procedure. The product’s unique design features a capture basket at the distal end, which can effectively prevent the thrombus fragments from dislodging into the blood stream, thereby improving the removal of the thrombus. Radiopaque wires in the stent and a radiopaque marker on the distal end allow for visualization of the entire retriever, enabling better visual guidance for physicians. The development of Syphonet® Stent Retriever also leads to the development of BASIS (Balloon Angioplasty with the distal protection of Stent retriever) technology. This innovative technology, with Syphonet® Stent Retriever as the core and the combination of balloon dilatation catheter and intermediate catheter, provides a safe and effective treatment option for patients with ICAS-LVO type of stroke.

- 3) Tethys AS<sup>®</sup> Aspiration Catheter is indicated for thrombus aspiration, featuring large lumen, increased deliverability and high compressive strength. The 0.071-inch large lumen of Tethys AS<sup>®</sup> largely increases the aspiration force, which can significantly shorten the procedure time. It features a 20cm soft segment at the distal end, which better conforms to the vessels and largely enhances its deliverability to the distal vessels. The device utilizes a double-layer design with outer braids and inner coils, which enables high compressive strength and helps maintain lumen integrity.
- 4) Fluxcap<sup>®</sup> Balloon Guide Catheter is an optimized product that was developed based on clinical feedback. Featuring 0.087-inch large lumen, the catheter is compatible with all 6F intermediate catheters or aspiration catheters on the market, as well as 8F introducer sheaths. The product addresses the challenge of poor compatibility of balloon guide catheters on the market and can significantly reduce the occurrence of vascular injury.

**4. WE ARE MAKING CONTINUOUS EFFORTS IN OPTIMIZING SUPPLY CHAIN AND IMPROVING PRODUCTION PROCESS FOR LONG-TERM SUCCESS.**

Main accomplishments include:

- 1) Expansion of production capacity and improvement of productivity to support business growth;
- 2) Introduction and verification of additional key raw material suppliers to enhance the supply chain security;
- 3) Optimization of the in-house manufacturing process of self-produced raw materials, focusing on mass production and product yield. In this way, we can ensure the stability of our raw material supply chain while keeping overall cost in check;
- 4) Automation and optimization of our manufacturing process. We have lowered our production cost with improved operating efficiency, increased product yield and reduced waste; and
- 5) Continuous investment in personnel training, including mentoring programs, to shorten the learning curve of employees.

## CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

For the year ended December 31, 2022

		Year ended December 31,	
		2022	2021
	Note	RMB'000	RMB'000
Revenue	4	250,833	136,534
Cost of sales	5	<u>(74,632)</u>	<u>(40,880)</u>
<b>Gross profit</b>		<b>176,201</b>	<b>95,654</b>
Selling and distribution expenses	5	(241,630)	(93,252)
Administrative expenses	5	(123,432)	(114,425)
Research and development expenses	5	(373,127)	(445,879)
Other income	6	12,760	9,727
Other gains/(losses) — net	7	<u>106,680</u>	<u>(50,626)</u>
<b>Operating loss</b>		<b>(442,548)</b>	<b>(598,801)</b>
Finance income		46,629	24,771
Finance costs		<u>(2,316)</u>	<u>(186)</u>
Finance income — net	8	<u>44,313</u>	<u>24,585</u>
<b>Loss before income tax</b>		<b>(398,235)</b>	<b>(574,216)</b>
Income tax expense	9	<u>(9,574)</u>	<u>—</u>
<b>Loss for the year</b>		<b><u>(407,809)</u></b>	<b><u>(574,216)</u></b>
<b>Total comprehensive loss for the year</b>		<b><u>(407,809)</u></b>	<b><u>(574,216)</u></b>
<b>Attributable to:</b>			
Equity owners of the Company		(407,809)	(574,216)
Non-controlling interests		<u>*</u>	<u>—</u>
		<b><u>(407,809)</u></b>	<b><u>(574,216)</u></b>
<b>Loss per share attributable to owners of the Company</b>			
Basic and diluted loss per share ( <i>in RMB per share</i> )	10	<u>(0.61)</u>	<u>(0.86)</u>

\* The non-controlling interests is less than RMB1,000.

# CONSOLIDATED BALANCE SHEET

As at December 31, 2022

		As at December 31,	
		2022	2021
	Note	RMB'000	RMB'000
<b>ASSETS</b>			
<b>Non-current assets</b>			
Right-of-use assets		21,620	25,014
Property, plant and equipment		305,819	151,205
Investment properties		7,008	7,549
Intangible assets		538,950	276,502
Investment accounted for using equity method		333	—
Other receivables	12	13,825	—
Prepayments		6,318	52,613
Term deposits		170,000	—
Financial assets at fair value through profit or loss		245,153	224,424
<b>Total non-current assets</b>		<b>1,309,026</b>	<b>737,307</b>
<b>Current assets</b>			
Inventories		127,184	66,107
Financial assets at fair value through profit or loss		71,564	—
Trade and other receivables	12	77,726	33,333
Prepayments		61,309	30,809
Cash and cash equivalents		1,669,665	2,296,112
<b>Total current assets</b>		<b>2,007,448</b>	<b>2,426,361</b>
<b>Total assets</b>		<b>3,316,474</b>	<b>3,163,668</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity attribute to owners of the Company</b>			
Share capital and share premium		6,369,548	6,339,597
Treasury shares held in a trust		(82,739)	(84,549)
Other reserves		63,617	69,139
Accumulated losses		(3,712,811)	(3,305,002)
Equity attributable to owners of the Company		2,637,615	3,019,185
Non-controlling interests		*	—
<b>Total equity</b>		<b>2,637,615</b>	<b>3,019,185</b>

		<b>As at December 31,</b>	
		<b>2022</b>	<b>2021</b>
	<i>Note</i>	<b>RMB'000</b>	<b>RMB'000</b>
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Lease liabilities		2,152	4,082
Deferred tax liabilities		20,320	20,320
Borrowings		70,770	—
Other payables	13	5,874	—
Deferred income		1,720	1,374
<b>Total non-current liabilities</b>		<u>100,836</u>	<u>25,776</u>
<b>Current liabilities</b>			
Lease liabilities		2,892	3,545
Borrowings		56,061	—
Trade and other payables	13	519,070	115,162
<b>Total current liabilities</b>		<u>578,023</u>	<u>118,707</u>
<b>Total liabilities</b>		<u>678,859</u>	<u>144,483</u>
<b>Total equity and liabilities</b>		<u>3,316,474</u>	<u>3,163,668</u>

\* The non-controlling interests is less than RMB1,000.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

For the year ended December 31, 2022

## 1 GENERAL INFORMATION

Peijia Medical Limited (the “**Company**”, or “**Peijia Medical**”) was incorporated in the Cayman Islands on May 30, 2012 as an exempted company with limited liability under the Company Law of the Cayman Islands. The Company and its subsidiaries (together, the “**Group**”) are principally engaged in the business of (i) research and development, manufacturing and sales of transcatheter valve therapeutic medical devices (“**Transcatheter Valve Therapeutic Business**”) and (ii) research and development, manufacturing and sales of neurointerventional procedural medical devices (“**Neurointerventional Business**”) in the People’s Republic of China (the “**PRC**”) and other countries. Transcatheter Valve Therapeutic Business is primarily operated by the subsidiaries of the Company mainly comprising of Peijia Medical Technology (Suzhou) Co., Ltd. (“**Peijia Suzhou**”) and Peijia Medical Technology (Shanghai) Co., Ltd. (“**Peijia Shanghai**”), and Neurointerventional Business is primarily operated by Achieva Medical Limited (“**Achieva Medical**”) together with its subsidiaries (“**Achieva Group**”).

The address of the Company’s registered office is Floor 4, Willow House, Cricket Square, Grand Cayman, KY1-9010 Cayman Islands.

These consolidated financial statements are presented in thousands of Renminbi Yuan (“**RMB**”), unless otherwise stated. These consolidated financial statements have been approved for issue by the Board of Directors on March 31, 2023.

## 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

This note provides a list of the significant accounting policies adopted in the preparation of these consolidated financial statements. These policies have been consistently applied to all the years presented, unless otherwise stated. The financial statements are for the Group consisting of Peijia Medical Limited and its subsidiaries.

### 2.1 Basis of preparation

#### (i) *Compliance with IFRS and HKCO*

The consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards (“**IFRSs**”) issued by International Accounting Standards Board (“**IASB**”) and requirements of the Hong Kong Companies Ordinance Cap. 622.

#### (ii) *Historical cost convention*

The financial statements have been prepared on a historical cost basis, except for the following:

- certain financial assets

**(iii) *New and amended standards adopted by the Group***

The Group has applied the following standards and amendments for the first time for their annual reporting period commencing January 1, 2022:

Amendments to IFRS 16	Covid-19-related Rent Concessions beyond June 30, 2021
Amendments to IAS 16	Property, Plant and Equipment: Proceeds before intended use
Amendments to IFRS 3	Reference to the Conceptual Framework
Amendments to IAS 37	Onerous Contracts — Cost of Fulfilling a Contract
Amendments to IFRSs	Annual improvements to IFRS standards 2018–2020 cycle
Revised Accounting Guideline 5	Amendments to Accounting Guideline 5
Merger Accounting for Common Control Combinations (AG 5)	

The adoption of these amendments to standards and interpretations did not have any impact on the consolidated financial statements or result in any significant changes in the Group's significant accounting policies.

**(iv) *New standards and interpretations not yet adopted***

Certain new accounting standards, amendments to accounting standards and interpretations have been published that are not mandatory for the year ended December 31, 2022 and have not been early adopted by the Group. These standards, amendments or interpretations are not expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

### **3 SEGMENT**

#### **Description of segments and principal activities**

The Group's business activities, for which discrete financial information is available, are regularly reviewed and evaluated by the CODM. The CODM, who is responsible for allocating resource and assessing performance of the operating segments, has been identified as the executive directors of the Company that make strategic decisions.

The CODM assessed the performance of the operation segments mainly based on segment revenues, cost of sales, selling and distribution expenses, administrative expenses, and research and development expenses of each operation segment. Thus, segment result would present revenues, cost of sales, selling and distribution expenses, administrative expenses, research and development expenses for each segment, which is in line with CODM's performance review.

As a result of this evaluation, the Group determined that it has operating segments as follows:

#### **Transcatheter Valve Therapeutic Business**

Transcatheter Valve Therapeutic Business is primarily operated by the subsidiaries of the Company mainly comprising of Peijia Suzhou and Peijia Shanghai, which is engaged in the business of research and development, manufacturing and sales of transcatheter valve therapeutic medical devices.

