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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, 2021

The board (the “**Board**”) of directors (the “**Directors**”) of Peijia Medical Limited (the “**Company**”) is pleased to announce the audited consolidated results of the Company and its subsidiaries (collectively, the “**Group**”) for the year ended December 31, 2021 (the “**Reporting Period**”), together with the audited comparative figures for the year ended December 31, 2020.

### FINANCIAL HIGHLIGHTS

	Year ended December 31,		Year-on-year change
	2021	2020	
	RMB'000	RMB'000	
Revenue	136,534	38,655	253.2%
Gross profit	95,654	25,223	279.2%
Loss before income tax	(574,216)	(2,068,656)	-72.2%
Loss for the period and attributable to the owners of the Company	(574,216)	(2,068,656)	-72.2%
Cash and cash equivalents	2,296,112	2,458,161	-6.6%
Research and development expenses	(445,879)	(103,365)	331.4%
Including: One-time expensing business development (“ <b>BD</b> ”) payments	(314,575)	Nil	—

For the year ended December 31, 2021, the Group recorded a revenue of RMB136.5 million, as compared to RMB38.7 million for the same period in 2020, representing an increase of 253.2% in total revenue as compared with 2020; and a net loss of RMB574.2 million, as compared to RMB2,068.7 million for the same period in 2020.

The net loss for the year ended December 31, 2021 was mainly due to the increase in R&D expenses. The Group made upfront and milestone payments in relation to four BD projects in 2021, resulting in RMB314.6 million of one-time expensing R&D payments.

The net loss for the year ended December 31, 2020 was mainly due to fair value loss of RMB1,675.5 million attributable to financial instruments and foreign exchange losses of RMB221.2 million. The fair value loss of financial instruments is a non-cash item, and there will be no further gains or losses on fair value changes upon the closing of the global offering in 2020.

## **BUSINESS HIGHLIGHTS**

- 1. Both Transcatheter Valve Therapeutic Business and Neurointerventional Business are in the fast lane of commercialization, establishing a long-term foundation for steady cash flow growth and effectively reducing the Company's overall operational risk.*

2021 was the first year of commercialization of our Transcatheter Valve Therapeutic Business and we have seen robust performance. The first-and second-generation Taurus systems not only obtained NMPA approval earlier than expected, but also quickly gained market access. The provincial tendering and hospital access of such systems were progressing well, with a total of 95 hospitals (equivalent to 102 centers) entered by the end of 2021. Clinical feedbacks on the products were positive, and the sales and implantation were in good progress. As of the date of this announcement, sales and implantation volume maintained an accelerating upward trend and excellent momentum was observed in the first quarter of 2022.

The commercialization of the hemorrhagic products under the Neurointerventional Business continued to expand, and the commercialization of newly launched products of the ischemic and vascular access products was rapidly advancing, with revenue from the Neurointerventional Business in 2021 increased by 144.7%.

The revenue of the Transcatheter Valve Therapeutic Business and the Neurointerventional Business in 2021 reached RMB41.9 million and RMB94.6 million, respectively, which led to an increase of 253.2% in total revenue as compared with 2020. The rapid advancement of commercialization has laid a solid cash foundation for the long-term development of the Company.

2. *We have developed a comprehensive pipeline with innovative technologies to seize huge unmet market needs, through internal development and BD projects in the Transcatheter Valve Therapeutic Business. Our widest and deepest pipeline differentiates us from the peers and strengthen our competitiveness in the next-generation technologies.*

*We have built a strong pipeline with a wide range of innovative product candidates through external acquisitions as well as internal development. Our strategy is to employ both approaches to build a comprehensive portfolio in the next-generation technologies. From late 2020 to the date of this announcement, we have harvested 4 BD projects, which are deployed in the fields of aortic valve replacement for AR, mitral valve replacement, tricuspid valve replacement and mitral valve coaptation augmentation, respectively:*

- (1) The Trilogy™ Heart Valve System of JenaValve Technology Inc. (“**JenaValve**”) is the first and the only transfemoral device of its kind to receive CE Mark approval for the treatment of both severe symptomatic Aortic regurgitation (“**AR**”) and Aortic Stenosis (“**AS**”) as of the date of this announcement. AR is one of the most common types of aortic valve diseases. According to Frost & Sullivan, there were approximately 3.9 million patients with AR in China in 2020. According to a research jointly published by Academician Runlin Gao and Professor Zengwu Wang from Fuwai Hospital through BMC Cardiovasc Disord in 2021, the most common valvular heart disease was AR (1.2%), followed by mitral regurgitation (“**MR**”, 1.1%) and tricuspid regurgitation (“**TR**”, 0.8%), among the enrolled group aged 35 years or older. We entered into a series of agreements with JenaValve in December 2021, for an exclusive license regarding Trilogy™ Heart Valve System for the treatment of AR and AS in the Greater China region. The transaction will enable us to have the most comprehensive TAVR pipeline covering major aortic valve diseases, compared to other players in China. We have initiated the technology transfer as of the date of this announcement.
- (2) The HighLife TSMVR System is a leading product candidate in the field of mitral valve replacement in terms of technical route and clinical progress in the world. HighLife TSMVR product adopted the unique “Valve-in-Ring” concept, allowing the system to realize self-centering and self-alignment. According to Frost & Sullivan, there were approximately 10.8 million patients with MR in China in 2020. We entered into an exclusive license agreement with HighLife SAS (“**HighLife**”) in the fourth quarter of 2020 and completed the technology transfer in the third quarter of 2021. The product is currently in the process of research clinical trial, and we are expecting to initiate the confirmatory clinical trial in China in 2022.

- (3) The MonarQ TTVR system of inQB8 Medical Technologies (“**inQB8**”) is one of the few product candidates under development in the field of transcatheters tricuspid valve treatment. According to Frost & Sullivan, there were approximately 9.2 million patients with TR in China in 2020. We entered into a series of agreements with inQB8 in May 2021, a US-based medical technology incubator, to explore innovative solutions for treating structural heart diseases. The transaction includes our acquisition of MonarQ TTVR technology from inQB8, for which inQB8 will continue with the device development in partnership with us. MonarQ is currently in the pre-clinical evaluation stage and we expect to carry out FIM clinical trial in 2022.
- (4) The Sutra Hemi Valve of Sutra Medical Inc. (“**Sutra**”) is a hybrid transcatheter mitral valve coaptation augmentation treatment system between valve replacement and repair technology. The initial closing of the purchase and sale of shares of Sutra by us occurred in August 2021. As of the date this announcement, the product candidate is in the animal studies stage.

*In addition to BD projects, our internally developed projects are also progressing smoothly. The exploration directions include improving the durability of valve materials, non-implant treatment solution for valve disease and developing innovative mitral valve repair products.*

- (1) TaurusNXT<sup>®</sup> is our internally developed third-generation TAVR system. TaurusNXT<sup>®</sup> incorporates our patented non-glutaraldehyde crosslinking tissue processing technology that removes the root cause of valve calcification, which is the number one cause of prosthetic valve degeneration. The technology is expected to greatly enhance the durability and biocompatibility of the prosthetic aortic valve (“**PAV**”). Furthermore, comparing to the traditional dry tissue technology using glycerin, TaurusNXT<sup>®</sup> adopts a vacuum freeze-drying technology to maintain the physical integrity of the valve tissue while allowing the PAV to be preloaded onto the DCS. The first patient implant of TaurusNXT<sup>®</sup> was completed in September 2021. We are currently carrying out the multi-center confirmatory clinical trial for TaurusNXT<sup>®</sup>.
- (2) TaurusApex is our internally developed fourth-generation aortic valve replacement system. By replacing bio-materials with long-lasting and stable polymer materials, TaurusApex could further improve durability and biocompatibility of prosthetic valve. It could also significantly simplify the product manufacturing process and reduce the production cost. The development of TaurusApex is a significant step that we take to explore innovative solutions to improve the durability of the valve. We are currently conducting animal studies on TaurusApex with promising results.

- (3) TaurusWave® Lithotripsy Valvuloplasty System is our internally developed non-implant solution, using shockwave technology to remodel calcification on valve annulus and leaflets. After the treatment, the hemodynamics of the native valves could better fit the native annulus. 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. We are currently proceeding with FIM clinical trial for this product.
  - (4) GeminiOne is our internally developed transcatheter edge-to-edge repair (“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 lock & unlock during the procedure, as well as multi-angular detachment that copes with a wider range of anatomy. GeminiOne is designed to treat mitral valve and tricuspid valve diseases. The product is currently in the pre-clinical preparations stage, targeting the launch of clinical trial in 2022.
3. ***We have simultaneously deployed our Neurointerventional Business in the sizeable hemorrhagic market and the fast-growing ischemic market, and achieved remarkable results in R&D and sales. In addition to continuously consolidating our leading position in the hemorrhagic market with existing advantages, we have also established a complete product portfolio for ischemic stroke.***

In 2021, we continued to deeply cultivate the sizeable hemorrhagic market. Our market share has further expanded, thanks to our continuous efforts in product upgrades and long-precipitated sales relationships. A revenue growth rate of 52.3% was recorded in 2021 for the hemorrhagic product line as compared with 2020.