## Neurointerventional Business

Neurointerventional Business is primarily operated by Achieva Medical together with its subsidiaries, which is engaged in the business of research and development, manufacturing and sales of neurointerventional procedural medical devices.

There were no separate segment assets and segment liabilities information provided to the CODM, as CODM does not use this information to allocate resources to or evaluate the performance of the operating segments.

The revenue is mainly generated in China.

The segment information provided to the Group's CODM for reportable segments for the relevant periods is as follows:

### Segment loss

	Year ended December 31, 2022		
	Transcatheter Valve Therapeutic Business RMB'000	Neurointerventional Business RMB'000	Total RMB'000
Revenue	107,311	143,522	250,833
Cost of sales	(21,830)	(52,802)	(74,632)
Selling and distribution expenses	(172,432)	(69,198)	(241,630)
Administrative expenses	(94,222)	(29,210)	(123,432)
Research and development expenses	(320,663)	(52,464)	(373,127)
Segment loss	<u>(501,836)</u>	<u>(60,152)</u>	<u>(561,988)</u>

  

	Year ended December 31, 2021		
	Transcatheter Valve Therapeutic Business RMB'000	Neurointerventional Business RMB'000	Total RMB'000
Revenue	41,941	94,593	136,534
Cost of sales	(7,221)	(33,659)	(40,880)
Selling and distribution expenses	(53,482)	(39,770)	(93,252)
Administrative expenses	(84,920)	(29,505)	(114,425)
Research and development expenses	(394,202)	(51,677)	(445,879)
Segment loss	<u>(497,884)</u>	<u>(60,018)</u>	<u>(557,902)</u>

#### 4 REVENUE

	Year ended December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Revenue from sales of goods		
— at a point in time	<u>250,833</u>	<u>136,534</u>

#### Information about major customers

The major customers which contributed more than 10% of the total revenue of the Group for the years ended December 31, 2022 and 2021 are listed as below:

	Year ended December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Customer A	59,301	20,722
Customer B	<u>48,005</u>	<u>16,384</u>
	<u>107,306</u>	<u>37,106</u>

## 5 EXPENSES BY NATURE

	Year ended December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Change of work in process and finished goods	(18,114)	(19,180)
Raw materials and consumables used	90,257	60,609
Employee benefits expenses	262,041	171,277
Service expenses for research and development	249,859	340,517
Professional service fees	39,862	27,641
Insurance expenses	35,257	7,830
Meeting expenses	25,381	15,215
Advertisement expenses	22,737	14,985
Depreciation of property, plant and equipment	19,479	14,170
Entertainment expenses	15,730	10,391
Utilities and office expenses	13,559	12,314
Travelling and transportation expenses	13,392	10,283
Amortisation of intangible assets	12,555	9,698
Auditor's remuneration		
— audit service	4,121	3,964
— non-audit service	930	1,001
Depreciation of right-of-use assets	3,439	3,077
Depreciation of investment properties	541	541
Others	21,795	10,103
	<hr/>	<hr/>
Total cost of sales, selling and distribution expenses, administrative expenses and research and development expenses	<b>812,821</b>	<b>694,436</b>

## 6 OTHER INCOME

	Year ended December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Government grants	10,264	8,300
Service income from an associate	1,271	—
Rental income	946	747
Others	279	680
	<hr/>	<hr/>
	<b>12,760</b>	<b>9,727</b>

**7 OTHER GAINS/(LOSSES) — NET**

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
Foreign exchange gains/(losses) — net	<b>123,346</b>	(48,139)
Fair value gains on financial assets at fair value through profit or loss	<b>581</b>	—
Losses on disposal of property, plant and equipment	<b>(33)</b>	(218)
Losses on early termination of operating lease	<b>(396)</b>	—
Loss from foreign exchange forward contracts — net	<b>(16,922)</b>	—
Share of losses of associate	<b>(167)</b>	—
Others	<b>271</b>	(2,269)
	<b><u>106,680</u></b>	<b><u>(50,626)</u></b>

**8 FINANCE INCOME — NET**

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
<b>Finance income:</b>		
Bank interest income	<b><u>46,629</u></b>	<u>24,771</u>
<b>Finance costs:</b>		
Interest expense on lease liabilities	<b>(311)</b>	(186)
Interest expense on borrowings	<b><u>(2,005)</u></b>	<u>—</u>
	<b><u>(2,316)</u></b>	<u>(186)</u>
<b>Finance income — net</b>	<b><u>44,313</u></b>	<b><u>24,585</u></b>

**9 INCOME TAX EXPENSE**

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
Current income tax	<b>(9,574)</b>	—
Deferred income tax	<b>—</b>	—
	<b><u>(9,574)</u></b>	<u>—</u>

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

(a) Mainland China

No provision for Mainland China income tax has been provided for at a rate of 25% or 15% 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.

According to the relevant laws and regulations promulgated by the State Administration of Taxation of the PRC that has been effective from 2018 onwards, enterprises engaging in research and development activities are entitled to claim 175%-200% of their research and development expenses incurred as tax deductible expenses when determining their assessable profits for that period.

(b) The income tax of the holding entities incorporated in United States are calculated based on the net assets and an income tax rate of 0.26%.

(c) Entities incorporated in other places are subject to income tax rates of 0% prevailing in the places in which the Group operated.

(d) The Group has arranged a sub-licensing for certain intellectual property under research and development from a subsidiary incorporated in Hong Kong to Peijia Suzhou, which incurred an income tax of RMB8,966,000 born by the Hong Kong subsidiary.

(e) A reconciliation of the expected income tax calculated at the applicable tax rate and loss before income tax, with the actual income tax is as follow:

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Loss before income tax	<u>(398,235)</u>	<u>(574,216)</u>
Tax calculated at statutory tax rates applicable to each group entity	<b>67,314</b>	63,468
Income tax due to sub-licensing within the Group	<b>(8,966)</b>	—
Tax effect of:		
Differences in prior years' tax filing	<b>2,846</b>	(8,014)
Expenses not deductible for tax purpose ( <i>Note (i)</i> )	<b>(2,556)</b>	(3,213)
Super deduction for research and development expenses	<b>27,461</b>	29,250
Utilization of previously unrecognized tax losses	<b>1,047</b>	—
Unrecognized tax losses carried forward ( <i>Note (ii)</i> )	<u><b>(96,720)</b></u>	<u>(81,491)</u>
Income tax expense	<u><b>(9,574)</b></u>	<u>—</u>

(i) Expenses not deductible for tax purpose primarily include expenses not related to business activities, welfare and entertainment expenses exceeding the tax deduction limits under the Corporate Income Tax Law.

- (ii) Deductible losses that are not recognized as deferred tax assets will be expired as follows:

*Tax losses carried forward*

	<b>As at December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
2023	2,402	2,402
2024	3,090	3,090
2025	4,363	4,363
2026	14,915	14,915
2027	36,251	37,126
2028	51,046	50,841
2029	107,440	122,350
2030	284,081	284,931
2031	386,095	325,967
2032	603,307	—
	<u>1,492,990</u>	<u>845,985</u>

The tax losses of the Company's PRC subsidiaries will expire within ten years for small and medium-sized high-tech enterprises.

## 10 LOSS PER SHARE

### (a) Basic loss per share

Basic loss per share is calculated by dividing the loss of the Group attributable to owners of the Company by weighted average number of ordinary shares issued for the years ended December 31, 2022 and 2021.

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Loss for the year and attributable to owners of the Company ( <i>RMB'000</i> )	(407,809)	(574,216)
Weighted average number of ordinary shares in issue ( <i>thousand</i> )	<u>673,160</u>	<u>661,656</u>
Basic loss per share ( <i>RMB</i> )	<u>(0.61)</u>	<u>(0.86)</u>

**(b) Diluted loss per share**

Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. For the year ended December 31, 2022, the Company had one category of potential ordinary shares: the stock options granted to employees. As the Group incurred losses for the years ended December 31, 2022 and 2021, the potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the years ended December 31, 2022 and 2021 are the same as basic loss per share.

**11 DIVIDEND**

No dividend has been paid or declared by the Company or the companies now comprising the Group for the year ended December 31, 2022 (2021: Nil).

**12 TRADE AND OTHER RECEIVABLES**

	As at December 31,	
	2022	2021
	RMB'000	RMB'000
Trade receivables from		
— third parties (a)	12,595	—
Other receivables from		
— employees (b)	29,984	—
— related parties	8,748	—
— third parties	8,498	3,639
Value-added tax recoverable	12,683	14,550
Interest receivables	10,302	5,475
Deposits	1,868	1,926
Others	6,873	7,743
<b>Total</b>	<b>91,551</b>	<b>33,333</b>
Less: non-current portion	(13,825)	—
Current portion	<u>77,726</u>	<u>33,333</u>

- (a) At December 31, 2022 and 2021, the aging analysis of the trade receivables based on invoice date were as follows:

	<b>As at December 31,</b>	
	<b>2022</b>	2021
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
Not overdue	<u><b>12,595</b></u>	<u>—</u>

- (b) Other receivables from employees included a loan to an employee amounted to RMB13,825,000, of which the nominal value was HKD16,000,000 (equivalent to RMB14,293,000). The loan was interest-free and will be repayable in March 2024.

### 13 TRADE AND OTHER PAYABLES

	<b>As at December 31,</b>	
	<b>2022</b>	2021
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
Trade payables — third parties	<b>361,580</b>	54,168
Other payables — third parties	<b>97,620</b>	31,116
Staff salaries and welfare payables	<b>41,434</b>	24,490
Liabilities arising from share-based payments with cash alternative	<b>9,045</b>	—
Tax payable	<u><b>15,265</b></u>	<u>5,388</u>
	<u><b>524,944</b></u>	<u>115,162</u>
Less: non-current position	<u><b>(5,874)</b></u>	<u>—</u>
Current position	<u><b>519,070</b></u>	<u>115,162</u>

The aging analysis of trade payables at the respective balance sheet dates is as follows:

	<b>As at December 31,</b>	
	<b>2022</b>	2021
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
Within 1 year	<b>361,444</b>	54,003
Between 1 year and 2 years	<b>6</b>	160
Between 2 year and 5 years	<u><b>130</b></u>	<u>5</u>
	<u><b>361,580</b></u>	<u>54,168</u>

# MANAGEMENT DISCUSSION AND ANALYSIS

## I. BUSINESS REVIEW

### Overview

We have built a medtech platform that focuses on the high-growth interventional procedural medical device markets in China and globally. Our products and product candidates target the vast, fast-growing and under-penetrated markets with high entry barriers, including transcatheter valve therapeutic medical device market and neurointerventional procedural medical device market.

### Products and Pipeline

During the Reporting Period, we obtained registration approvals from the NMPA for four neurointerventional products, namely, Syphonet<sup>®</sup> Stent Retriever, Tethys AS<sup>®</sup> Aspiration Catheter, Fastunnel<sup>®</sup> Delivery Balloon Dilatation Catheter (formerly named as Neway Balloon Microcatheter) and Fluxcap<sup>®</sup> Balloon Guide Catheter.

As of the date of this announcement, for our Transcatheter Valve Therapeutic Business, we had five registered products and nine product candidates at various development stages. For our Neurointerventional Business, we had fourteen registered products and seven product candidates at various development stages. The following chart summarizes the development status of our product portfolio as of December 31, 2022:

Products / Product Candidate		Pre-Clinical	Clinical	Registration	Commercialization
Transcatheter Valve Therapeutic	TAVR(r) (AS)				
	TaurusOne® TAVR System		NMPA Approval		
	TaurusElite® Retrievable TAVR System		NMPA Approval		
	TaurusNXT® "Non-glutaraldehyde Crosslinking" Dry-tissue TAVR System		Multi-center Registration Clinical Trial		
	TaurusWave® Lithotripsy Valvuloplasty System		FIM Clinical Trial		
	TaurusApex® Polymer Leaflets TAVR System	Animal Studies			
	TAVR (AR)				
	TaurusTrio™ TAVR System (Licensed-in Trilogy™ TAVR System)	Technology Transfer			
	Trilogy™ TAVR System (Licensed-in)		Implantation Preparation (HK & Macau or the rest of the Greater Bay Area within the Greater China region)		CE Mark
	HighLife® TSMVR System (Licensed-in)		Multi-center Registration Clinical Trial		
	TMVR(r)				
	Sutra TMV Coaptation Augmentation System	Animal Studies			
	GeminiOne® TEER System		Multi-center Registration Clinical Trial		
	TTVR(r)				
	MonarQ™ TTVR System (Global IP)		FIM Clinical Trial		
	GeminiOne® TEER System		Preparing for FIM Clinical Trial		
	Platform Technologies				
	Non-glutaraldehyde Crosslinked Dry-tissue Technology (Utilized in TaurusNXT®)		Multi-center Registration Clinical Trial		
Lithotripsy Valvuloplasty Technology (Utilized in TaurusWave®)		FIM Clinical Trial			
Polymeric Trileaflet (Utilized in TaurusApex®)		Animal Studies			
Procedural Accessories					
TaurusAtlas® Transfemoral Balloon Catheter	▲		NMPA Approval		
TaurusNavi® Introducer Sheath	▲		NMPA Approval		
TaurusExplora® Pre-shaped Guidewire	▲		NMPA Approval		
Neurointerventional	Hemorrhagic				
	Jasper® Detachable Coil			NMPA Approval, CE Mark, Registered in Brazil, Indonesia, and Ecuador	
	Presgo® Detachable Coil			NMPA Approval; CE Mark; Registered in Brazil	
	Jasper® SS Detachable Coil			NMPA Approval	
	Detachable Coil (Thermal Detachment)			Submitted Application for NMPA Registration Approval	
	Intracranial Adjunctive Stent		Design Stage		
	Delivery Occlusion Balloon Catheter		Initiation		
	Ischemic (AIS)				
	Fluxcap® Balloon Guide Catheter	▲		NMPA Approval	
	Tethys AS® Aspiration Catheter			NMPA Approval	
	Aspiration Catheter (Larger Lumen)		Design Stage		
	Syphonet® Stent Retriever			NMPA Approval	
	Fastunnel® Delivery Balloon Dilation Catheter	▲		NMPA Approval	
	SacSpeed® Balloon Dilatation Catheter			NMPA Approval	
	NeuroStellar® Intracranial Stent			Registration Clinical Trial	
	Vascular Access & Other				
	Presgo® Microcatheter	▲		NMPA Approval; Registered in Brazil	
	Microcatheter (Next Generation)	▲	Design Stage		
Presgo® Micro Guidewire	▲		NMPA Approval; CE Mark; Registered in Brazil		
Micro Guidewire (Next Generation)	▲		Submitted Application for NMPA Registration Approval		
Heralder® Guide Catheter	▲		NMPA Approval		
Heralder® DA Distal Access Guide Catheter	▲		NMPA Approval		
Tethys® Intermediate Catheter	▲		NMPA Approval		
Jasper® Power Supply			NMPA Approval		

▲ Among our products, these devices are exempted from clinical trial requirements in accordance with the Catalogue of Medical Device Exempted from Clinical Trials (免於臨床評價醫療器械目錄) promulgated by the NMPA, as amended.

## **Transcatheter Valve Therapeutic Products and Product Candidates**

Our Transcatheter Valve Therapeutic Business focuses on treating the most prevalent heart valve diseases, including AS, AR, MR and TR, via transcatheter approaches.

We have a comprehensive portfolio of commercialized and pipeline products. For the year ended December 31, 2022, our revenue generated from the sales of transcatheter valve therapeutic products amounted to RMB107.3 million, representing an increase of 155.9% from RMB41.9 million recorded during the year ended December 31, 2021.

### **TAV Replacement and Repair Products and Product Candidates**

#### ***TaurusOne® — First-Generation TAVR System***

TaurusOne® is our internally developed first-generation TAVR product, and is designed to treat severe calcific aortic stenosis using catheter-based approach. The product consists of a PAV, a delivery catheter system and a loading system. The PAV includes bovine pericardial leaflets, a nitinol frame, and a sealing skirt to prevent paravalvular leakage. Compared to porcine pericardial leaflets, bovine pericardial leaflets are generally more durable and perform better in terms of hemodynamic profile. The clinical trial of TaurusOne® was the first ever TAVR product registration clinical trial completed entirely by Chinese physicians. It is also the first domestic TAVR product whose clinical results were published in the top quartile research journal. We received the NMPA approval for the registration application of TaurusOne® in April 2021 and commercialized the product in May 2021.

#### ***TaurusElite® — Second-Generation Retrievable TAVR System***

TaurusElite® is our internally developed second-generation retrievable TAVR product. TaurusElite® has a valve design similar to that of TaurusOne® but features a key upgrade to its delivery catheter system — allowing physicians to retrieve and reposition the PAV during placement, addressing one of the key challenges. This also improves the success rate of TAVR procedures and the long-term benefits to patients, which will ultimately promote wider clinical adoption. Furthermore, the design consists of inner and outer tubes that further enhance the pushability and flexibility of the delivery catheter system, and effectively deal with the challenges posed by the complex anatomy of the aortic arch and horizontal aorta. The TaurusElite® delivery catheter system is also available in an inline sheath model to meet the diverse needs of doctors and treat patients with complicated vascular anatomy.

We received the NMPA approval for the registration application of TaurusElite® in June 2021 and commercialized the product in July 2021. As of the date of this announcement, TaurusElite® is the record-breaking domestic retrievable TAVR product in terms of approval time.

In addition to the products mentioned above, we also received the NMPA approvals for the registration application of a number of procedural accessories in 2021, including TaurusAtlas<sup>®</sup> Transfemoral Balloon Catheter, TaurusNavi<sup>®</sup> Introducer Sheath and TaurusExplora<sup>®</sup> Pre-shaped Guidewire. These are important accessories to help physicians perform the TAVR procedures using Taurus-series products.

We have successfully achieved commercial implantation of our TAVR products in 290 hospitals as of December 31, 2022, benefiting from the increasing number of experienced physicians and hospitals, the positive user experience of our products, and our dedicated marketing and sales capabilities for TAVR products. For the Reporting Period, the sales from TaurusElite<sup>®</sup> comprised the majority of our sales in the Transcatheter Valve Therapeutic Business.

### ***TaurusNXT<sup>®</sup> — Third-Generation Non-glutaraldehyde Crosslinked Dry-tissue TAVR System***

TaurusNXT<sup>®</sup> is our internally developed third-generation TAVR system, and has significantly different tissue and structure from TaurusOne<sup>®</sup> and TaurusElite<sup>®</sup>. TaurusNXT<sup>®</sup> incorporates our patented non-glutaraldehyde bio-tissue crosslinking technology that removes the main source of valve calcification, the primary cause of prosthetic valve degeneration. The technology is expected to greatly enhance the durability and biocompatibility of the PAV. Additionally, compared to the traditional dry tissue technology using glycerin, TaurusNXT<sup>®</sup> utilizes an ultra-low temperature vacuum freeze-drying technology to maintain the physical integrity of the valve tissue while allowing the PAV to be pre-loaded onto the delivery catheter system. The delivery catheter system of TaurusNXT<sup>®</sup> is both retrievable and steerable, making it much easier for physicians to guide the PAV to its target position, thereby further improving the safety of the procedure. The first patient implant of TaurusNXT<sup>®</sup> was completed in September 2021. As of the date of this announcement, we are carrying out the multi-center registration clinical trial for TaurusNXT<sup>®</sup>.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TaurusNXT® SUCCESSFULLY.**

***TaurusApex® — Polymeric Trileaflet TAVR System***

TaurusApex® is our internally developed fourth-generation TAVR system featuring the polymeric trileaflet instead of biological tissue. By replacing bio-materials with high strength, stable and soft polymer materials, we are able to further improve durability and biocompatibility of the prosthetic valves. The leaflets of TaurusApex® adopt the multi-layer bionic composite braided structure which better mimics the features and hemodynamic performance of human's native valves. Polymeric trileaflet excels biological tissue in durability, tear resistance and wear resistance. As of the date of this announcement, we are conducting animal studies and associated long-term follow-up evaluation on TaurusApex®, with promising results.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TaurusApex® SUCCESSFULLY.**

***TaurusWave® — Lithotripsy Valvuloplasty System***

Our TaurusWave® Lithotripsy Valvuloplasty system applies shockwave technology to remodel calcification on the valves. After the treatment, the mobility of the native valve is improved, leading to better hemodynamic performance. The system can be used as a stand-alone TAV treatment or be used prior to TAVR, in order to alleviate valve stenosis. The first patient treatment using TaurusWave® was completed in October 2021. As of the date of this announcement, we are proceeding with FIM clinical trial for this product.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TaurusWave® SUCCESSFULLY.**

## ***TaurusTrio™ TAVR System — Licensed-in Trilogy™ TAVR Product for AR Indication***

We entered into a collaboration and license agreement, a service agreement and a stock purchase agreement with JenaValve, a U.S.-based medical device company, in December 2021. Pursuant to these agreements, JenaValve has granted us an exclusive license for Trilogy™ Heart Valve System in the treatment of symptomatic severe AR or symptomatic severe AS. We are entitled to develop, manufacture, and commercialize the product in the Greater China region, and JenaValve agreed to provide services, allowing us to leverage the value of the product within the region. For further details, please refer to our announcement dated January 14, 2022.