Our wide and complete product offering is paying off and three core products treating ischemic stroke have been launched or will be launched successively, including Syphonet® Stent Retriever, Tethys AS® Aspiration Catheter and Fluxcap® Balloon Guiding Catheter. Together with the Tethys® Intermediate Guiding Catheter, we have been able to provide a fully-integrated solution for treating acute ischemic stroke. The commercialization of the approved ischemic products progressed smoothly. For example, the SacSpeed® Balloon Dilatation Catheter, which was fully commercialized in 2021, has quickly become the market leader since its commercial launch. The subsequent launch of ischemic products will further increase the attractiveness of our product portfolio.

According to Frost & Sullivan, the embolization coiling market size in 2020 was approximately RMB1.7 billion, and will continue to expand at a compound annual growth rate of 15.3% between 2020 and 2030; the market size of ischemic stroke, excluding intracranial atherosclerotic disease (“**ICAD**”) was approximately RMB970.0 million in 2020, and will continue to expand at a compound annual growth rate of 32.0% between 2020 and 2030; the market size of ICAD was appropriately RMB400.0 million, and will continue to expand at a compound annual growth rate of 28.7% between 2020 and 2030. The simultaneous deployment in the large hemorrhagic market and the fast-growing ischemic market provides us with stable and continuous cash flow as well as room for rapid growth.

In 2021, the revenue from the ischemic and vascular access products accounted for 20.6% and 24.9% of the revenue from the Neurointerventional Business, respectively, while the revenue from the hemorrhagic products accounted for 54.2% of the revenue from the Neurointerventional Business in 2021, decreasing from 87.1% in 2020. The diversification of product portfolio not only improves our ability to resist risks, but also constantly increases the attractiveness and synergy of our product portfolio.

**4. *Our continual efforts made in optimizing supply chain for long term success.***

*Key achievements include:*

- (1) Expanding production capacity and production labor force to support business growth;
- (2) Diversifying and localizing material sourcing (such as bovine pericardium) to improve the supply chain stability and security while controlling cost;
- (3) Streamlining production process to improve efficiency and reduce production cost.



## CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

For the year ended 31 December 2021

	Note	Year ended 31 December	
		2021 RMB'000	2020 RMB'000
Revenue	4	136,534	38,655
Cost of sales	5	(40,880)	(13,432)
<b>Gross profit</b>		<b>95,654</b>	<b>25,223</b>
Selling and distribution expenses	5	(93,252)	(21,126)
Administrative expenses	5	(114,425)	(117,972)
Research and development expenses	5	(445,879)	(103,365)
Other income	6	9,727	12,435
Other losses — net	7	(50,626)	(198,912)
<b>Operating loss</b>		<b>(598,801)</b>	<b>(403,717)</b>
Finance income		24,771	33,604
Finance costs		(186)	(23,017)
Finance income — net	8	24,585	10,587
Fair value change in financial instruments issued to investors		—	(1,675,526)
<b>Loss before income tax</b>		<b>(574,216)</b>	<b>(2,068,656)</b>
Income tax expense	9	—	—
<b>Loss for the year and attributable to owners of the Company</b>		<b>(574,216)</b>	<b>(2,068,656)</b>
<b>Other comprehensive income:</b>			
Items that will not be reclassified to profit or loss:			
— Fair value change relating to preferred shares due to own credit risk		—	—

	Year ended 31 December	
	2021	2020
<i>Note</i>	<i>RMB'000</i>	<i>RMB'000</i>
<b>Other comprehensive income for the year, net of tax</b>	—	—
<b>Total comprehensive loss for the year and attributable to owners of the Company</b>	<u><u>(574,216)</u></u>	<u><u>(2,068,656)</u></u>
<b>Loss per share attributable to owners of the Company</b>		
Basic and diluted loss per share <i>(in RMB per share)</i>	<i>10</i> <u><u>(0.86)</u></u>	<u><u>(4.43)</u></u>



# CONSOLIDATED BALANCE SHEET

As at 31 December 2021

	As at 31 December	
	2021	2020
Note	RMB'000	RMB'000
<b>ASSETS</b>		
<b>Non-current assets</b>		
Right-of-use assets	25,014	18,133
Property, plant and equipment	151,205	89,217
Investment properties	7,549	8,090
Intangible assets	276,502	213,720
Prepayments and other receivables	52,613	8,026
Financial assets at fair value through profit or loss	224,424	—
<b>Total non-current assets</b>	<b>737,307</b>	<b>337,186</b>
<b>Current assets</b>		
Inventories	66,107	25,285
Financial assets at fair value through profit or loss	—	3,262
Prepayments and other receivables	64,142	57,355
Cash and cash equivalents	2,296,112	2,458,161
<b>Total current assets</b>	<b>2,426,361</b>	<b>2,544,063</b>
<b>Total assets</b>	<b>3,163,668</b>	<b>2,881,249</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Equity attribute to owners of the Company</b>		
Share capital and share premium	6,339,597	5,512,758
Treasury shares held in a trust	(84,549)	(23,126)
Other reserves	69,139	54,409
Accumulated losses	(3,305,002)	(2,730,786)
<b>Total equity</b>	<b>3,019,185</b>	<b>2,813,255</b>