As of the date of this announcement, JenaValve Trilogy™ system is the only commercial transfemoral TAVR system (CE Mark) with both AR and AS indications globally. The system's proprietary locator can not only anchor without calcification but also ensure valve commissure alignment. Its design, which includes supra-annular prosthesis and large-open cells, also benefits long-term hemodynamic and future percutaneous coronary intervention (PCI). Its valve inflow end is designed with 24 high-density mesh holes to provide annular compliance and sealing.

As of the date of this announcement, the technology transfer is in progress. We are preparing the roll out of Trilogy™ in Hong Kong and Macau or the rest of the Greater Bay Area within the Greater China region and the registration clinical trials in the mainland China.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TaurusTrio™ SUCCESSFULLY.**

## **TMV Replacement and Repair Product Candidates**

### ***HighLife® — Licensed-in TSMVR Product***

In December 2020, we entered into an exclusive license agreement with HighLife, a French-based medical device company focusing on the development of a novel transseptal replacement system for treating MR. Pursuant to the agreement, we are entitled to, among other things, manufacture, develop, and commercialize the HighLife® TSMVR device in the Greater China region. Mr. Georg BÖRTLEIN, the founder of HighLife, is also the co-founder of CoreValve Inc, a TAVR company which was acquired by Medtronic in 2009.

The field of TMVR still faces many technical difficulties, including access to the target site, anchoring and the risk of paravalvular leakage, and LVOT obstruction. Most existing approaches are either transapical or anchoring using radial force. HighLife® TSMVR product adopted the unique “Valve-in-Ring” concept, allowing the system to self-center and self-align. This system separates the valve from its anchoring ring and delivers the two components through the femoral artery and femoral vein, respectively, through a simple three-step procedure. The 2-component design designed for mitral valve anatomy helps to mitigate the risk of paravalvular leakage and effectively reduces catheter size. The procedure can be successfully completed using teleproctoring support. The learning curve is relatively short, evidenced by significant reduction of procedure time by the same physician.

As of the date of this announcement, the multi-center registration clinical trial of the product is underway, with the first patient enrollment having been successfully completed in November 2022.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET HighLife® SUCCESSFULLY.**

## *GeminiOne® — TEER System*

GeminiOne® is our internally developed TEER device, designed to treat mitral valve and tricuspid valve diseases. The product has a unique design, which enables a longer coaptation length while still maintaining smaller implant size and delivery system. Other innovations include its independent leaflet grasp that reduces the complexity of the procedure, auto-locking mechanism that avoids repeated locking and unlocking during the procedure, as well as multi-angular detachment that copes with a wider range of anatomy.

Our medical consultants for GeminiOne® are Dr. Saibal KAR, one of the earliest advocates for the TEER technique and a world-leading doctor specializing in TEER, and Dr. Khung Keong YEO, a renowned interventional cardiologist from Singapore.

As of the date of this announcement, the multi-center registration clinical trial of the product to treat moderate to severe or severe degenerative MR is underway, with the first patient enrollment having been successfully completed in November 2022.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET GeminiOne® SUCCESSFULLY.**

## *Sutra Hemi Valve — TMV Coaptation Augmentation System*

In April 2021, we entered into a stock purchase agreement with Sutra Medical Inc. (“**Sutra**”), a U.S.-based medical device company that designs and develops transcatheter solutions to treat valvular heart diseases. Sutra’s key product candidate, Sutra Hemi Valve, is a transcatheter mitral valve therapeutic device that adopts a hybrid approach between valve replacement and repair technology. The device is designed to treat MR using a coaptation augmentation technology that targets only the posterior mitral valve leaflet. As of the date of this announcement, Sutra Hemi Valve is in the animal studies stage.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET Sutra Hemi Valve SUCCESSFULLY.**

## **TTV Replacement and Repair Product Candidates**

### ***MonarQ™ — Acquired TTVR Product***

We entered into an IP acquisition agreement, a service agreement and a stock purchase agreement with inQB8, a U.S.-based medical technology incubator, in May 2021, to explore innovative solutions for treating structural heart diseases. The transaction includes our acquisition of a TTVR technology, namely MonarQ™, from inQB8, and for which inQB8 will continue to develop the device in partnership with us.

The MonarQ™ TTVR system is an innovative option for treating TR. Such system has a unique biodynamic attachment system that utilizes and preserves the heart's natural motion to secure the implant to the native leaflets, distribute systolic loads, and minimize paravalvular leaks over a wide range of annulus sizes.

As of the date of this announcement, the FIM clinical trial of the product is underway, with the first patient implant having been successfully completed in November 2022.

In addition, we are exploring the application of GeminiOne® TEER technology in treating tricuspid valve disease. The FIM clinical trial is under preparation.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MonarQ™ SUCCESSFULLY.**

### **Platform Technologies**

We are committed to constantly exploring platform technologies that can be applied to a variety of therapies. As of the date of this announcement, we have three patented platform technologies, namely *Non-glutaraldehyde Crosslinked Dry-tissue Technology*, *Polymeric Trileaflet Technology* and *Lithotripsy Valvuloplasty Technology*.

*Non-glutaraldehyde Crosslinked Dry-tissue Technology* and *Polymeric Trileaflet Technology* are currently utilized in our third-generation TAVR product, TaurusNXT®, and our fourth-generation TAVR product, TaurusApex®. These technologies can also be utilized with other TAVR, TMVR or TTVR product candidates.

*Lithotripsy Valvuloplasty Technology*, currently utilized in the TaurusWave® system, is a non-implant solution to treat AS by remodeling the severe calcification. We are currently carrying out an FIM clinical trial for the technology. The initial results indicate the safety and efficacy of the technology. The technology can be applied on a stand-alone basis or as a pre-implantation step during the transcatheter valve replacement procedure.

## **Neurointerventional Products and Product Candidates**

We have a comprehensive portfolio of commercialized and pipeline products that target both hemorrhagic and ischemic stroke areas. For the year ended December 31, 2022, our revenue generated from the sales of neurointerventional products amounted to RMB143.5 million, representing an increase of 51.7% from approximately RMB94.6 million recorded during the year ended December 31, 2021.

## **Hemorrhagic Products and Product Candidates**

For the year ended December 31, 2022, we generated a total revenue of RMB56.5 million from hemorrhagic products, representing an increase of 10.2% from approximately RMB51.3 million for the year ended December 31, 2021 and accounting for 39.4% of the total revenue of the Neurointerventional Business.

***Detachable Coils:*** we have three registered detachable coil products with different detachment methods, namely, Jasper® Detachable Coil, Presgo® Detachable Coil and Jasper® SS Detachable Coils. We received the NMPA approval for the registration application of Jasper® SS Detachable Coil, our latest generation detachable coil, in June 2021. The detachment process of Jasper® SS Detachable Coil is the same as that of the previous generation, Jasper® Detachable Coil, whereas Jasper® SS Detachable Coil is much softer in order to address specific clinical needs during the fill and finish processes of a cerebral aneurysm endovascular coiling procedure.

We are also in the process of developing a coil product that can be thermally detached. The coil is designed for framing, filling and finishing. It is a significant addition to our existing product offering of embolization coils, providing an alternative detachment method to physicians. As of the date of this announcement, the registration application of this coil is pending for approval by the NMPA.

***Intracranial Adjunctive Stent:*** Intracranial Adjunctive Stent is indicated for use with neurovascular embolization coils in the endovascular treatment of intracranial aneurysms. Stent-assisted coil embolization allows endovascular treatment of complex shaped and wide necked intracranial aneurysms. As of the date of this announcement, the product is in the design stage.

***Delivery Occlusion Balloon Catheter:*** Balloon-assisted coil embolization is a technique involving the intra-procedural remodeling of the aneurysm neck, through the inflation of balloon. By ensuring the framing stability and even distribution of the coils, packing density can be largely improved with proper remodeling of the aneurysm neck, thus reducing the chances of endovascular stent implantation. In addition, if the aneurysm neck requires permanent support after the coil embolization procedure, the endovascular stent can be delivered directly through the inner lumen of the catheter. The catheter provides an alternative treatment solution to physicians while simplifying the procedure.

## **Ischemic Products and Product Candidates**

For the year ended December 31, 2022, we generated a total revenue of RMB39.5 million from ischemic products, representing an increase of 103.1% from approximately RMB19.5 million for the year ended December 31, 2021 and accounting for 27.6% of the total revenue of the Neurointerventional Business.

### ***Products Designed for Treating AIS***

***Syphonet® Stent Retriever*** (formerly named as Shenyi® in English): Syphonet® Stent Retriever is a significant product designed for removing thrombus in intracranial vessels in a mechanical thrombectomy procedure for patients with AIS. The product's unique design features a capture basket at the distal end, which can effectively prevent the thrombus debris from dislodging into the blood stream, thereby improving the removal of the thrombus. Additionally, the stent is designed with an optimized radial force to maintain the integrity of the lumen, even in tortuous vessels. Radiopaque wires in the stent and a radiopaque marker on the distal end allow for visualization of the entire retriever, providing physicians with better visual guidance. The Syphonet® Stent Retriever has various specifications, all compatible with 0.017-inch microcatheter. The compatibility will improve the success rate of deployment and reduce procedure time. We received the NMPA approval for the registration application of Syphonet® Stent Retriever in February 2022. As of the date of this announcement, we have initiated and are continuing facilitating the commercialization of this product.

***Tethys AS® Aspiration Catheter:*** our Tethys AS® Aspiration Catheter is specially designed for direct aspiration in mechanical thrombectomy. The 0.071-inch large lumen of the product largely increases the aspiration force, which can significantly shorten procedure time. It features a 20cm soft segment at the distal end, which conforms to the tortuous vessels and largely enhances its deliverability to the distal vessels. The optimized design of the transitional structure improves the trackability of the catheter, allowing the device to be delivered to the target vessel more easily. The entire device adopts a double-layer design with outer braids and inner coils, which allows high compressive strength and helps maintain lumen integrity. We received the NMPA approval for the registration application of Tethys AS® Aspiration Catheter in May 2022. As of the date of this announcement, we have initiated and are continuing facilitating the commercialization of this product.

***Fluxcap® Balloon Guide Catheter:*** Fluxcap® Balloon Guide Catheter has 0.087-inch large lumen and is compatible with 6F intermediate catheters or aspiration catheters. The reinforced layer with transition zones leads to a balance of proximal support and distal flexibility, offering a stable passage for intracranial devices. The 0.75mm non-radiopaque segment at the tip can reduce the blind spots of the physicians and thus, improving the safety of the procedure. The compliant balloon, at its tip, can block proximal flow and effectively prevent the thrombus from dislodging into the distal vessels. We received the NMPA approval for the registration application of Fluxcap® Balloon Guide Catheter in June 2022. As of the date of this announcement, we have initiated and are continuing facilitating the commercialization of this product.

With the successive launch of Syphonet® Stent Retriever, Tethys AS® Aspiration Catheter and Fluxcap® Balloon Guide Catheter, we are able to provide physicians a fully integrated solution for mechanical thrombectomy. Physicians can rely on our product combinations for different procedures, based on the clinical needs of patients.

***Aspiration Catheter (Larger Lumen):*** Aspiration Catheter (Larger Lumen) is a product candidate for treating AIS, which is in the design stage. The product features large lumen to improve aspiration capacity and efficiency, with 8F outer diameter and 0.097-inch inner diameter.

## ***Products Designed for Treating ICAD***

***SacSpeed® Balloon Dilatation Catheter:*** we commercially launched SacSpeed® Balloon Dilatation Catheter in the fourth quarter of 2020. The Catheter is used for dilatating stenosis to help with intracranial blood supply, while treating ICAD.

***Fastunnel® Delivery Balloon Dilatation Catheter*** (formerly named as Neway Balloon Microcatheter): Fastunnel® Delivery Balloon Dilatation Catheter is designed for treating ICAD. As the first medical device in China which combines balloon dilation and stent delivery in one device, its unique “zero exchange” technology redefines ICAD treatment. The product utilizes an integrated design combining the features of both balloon dilatation catheter and microcatheter, which can reduce the number of device exchanges and improve the safety of the procedure. The balloon uses Pebax® semi-compliant materials to achieve steady shape and safe expansion. Meanwhile, the stainless steel structure reinforces the entire device, and thus improves the trackability of the catheter and the deliverability of the intracranial stent system. In addition, the 150cm delivery system is compatible with intermediate catheters length of 135cm and below. We received the NMPA approval for the registration application of Fastunnel® Delivery Balloon Dilatation Catheter in May 2022. As of the date of this announcement, we have initiated and are continuing facilitating the commercialization of this product.

***NeuroStella® Intracranial Stent:*** NeuroStella® Intracranial Stent is designed for treating ICAD. The product is compatible with 0.017-inch microcatheter and is designed with optimized radial force which enables better stent apposition. As of the date of this announcement, the product is under registration clinical trial stage.

## **Vascular Access Products and Product Candidates**

For the year ended December 31, 2022, we generated a total revenue of RMB47.2 million from vascular access products, representing an increase of 100.4% from approximately RMB23.5 million for the year ended December 31, 2021 and accounting for 32.9% of the total revenue in the Neurointerventional Business.

***Tethys® Intermediate Catheter:*** we received the NMPA approval for the registration application of Tethys® Intermediate Catheter in October 2020. Our Tethys® Intermediate Catheter assists the delivery of diagnostic devices and/or treatment devices to the neurovascular and peripheral vascular system. It is applicable in various procedures, including aneurysm embolization, mechanical thrombectomy and ICAD procedures. The catheter provides strong support and stability for the operation of microcatheters, embolization coils, stent retrievers, and balloon dilatation catheters in distal blood vessels.

***Heralder® DA Distal Access Catheter:*** we received the NMPA approval for the registration application of Herald® DA Distal Access Catheter in June 2021, providing more options for the delivery of devices to different positions.

Other registered vascular access products include Presgo® Microcatheter, Presgo® Micro Guidewire and Herald® Guide Catheter.

Additional vascular access product candidates include the Micro Guidewire (Next Generation) and the Microcatheter (Next Generation). As of the date of this announcement, the registration application of the Micro Guidewire (Next Generation) is pending for approval by the NMPA, and the Microcatheter (Next Generation) is in the design stage. The Micro Guidewire (Next Generation) is a newly designed micro guidewire that can be more easily handled by physicians, achieving 1:1 torque ratio. The Microcatheter (Next Generation) utilizes more advanced cutting techniques for better support and pushability, applicable in endovascular procedures for both hemorrhagic and ischemic strokes.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP OR MARKET THE ABOVE PRODUCTS OR PRODUCT CANDIDATES SUCCESSFULLY.**

### **Research and Development**

In-house innovation and business development opportunities are crucial to the Company's R&D pipeline. Our core R&D team is led by Dr. Yi ZHANG (Board Chairman and Chief Executive Officer), Mr. Kongrong Karl PAN (Chief Operating Officer) and Dr. Jian Fong TAN (Chief Technology Officer). All of them are industry veteran with impressive academic and professional backgrounds, having previously worked in managerial positions at various leading players in the medical device sector.

We have extensive relationships with global leaders in both the transcatheter valve therapeutic and neurointerventional fields, including world-class scientists, physicians and industry experts. In addition to the licensing of cutting-edge technologies, we have also established overseas R&D capabilities through close collaboration:

For Sutra, the Company is the second-largest shareholder beside the founder, and has the right of first offer if Sutra proposes to offer or sell any new securities, subject to certain customary exceptions. We share R&D facilities with Sutra in the United States, and they have assisted us in expanding our R&D presence in North America. The founding team of Sutra is composed of professionals with extensive academic and industrial experience.

For inQB8, it is a medtech incubator in partnership with the Company. Under the partnership, we will have exclusive global privileges and rights to the technologies regarding the joint development of novel products and solutions in treating structural heart disease. The founding team of inQB8 has a multidisciplinary background in medtech and engineering. Before founding inQB8, the team founded CardiAQ Valve Technologies, which developed the world's first TMVR system and was later acquired by Edwards Lifesciences.

We have established close working relationship with world-class consultants, who provide services exclusively for us in China. They are heavily involved in our R&D process, contributing significantly to our innovative aortic, mitral and tricuspid valve products:

Dr. Nicolo PIAZZA is a renowned interventional cardiologist at McGill University Health Center and the German Heart Center in Munich. He has also served as either the chairman or a core team member in many premier transcatheter valve therapeutics conferences, including EuroPCR, PCR London Valves and PCR-CIT China Chengdu Valves. He is actively involved in our overseas business development, product promotion and clinical trials, including the clinical trial and technology transfer of HighLife® as well as the clinical trial of TaurusWave®.

Dr. Saibal KAR joined the Company as a consultant in September 2021. He is a world-leading doctor well-known for his research and achievements in the field of structural heart therapies, particularly in mitral repair space. Dr. Saibal KAR also serves as an external consultant for various multinational medical device companies such as Medtronic plc, Boston Scientific Corporation, and Abbott Vascular Inc. He has worked as a principal investigator in several multi-center studies and randomized studies for MitraClip™. Dr. Saibal KAR is currently advising on the R&D of our mitral edge-to-edge therapies.

Dr. Khung Keong YEO joined the Company as a consultant in April 2022. He is the deputy Chief Executive Officer (data science and innovation) and a senior consultant with the Department of Cardiology at the National Heart Center Singapore (NHCS). Dr. YEO currently leads Asia's first MitraClip™ program at NHCS. He is advising the R&D of our mitral and tricuspid edge-to-edge repair therapies.

Suzhou SITRI Interventional Medtech Institute (“**IMI**”), an innovation incubation and investment platform dedicated to the field of vascular interventional medical devices, was established in October 2021. The IMI was proposed and funded together by the Company and with Suzhou Industrial Park Administrative Committee, Suzhou Industrial Technology Research Institute, and IMI management team. The establishment of IMI will facilitate our R&D activities by providing us with access to emerging medical device technologies that might have significant global impact, which will benefit our future business expansion.

As of December 31, 2022, we had an in-house team of 133 employees dedicated to the research and development of our transcatheter valve therapeutic products and neurointerventional products.

## **Intellectual Property**

As of December 31, 2022, we had a robust intellectual property portfolio, consisting of a total of 101 granted and valid patents and 126 patents under application. Specifically, there are 63 granted and valid patents and 105 patents under application for our Transcatheter Valve Therapeutic Business, and 38 granted and valid patents and 21 patents under application for our Neurointerventional Business.

## **Manufacturing**

We manufacture, assemble and inspect our products at two production facilities. One is located in an 18,843.9 sq.m. self-owned properties in Suzhou, Jiangsu province, and the other one is located in an 1,188.4 sq.m. leased properties in Shanghai.

In our Neurointerventional Business, we currently manufacture Presgo<sup>®</sup> Detachable Coil, Presgo<sup>®</sup> Micro Guidewire, Presgo<sup>®</sup> Microcatheter, Jasper<sup>®</sup> Detachable Coil and Jasper<sup>®</sup> Power Supply in Shanghai. The Herald<sup>®</sup> Guide Catheter, Tethys<sup>®</sup> Intermediate Catheter, SacSpeed<sup>®</sup> Balloon Dilatation Catheter, Jasper<sup>®</sup> SS Detachable Coil, Herald<sup>®</sup> DA Distal Access Catheter, Syphonet<sup>®</sup> Retriever Stent, Tethys AS<sup>®</sup> Aspiration Catheter, Fastunnel<sup>®</sup> Delivery Balloon Dilatation Catheter and Fluxcap<sup>®</sup> Balloon Guide Catheter are manufactured in our Suzhou facility.

In our Transcatheter Valve Therapeutic Business, we had five registered products as of December 31, 2022. All of them, namely, TaurusOne<sup>®</sup>, TaurusElite<sup>®</sup>, our first and second generation TAVR products, TaurusAtlas<sup>®</sup> Transfemoral Balloon Catheter, TaurusNavi<sup>®</sup> Introducer Sheath and TaurusExplora<sup>®</sup> Pre-shaped Guidewire, are manufactured in our Suzhou facility. Our Suzhou facility is also equipped with multiple production lines dedicated to TaurusNXT<sup>®</sup>, TaurusWave<sup>®</sup>, HighLife<sup>®</sup> and other production lines for transcatheter valve therapeutic product candidates.

We have developed the Risk Management and Control Procedures (《風險管理控制程序》) to monitor compliance with our quality control system at every phase in a product life cycle and use scientific tools to identify, analyze, evaluate and control risks to ensure the safety and efficacy of medical devices.

We have established an advanced quality management system. It is our responsibility to develop products that allow patients to enjoy healthy lives and strictly abide by the Product Quality Law of the People's Republic of China (《中華人民共和國產品質量法》), Measures for the Supervision and Administration of Medical Device Production (《醫療器械生產監督管理辦法》), Good Manufacturing Practices for Medical Devices (《醫療器械生產質量管理規範》) and other laws and regulations. Our Quality Management System is aligned to relevant laws and international standards, including GMP standards and the ISO 13485:2016 Medical devices — Quality management systems.

We have continuously expanded our production capacity to meet growing market demand. Our new headquarter in Suzhou Industrial Park with a total planned construction area of around 77,600 sq.m. is under construction. Phase I will be ready for production in 2023.

## **Commercialization**

As of December 31, 2022, we had a sales and marketing team of 262 employees, with 185 employees focusing on the sales and marketing of our transcatheter valve therapeutic products and 77 employees focusing on the sales and marketing of neurointerventional products.

For our Transcatheter Valve Therapeutic Business, through well-planned internal training system and rigorous staff development plan, we have built a professional sales and marketing team with leading expertise in academic education and marketing. Our team is comprised of:

- product specialists, who collaborate with the R&D team to align product roadmaps with the lifecycle of our product portfolio to address unmet clinical needs;
- marketing specialists, who promote brand awareness and make connections with KOLs/hospitals, emphasizing on the optimization and iteration of product candidates;
- professional education specialists, who promote brand awareness and make connections with KOLs/hospitals emphasizing on market education;
- clinical support specialists, who provide seamless technical support and intensive involvement to ensure the best patient outcomes; and

- frontline sales, who stay connected with physicians and hospitals to complete sales processes.

In addition to the sales and marketing staff as mentioned above, we also have a team of medical specialists. They are licensed physicians with extensive clinical experience and can provide full medical support for patient evaluation, procedure planning and other clinical needs.

To increase our academic influence in the industry, we have participated in domestic and international academic conferences, as well as branded academic promotion activities organized by relevant associations in the cardiovascular field. We work closely with domestic and foreign experts and scholars, to promote the adoption of TAVR technology and increase regional implantation volume. At the same time, we have created a series of Peijia branded academic programs through Yijia Institute, a professional education platform, and other digital academic media outlets. We use these academic programs to educate physicians about the Taurus-series products and increase product adoption by new and emerging hospitals:

- Yijia Institute is Peijia Medical's professional clinical education and training center that includes both online and offline channels. Yijia Institute was established to facilitate the adoption of TAVR technology through procedure demonstration, academic thematic discussion, case analysis, patient diagnosis and screening and etc.;
- Yijia Institute is equipped with training classrooms, laboratories, operation rooms facilities. The institute can provide professional trainings, imaging trainings, live-streaming of procedures, and other activities. The institute also offers online programs include Round Table Discussions, Cloud Classrooms, Imaging Interpretation Competitions and others to help more physicians to learn and communicate online;
- In June 2022, we launched the WeChat official and video accounts for Yijia Institute. As a professional education platform, the accounts provide educational resources and the latest industry information in transcatheter valve interventions. By combining resources from both theory and practice, the platform benefits the experts and physicians during their use of TAVR technologies. Yijia Institute promotes the digital dissemination of professional education and industry information in transcatheter valve interventions in China, facilitating the further development of the therapy.

Since the launch of these programs, more than 450 experts and physicians have participated in our activities as guest speakers, with more than 50,000 attendees. Through these programs, we have forged long-term ties with leading experts and scholars.

The three key building blocks for accelerated commercialization of our TAVR products are: accurate product positioning and superior product performance; well rounded marketing and sales support; and a high-touch sales model covering every production stage of the product. We are dedicated to becoming the best product partner and service provider to physicians.

As of December 31, 2022, we had TAVR implantations in 290 hospitals, well ahead of schedule. We will continue to strengthen our research cooperation with TOP/KA hospitals and size up the sales team for more coverage and adoption of our TAVR products.

For our Neurointerventional Business, our experienced marketing team has tailored marketing strategies to maximize product visibility and penetration, based on the commercialization stage and design characteristics of each product. We work closely with KOLs and physicians in the industry. In addition to actively participating in academic and industry conferences on neurointerventional therapies, we live-streamed neurointerventional procedures conducted by physicians from top hospitals, which effectively enhanced our product reputation and brand awareness.

In addition, we have a sales team with strong product knowledge and clinical resources. Our sales team has established extensive relationships with industry experts, physicians and hospitals, and maintained long-term cooperation with experienced distributors. Most of our products are sold directly to hospitals through distributors. We believe that through a single-tier distribution system, we can leverage our distributors' local networks and expertise to reach a wider range of end customers. In return, we can better adapt to changes in end-user demand and be more responsive to clinical feedback. The single-tier distribution system can also enable predictable inventory-levels, reduce channel costs and lower product return rate as compared to multi-tier distribution system.

As of December 31, 2022, we had 205 distributors, covering around 2,000 hospitals in 31 provinces nationwide. We will continue to build our sales team and distributor coverage to serve our expanding ischemic product portfolio.

## **Impact of the COVID-19 Pandemic**

The Chinese government has strengthened the epidemic prevention and control since the outbreak of successive Delta variant and Omicron variant cases in 2021. Despite of the social restrictions imposed, our revenue for the Reporting Period increased by 83.7% to RMB250.8 million from RMB136.5 million for the year ended December 31, 2021. The adverse impact on our product sales, financial condition and results of procedures were limited due to our prompt and proactive actions.

## **Future Outlook**

In the future, we will uphold our corporate vision and continue our commitment to the development and commercialization of interventional solutions for structural heart and neurovascular diseases in China and globally. For our Transcatheter Valve Therapeutic Business, our sales and marketing team will focus on the commercialization of our registered TAVR products, including TaurusOne<sup>®</sup> and TaurusElite<sup>®</sup>. In addition, we will continue to actively launch clinical trials for our pre-clinical stage product candidate including TaurusTrio<sup>™</sup>, TaurusApex<sup>®</sup> etc., and facilitate the progress of those that are currently in the clinical stage, including TaurusNXT<sup>®</sup>, HighLife<sup>®</sup>, GeminiOne<sup>®</sup> and MonarQ<sup>™</sup>.

For our Neurointerventional Business, we intend to maintain the sales growth momentum through further penetration of our existing products. We will continue to facilitate the commercialization of the new products approved by the NMPA during the Reporting Period, including Syphonet<sup>®</sup> Stent Retriever, Tethys AS<sup>®</sup> Aspiration Catheter, Fastunnel<sup>®</sup> Delivery Balloon Dilatation Catheter and Fluxcap<sup>®</sup> Balloon Guide Catheter.

We will continue to enhance our pipeline, including TMV/TTV treatment device, and other transcatheter valve therapeutic and neurointerventional product candidates by strengthening our in-house R&D capabilities while seeking strong, cooperative and strategic partnerships around the globe. We believe this will strengthen our international patent portfolio and further advance our globalization strategy.

## II. FINANCIAL REVIEW

### Revenue

For the year ended December 31, 2022, our Group's revenue was RMB250.8 million, representing an increase of 83.7% as compared to RMB136.5 million for the year ended December 31, 2021. Revenue from Neurointerventional Business and Transcatheter Valve Therapeutic Business were RMB143.5 million and RMB107.3 million, representing an increase of 51.7% and 155.9% as compared to RMB94.6 million and RMB41.9 million for the year ended December 31, 2021, respectively.

The increase in revenue was primarily attributable to: (i) commercialization of the second generation retrievable TAVR product TaurusElite®, of which the revenue increased by RMB57.7 million; (ii) increase in sales volume of Tethys® Intermediate Catheter, of which the revenue increased by RMB22.7 million; and (iii) increase in sales volume of Jasper® SS Detachable Coil, of which the revenue increased by RMB19.5 million.

The following table sets forth a breakdown of our revenue generated from Neurointerventional Business for the periods indicated:

	Year ended December 31,			
	2022		2021	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
Hemorrhagic	<b>56,521</b>	<b>39.4</b>	51,293	54.2
Ischemic	<b>39,541</b>	<b>27.6</b>	19,465	20.6
Vascular Access	<b>47,173</b>	<b>32.9</b>	23,539	24.9
others	<b>287</b>	<b>0.1</b>	296	0.3
<b>Total</b>	<b><u>143,522</u></b>	<b><u>100.0</u></b>	<b><u>94,593</u></b>	<b><u>100.0</u></b>

### Cost of Sales

For the year ended December 31, 2022, our Group's cost of sales was RMB74.6 million, representing an increase of 82.6% as compared to RMB40.9 million for the year ended December 31, 2021. The increase was primarily attributable to the increase in the material costs, labor costs and overheads as a result of the increased sales volume of the Transcatheter Valve Therapeutic Business and Neurointerventional Business.

## **Gross Profit and Gross Profit Margin**

As a result of the aforementioned factors, our Group's gross profit increased by 84.2%, from RMB95.7 million for the year ended December 31, 2021 to RMB176.2 million for the year ended December 31, 2022, in line with the increase in sales revenue. Gross profit margin is calculated as gross profit divided by revenue and multiplying the result by 100%. Our Group's gross profit margin was 70.2% for the year ended December 31, 2022, as compared to 70.1% for the year ended December 31, 2021.

## **Selling and Distribution Expenses**

Selling and distribution expenses increased by 159.1% from RMB93.3 million for the year ended December 31, 2021 to RMB241.6 million for the year ended December 31, 2022. Such increase was primarily attributable to (i) promotion for new products; (ii) development for multi-sales channels; (iii) increase in the headcount of sales team to expand the market in Mainland China.

## **Administrative Expenses**

Administrative expenses increased by 7.9% from RMB114.4 million for the year ended December 31, 2021 to RMB123.4 million for the year ended December 31, 2022. The increase was primarily attributable to increase in staff costs.

## **Research and Development Expenses**

Research and development expenses decreased by 16.3% from RMB445.9 million for the year ended December 31, 2021 to RMB373.1 million for the year ended December 31, 2022. Such decrease was primarily attributable to the service expenses paid for the research and development of TSMVR products.

For the year ended December 31, 2022, R&D investment used in Transcatheter Valve Therapeutic Business and Neurointerventional Business amounted to RMB320.6 million and RMB52.5 million, respectively. The following table sets forth the components of research and development expenses for the periods indicated:

	Year ended December 31,			
	2022		2021	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
Service expenses for research and development	<b>249,859</b>	<b>67.0</b>	340,517	76.4
Employee benefits expenses	<b>69,649</b>	<b>18.7</b>	60,117	13.5
Raw materials and consumables used	<b>42,892</b>	<b>11.5</b>	33,731	7.7
Depreciation and amortization	<b>6,358</b>	<b>1.7</b>	5,253	1.2
Other	<b>4,369</b>	<b>1.1</b>	6,261	1.3
<b>Total</b>	<b><u>373,127</u></b>	<b><u>100.0</u></b>	<b><u>445,879</u></b>	<b><u>100.0</u></b>

### Other Gains/(Losses) — net

Other gains/(losses) — net increased from a net other losses of RMB50.6 million for the year ended December 31, 2021 to a net other gains of RMB106.7 million for the year ended December 31, 2022. The increase was mainly due to the foreign exchange gains.

### Finance Income

Finance income increased from RMB24.8 million for the year ended December 31, 2021 to RMB46.6 million for the year ended December 31, 2022. The increase was mainly due to the bank interest income.

### Gearing Ratio

Gearing ratio is calculated by dividing total liabilities by total equity and multiplying the result by 100%. As at December 31, 2022, the gearing ratio of our Group increased to 25.7% from 4.8% as of December 31, 2021. The increase was primarily attributable to the outstanding milestone payable for certain business development project.

### Net Current Assets

As of December 31, 2022, our Group's net current assets were RMB1,429.4 million, as compared with RMB2,307.7 million as of December 31, 2021.

## **Borrowings**

As of December 31, 2022, our Group's total borrowings amounted to RMB126.8 million, consisting of a long-term borrowing of RMB70.8 million which bore an interest rate of 3.8%–3.85% and a short-term borrowing of RMB56.0 million which bore an interest rate of 3.58%. The purpose of the long-term borrowing was for financing the construction of the new headquarter, while the purpose of the short-term borrowing was for purchasing raw materials, paying staff salaries and commencing service outsourcing.

## **Capital Management**

The primary goal of our Group's capital management is to maintain our Group's stability and growth, safeguard its normal operations and maximize Shareholders' value. Our Group reviews and manages its capital structure on a regular basis. Timely adjustments are made in light of changes in operating and market conditions.

## **Liquidity and Financial Resources**

As of December 31, 2022, our Group's total cash, cash equivalents and term deposits amounted to approximately RMB1,839.7 million, representing a decrease of 19.9% as compared to RMB2,296.1 million as of December 31, 2021. Our Group continues to maintain a strong financial position and is confident that it has sufficient funds to meet its daily business operation requirements.

We rely on capital contributions by our Shareholders as the major sources of liquidity. We also generate cash from our sales of existing commercialized products. As our business develops and expands, we expect to generate more net cash from our operating activities, through increasing sales revenue of existing commercialized products and by launching new products, as a result of the broader market acceptance of our existing products and our continued efforts in marketing and expansion, and improving cost control and operating efficiency.

Our Group adopts conservative treasury policies in cash and financial management. To achieve better risk control and minimize the cost of funds, our Group's treasury is centralized. Cash is generally placed in deposits mostly denominated in U.S. Dollars, Hong Kong dollars and RMB. Our Group's liquidity and financing requirements are reviewed regularly.

## **Capital Expenditure**

For the Reporting Period, our Group's total capital expenditure amounted to approximately RMB202.3 million, which was mainly used in (i) the construction of new headquarter; (ii) equipment procurement; and (iii) technologies.

## **Significant Investment**

As of December 31, 2022, our Group had unlisted equity investments of RMB245.2 million and unlisted debt investment of RMB71.6 million measured at fair value through profit or loss.

Save as disclosed above, our Group did not hold any significant investments in any other companies' equity interest during the Reporting Period.

## **Contingent Liabilities**

As of December 31, 2022, our Group did not have any significant contingent liabilities.

## **Material Acquisitions and Disposals**

For the year ended December 31, 2022, our Group did not have any material acquisitions and disposals of subsidiaries, associates and joint ventures.

## **Charge on Assets**

As of December 31, 2022, a land use right and a building under construction of our Group with carrying amounts of RMB9.6 million and RMB161.5 million respectively have been mortgaged for a long-term bank borrowing.

## **Foreign Exchange Exposure**

Our Group has transactional currency exposures. Certain cash and cash equivalents as well as financial assets at fair value through profit or loss are dominated in foreign currencies and are exposed to foreign currency risk. Our Group will constantly review the economic situation and its foreign exchange risk profile, and will consider appropriate hedging measures in the future, as may be necessary.

## USE OF PROCEEDS FROM THE GLOBAL OFFERING

Net proceeds from the Global Offering and the Listing on the Listing Date, and the full exercise of the Over-allotment Option, after deduction of the underwriting fees and commissions and expenses of the Company in connection with the Global Offering was approximately HK\$2,587.98 million. The Group would apply such proceeds in a manner consistent with the intended use of proceeds as disclosed in the Prospectus.

The use of net proceeds from the Global Offering during the period from the Listing Date up to December 31, 2022 and the expected timeline of the unutilized amount as at December 31, 2022 are set out as follows:

Business objective as stated in the Prospectus	Percentage to total amount %	Net proceeds HK\$ million	Unutilized amount as at January 1, 2022 HK\$ million	Utilized amount during the year ended December 31, 2022 HK\$ million	Unutilized amount as at December 31, 2022 HK\$ million	Expected timeline for unutilized amount
Development and commercialization of our Core Product and other major product candidates	65	1,682.18	1,498.85	338.54	1,160.31	Yr2025
Ongoing pre-clinical studies and planned clinical trials, preparation for registration filings and potential commercial launches (including sales and marketing) of our other product candidates in our pipeline	10	258.80	53.66	53.66	0	
Strengthen our research and development capabilities to enrich our product pipeline	8	207.04	167.47	40.07	127.4	Yr2024
Expand our product portfolio or intellectual property portfolio through potential strategic acquisitions, investments, partnerships and licensing opportunities	10	258.80	100.83	100.83	0	
Working capital and other general corporate purposes	7	181.16	53.08	53.08	0	
<b>Total</b>	<b>100</b>	<b>2,587.98</b>	<b>1,873.89</b>	<b>586.18</b>	<b>1,287.71</b>	

*Note:* The expected timeline for utilization of the unutilized net proceeds above is based on the Company's best estimation and is subject to change based on the future development of market conditions.

As at December 31, 2022, net proceeds from the Global Offering not yet utilized were deposited with certain licensed banks in Hong Kong or the PRC.

## **USE OF PROCEEDS FROM THE PLACING**

On January 22, 2021, the Company entered into the Placing Agreement with Morgan Stanley & Co. International plc, pursuant to which the Company appointed Morgan Stanley & Co. International plc as its placing agent to procure no less than six Placees who are Independent Third Parties to subscribe up to 33,800,000 Placing Shares at the placing price of HK\$29.38 per Placing Share in accordance with the terms and conditions of the Placing Agreement. The net placing price per Placing Share after deducting related fees and expenses was approximately HK\$28.74 per Share. The Placing Shares had a market value of approximately HK\$1,012.31 million based on the closing price of HK\$29.95 per Share as of January 21, 2021 and an aggregate nominal value of US\$3,380.

The Placing Shares represented approximately 5.3% of the existing issued share capital of the Company as of the Placing Agreement date, and approximately 5.1% of the enlarged issued share capital of the Company immediately following the completion of the Placing.

The Placing was completed on January 29, 2021. An aggregate of 33,800,000 Placing Shares have been successfully placed to no less than six Placees. To the best of the Directors' knowledge, information and belief, having made all reasonable enquiries, the Placees and their respective ultimate beneficial owners are professional, institutional, or other investors who are Independent Third Parties. The net proceeds from the Placing were approximately HK\$971.48 million, of which the intended use was set out in the announcement of the Company dated January 22, 2021. The Placing was being undertaken to strengthen the Group's financial position and for the long term funding of its business, expansion and growth plan. The use of net proceeds from the Placing during the period from the Listing Date up to December 31, 2022 and the expected timeline of the unutilized amount as at December 31, 2022 are set out as follows:

<b>Business objective as stated in the announcement of the Company dated January 22, 2021</b>	<b>Percentage to total amount</b> %	<b>Net proceeds</b> HK\$ million	<b>Unutilized amount as at January 1, 2022</b> HK\$ million	<b>Utilized amount during the year ended December 31, 2022</b> HK\$ million	<b>Unutilized amount as at December 31, 2022</b> HK\$ million	<b>Expected timeline for unutilized amount</b>
To fund potential product licensing and possible merger and acquisition opportunities in the area of mitral valve replacement and repair treatment, including a collaboration and license agreement for transeptal mitral valve replacement with HighLife SAS dated December 18, 2020 (for further details, please refer to the voluntary announcement of the Company, published on December 21, 2020)	30	291.44	38.52	13.21	25.31	Yr2025
To fund potential product licensing and possible merger and acquisition opportunities in other areas including tricuspid valve replacement and repair treatment	40	388.59	118.64	0	118.64	Yr2023
To fund ongoing technology transfer, product development, and research and development, across the Group	25	242.87	155.53	0	155.53	Yr2023
For other general corporate purposes	5	48.58	48.58	0	48.58	Yr2023
<b>Total</b>	<b>100</b>	<b>971.48</b>	<b>361.27</b>	<b>13.21</b>	<b>348.06</b>	

*Note:* The expected timeline for utilization of the unutilized net proceeds from the Placing above is based on the Company's best estimation and is subject to change based on the future development of market conditions.

As of December 31, 2022, net proceeds from the Placing not yet utilized were deposited with certain licensed banks in Hong Kong or the PRC.

## **HUMAN RESOURCES**

As of December 31, 2022, our Group had 927 employees, all of whom were based in China. Our Group's total employee benefits for the Reporting Period were approximately RMB262.0 million, consisted of (i) wages, salaries and bonuses, (ii) social security costs and housing benefits, (iii) employee welfare and (iv) share-based compensation expenses.

We recruit our employees based on a number of factors, including work experience, educational background and the requirements of a relevant position. We invest in continuing education programs for our management staff and other employees to improve their relevant skills and knowledge. We provide our employees with regular feedback as well as internal and external training in various areas, such as product training, project development and team building. We also assess our employees based on their performance to determine their salaries, 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.

## **SUBSEQUENT EVENT AFTER THE REPORTING PERIOD**

Save for those disclosed in this announcement, our Group is not aware of any material subsequent events after the Reporting Period.

## **FINAL DIVIDEND**

The Board has resolved not to declare any final dividend for the Reporting Period (year ended December 31, 2021: nil).

## **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 Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the Shareholders as a whole. The Company has adopted the code provisions as set out in the CG Code, as its own code to govern its corporate governance practices.

Under the code provision C.2.1 of the CG Code, the roles of chairman and chief executive should be separate and should not be performed by the same individual. Under the current organization structure of the Company, Dr. Zhang 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 since its establishment, Dr. Zhang is in charge of overall management, business, strategic development and scientific R&D of our Group. 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 our Group. The balance of power and authority is ensured by the operation of the Board, which comprises experienced and diverse individuals. The Board currently comprises three executive Directors (including Dr. Zhang), four non-executive Directors and four independent non-executive Directors, and therefore has a strong independent element in its composition.

Save as disclosed above, in the opinion of the Directors, the Company has complied with the relevant code provisions contained in the CG Code during the year ended December 31, 2022.

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 and the Company's senior management who, because of his/her office or employment, is likely to possess inside information in relation to the Company's securities.

Upon specific enquiries, all Directors confirmed that they have complied with the Model Code during the year ended December 31, 2022. In addition, the Company is not aware of any non-compliance of the Model Code by the senior management of the Group during the year ended December 31, 2022.

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

As of December 31, 2022, the trustee of the RSU Scheme has purchased an aggregate of 5,859,000 Shares (representing approximately 0.8649% of the total issued share capital of the Company) under the RSU Scheme.

Save for those disclosed above, neither the Company nor any of its subsidiaries have purchased, sold or redeemed any of the Company's listed securities during the year ended December 31, 2022.

## **REVIEW OF FINANCIAL INFORMATION**

### **Audit Committee**

The Company has established an Audit Committee with written terms of reference in accordance with the Listing Rules. As of the date of this announcement, the Audit Committee comprises one non-executive Director, namely Mr. Jifeng GUAN, and three independent non-executive Directors, namely, Mr. Robert Ralph PARKS, Mr. Wai Ming YIP and Mr. Huacheng WEI. Mr. Wai Ming YIP is the chairman of the Audit Committee.

The Audit Committee has held relevant discussions with the Company's management, and reviewed the audited consolidated financial statements of our Group for the Reporting Period. The Audit Committee considered that the annual results of our Group for the Reporting Period are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof.

### **Scope of Work of the Company's Auditors**

The figures in respect to the Group's consolidated statement of comprehensive loss, consolidated balance sheet and the related notes thereto for the year ended December 31, 2022 as set out in the preliminary announcement have been agreed by the Company's auditors, PricewaterhouseCoopers, to the amounts set out in the Group's audited consolidated financial statements for the year.

The work performed by PricewaterhouseCoopers 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 PricewaterhouseCoopers on the preliminary announcement.

## **PUBLICATION OF RESULTS ANNOUNCEMENT AND ANNUAL REPORT**

This announcement is published on the website of the Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company's website ([www.peijiamedical.com](http://www.peijiamedical.com)). The annual report of the Company for the Reporting Period containing all the information required by the Listing Rules will be dispatched to Shareholders and published on the above websites in due course.

## **APPRECIATION**

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

## **DEFINITIONS**

In this annual results announcement, the following expressions shall have the meanings set out below, unless the context otherwise requires:

“Achieva” or “Achieva Group”	includes Achieva Medical and its subsidiaries, i.e., Achieva HK, Achieva Shanghai, Achieva Suzhou and Jiangxi Zhisheng
“Achieva Medical”	Achieva Medical Limited, an exempt limited liability company incorporated under the laws of the Cayman Islands on November 2, 2005, being a wholly-owned subsidiary of our Company
“AIS”	acute ischemic stroke, a disease occurs when the blood flow through the cerebral arteries is blocked by a clot (i.e., a large amount of thickened blood)
“aortic valve”	a valve in the human heart between the left ventricle and the aorta
“AR”	aortic regurgitation
“AS”	aortic stenosis
“Audit Committee”	the audit committee of the Board
“BD”	business development
“Board of Directors” or “Board”	the board of Directors

“CG Code”	the Corporate Governance Code as set out in Appendix 14 to the Listing Rules
“China” or “PRC”	the People’s Republic of China, which for the purpose of this announcement and for geographical reference only, Hong Kong, Macau and Taiwan
“CODM”	chief operating decision-maker
“Company” or “our Company”	Peijia Medical Limited (沛嘉醫療有限公司), an exempt limited liability company incorporated under the laws of the Cayman Islands on May 30, 2012
“connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“Core Product”	has the meaning ascribed thereto in Chapter 18A of the Listing Rules, which, for purposes of this announcement, refers to TaurusOne®
“delivery catheter system”	an integral delivery catheter with a tip, a sheath tube, a catheter and a handle system used to deliver and release the PAV to the target position
“Director(s)”	the director(s) of the Company
“Dr. Zhang”	Dr. Yi Zhang, one of our Founders, and our chairman, Chief Executive Officer, an executive Director of our Company and our substantial shareholder upon Listing
“FIM”	First-in-man, a stage of clinical trial
“Global Offering”	has the meaning as ascribed to it under the Prospectus
“Group,” “our Group,” “our,” “we,” or “us”	our Company and all of its subsidiaries (including but not limited to Achieva), or any one of them as the context may require or, where the context refers to any time prior to its incorporation or the Share Swap, 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

“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong dollars”, “HKD” or “HK\$”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
“ICAD”	intracranial atherosclerotic disease
“ICAS-LVO”	intracranial atherosclerosis-related large vascular occlusion
“IFRS”	International Financial Reporting Standards, as issued from time to time by the International Accounting Standards Board
“Independent Third Party” or “Independent Third Parties”	a person or entity who is not a connected person of our Company under the Listing Rules
“KOL(s)”	Key Opinion Leader(s), renowned physicians that are able to influence their peers’ medical practice
“Listing”	the listing of the Shares on the Main Board of the Stock Exchange
“Listing Date”	the date, Friday, May 15, 2020, on which the Shares were listed and dealings in the Shares first commence on 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)
“LVOT”	Left ventricular outflow tract
“mechanical thrombectomy”	a type of minimally-invasive therapy in which blood clot is removed from arteries using imaging techniques guiding medical devices through patients’ arteries to the blood clot
“mitral valve”	the valve that lets blood flow from one chamber of the heart, the left atrium, to another called the left ventricle
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 to the Listing Rules

“MR”	mitral regurgitation
“Neurointerventional Business”	the business of the Group in research and development of neurointerventional procedural medical devices
“neurointerventional procedural medical devices”	medical devices for treatment of neurovascular diseases using interventional endovascular technique
“neurovascular diseases”	also known as cerebrovascular diseases, including any abnormality of the blood vessels within the brain and spine or abnormality with supplying blood to such areas
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局), formerly known as the China Food and Drug Administration or the CFDA
“Over-allotment Option”	has the meaning as ascribed to it under the Prospectus
“PAV”	prosthetic aortic valve, the artificial valve of our TAVR Products
“Peijia Shanghai”	Peijia Medical Technology (Shanghai) Co., Ltd. (沛嘉醫療科技(上海)有限公司), a limited liability company incorporated under the laws of PRC on February 24, 2012, being an indirect wholly-owned subsidiary of our Company
“Peijia Suzhou”	Peijia Medical Technology (Suzhou) Co., Ltd. (沛嘉醫療科技(蘇州)有限公司), a limited liability company incorporated under the laws of PRC on March 4, 2013, being an indirect wholly-owned subsidiary of our Company
“Placee(s)”	any individuals, corporate, institutional or other investor(s) procured by the Placing Agent or their respective agents to subscribe for any of the Placing Shares pursuant to the Placing Agreement
“Placing”	the placing of 33,800,000 Placing Shares pursuant to the terms of the Placing Agreement

“Placing Agreement”	the conditional placing agreement entered into between the Company and Morgan Stanley & Co. International plc dated January 22, 2021 in relation to the Placing
“Placing Shares”	33,800,000 Placing Shares to be placed pursuant to the Placing Agreement
“Prospectus”	the prospectus of the Company dated May 5, 2020, in relation to the Global Offering
“registration clinical trial”	a controlled clinical trial of a medical device product designed to demonstrate statistically significant clinical efficacy and safety of such product as used in human patients (in conjunction with the performance of a therapeutic procedure), for regulatory approval of such product
“Remuneration Committee”	the remuneration committee of the Board
“Reporting Period”	the year ended December 31, 2022
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“RSU Scheme”	the restricted share unit award scheme of the Company conditionally approved and adopted by our Shareholders on April 28, 2020, the principal terms of which are set out in Prospectus
“R&D”	research and development
“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) with nominal value of US\$0.0001 each in the share capital of the Company
“Shareholder(s)”	holder(s) of the Share(s)
“sq.m.”	square meter, a unit of area
“Stock Exchange”	The Stock Exchange of Hong Kong Limited

“subsidiary”	has the meaning ascribed thereto under the Listing Rules
“substantial shareholder(s)”	has the meaning ascribed thereto under the Listing Rules
“TAVR”	transcatheter aortic valve replacement, a catheter-based technique to implant a new aortic valve in an interventional procedure that does not involve open-chest surgery
“TEER”	transcatheter edge-to-edge repair
“TMVR”	transcatheter mitral valve replacement, a catheter-based technique to implant a new mitral valve in an interventional procedure that does not involve open-chest surgery
“TOP/KA hospitals”	hospitals in China which complete at least 100 (TOP) or 50 (KA) TAVR operations each year
“TR”	tricuspid regurgitation
“transcatheter valve therapeutic medical devices”	medical devices for the treatment of valvular heart diseases using cardiovascular interventional technique by implanting a prosthetic valve through an artery
“tricuspid valve”	the valve on the right dorsal side of the mammalian heart, between the right atrium and the right ventricle, the function of which is to prevent back flow of blood from the right ventricle into the right atriums
“TSMVR”	transseptal mitral value replacement
“TTVR”	transcatheter tricuspid valve replacement, a catheterbased technique to implant a new tricuspid valve in an interventional procedure that does not involve open-chest surgery
“U.S. dollars”, “US\$” or “USD”	United States dollars, the lawful currency of the United States
“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“valvular heart diseases”	the failure or dysfunction of one or more of the four heart valves, where the valves become too narrow and hardened to open fully, or are unable to close completely

“valvuloplasty”

a procedure using balloons to repair a heart valve with a narrowed opening and to improve blood flow through the valve

“%”

per cent

By order of the Board  
**Peijia Medical Limited**  
**Dr. Yi Zhang**  
*Chairman and Executive Director*

Hong Kong, March 31, 2023

*As of the date of this announcement, the Board comprises Dr. Yi Zhang, Mrs. Ping Ye Zhang and Ms. Hong Ye as executive Directors, Dr. Zhiyun Yu, Mr. Jifeng Guan, Mr. Fei Chen, Mr. Jun Yang as non-executive Directors, and Dr. Stephen Newman Oesterle, Mr. Robert Ralph Parks, Mr. Wai Ming Yip and Mr. Huacheng Wei as independent non-executive Directors.*