		<b>As at 31 December</b>	
		<b>2021</b>	<b>2020</b>
	<i>Note</i>	<b>RMB'000</b>	<b>RMB'000</b>
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Lease liabilities		<b>4,082</b>	—
Deferred tax liabilities		<b>20,320</b>	20,320
Deferred income		<b>1,374</b>	3,284
		<hr/>	<hr/>
<b>Total non-current liabilities</b>		<b>25,776</b>	23,604
		<hr/>	<hr/>
<b>Current liabilities</b>			
Lease liabilities		<b>3,545</b>	9,129
Trade and other payables	<i>12</i>	<b>115,162</b>	34,552
Contract liabilities		<b>—</b>	709
		<hr/>	<hr/>
<b>Total current liabilities</b>		<b>118,707</b>	44,390
		<hr/>	<hr/>
<b>Total liabilities</b>		<b>144,483</b>	67,994
		<hr/> <hr/>	<hr/> <hr/>
<b>Total equity and liabilities</b>		<b>3,163,668</b>	2,881,249
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# NOTES TO THE CONDENSED CONSOLIDATED ANNUAL FINANCIAL INFORMATION

*For the year ended December 31, 2021*

## 1 GENERAL INFORMATION

Peijia Medical Limited 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 are principally engaged in the business of (i) research and development of transcatheter valve therapeutic medical devices (“**Transcatheter Valve Therapeutic Business**”) and (ii) research and development 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.

The Company’s shares have been listed on the main board of the Stock Exchange of Hong Kong Limited since May 15, 2020 (the “**Listing Date**”).

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, 2022.

## 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of the consolidated financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

### 2.1 Basis of preparation

The consolidated financial statements of the Group have been prepared in accordance with all applicable International Financial Reporting Standards (“**IFRSs**”) issued by International Accounting Standards Board (“**IASB**”). The consolidated financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets and financial liabilities at fair value through profit or loss, which are carried at fair value.

The preparation of the consolidated financial statements in conformity with IFRSs requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group’s accounting policies.

## 2.1.1 Changes in accounting policy and disclosures

### (a) *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, 2021:

Amendments to IFRS 16	Covid-19-related Rent Concessions
Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16	Interest Rate Benchmark Reform Phase 2

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.

### (b) *New standards and interpretations not yet adopted*

Standards and amendments to standards that have been issued but not yet effective and not been early adopted by the Group during the year are as follows:

		<b>Effective date</b>
IFRS 17	Insurance contracts	January 1, 2023
Amendments to IFRS 3	Reference to the conceptual framework	January 1, 2022
Amendments to IAS 1	Classification of liabilities as current or non-current	January 1, 2022
Amendments to IAS 37	Onerous contracts — cost of fulfilling a contract	January 1, 2022
Amendments to IFRSs	Annual improvements to IFRS standards 2018–2020 cycle	January 1, 2022
Amendments to IAS 16	Property, plant and equipment: proceeds before intended use	January 1, 2022
Amendments to IFRS 10 and IAS 28	Sale or contribution of assets between an investor and its associate or joint venture	To be determined
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies	January 1, 2023
Amendments to IAS 8	Definition of Accounting Estimates	January 1, 2023
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction	January 1, 2023

The Group has already commenced an assessment of the related impact of the above standards and amendments to standards which are relevant to the Group's operation.

There are no other standards that are not yet effective and that are expected to have a material impact on the Group's financial performance and position.

### 3 SEGMENT

The Group's business activities, for which discrete financial information is available, are regularly reviewed and evaluated by the Chief Operating Decision Maker ("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 revenues, selling and distribution expenses, administrative expenses, and research and development expenses of each operation segment. Thus, segment result would present revenues, cost of revenues, selling and distribution expenses, administrative expenses, research and development expenses and gross profit 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 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 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:

	<b>Year ended December 31, 2021</b>		
	<b>Transcatheter Valve Therapeutic Business RMB'000</b>	<b>Neurointerventional Business RMB'000</b>	<b>Total RMB'000</b>
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>

**Year ended December 31, 2020**

	<b>Transcatheter Valve Therapeutic Business RMB'000</b>	<b>Neurointerventional Business RMB'000</b>	<b>Total RMB'000</b>
Revenue	—	38,655	38,655
Cost of sales	—	(13,432)	(13,432)
Selling and distribution expenses	—	(21,126)	(21,126)
Administrative expenses	(87,883)	(30,089)	(117,972)
Research and development expenses	(57,291)	(46,074)	(103,365)
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Segment loss	<u>(145,174)</u>	<u>(72,066)</u>	<u>(217,240)</u>

**4 REVENUE**

	<b>Year ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Revenue from sales of goods		
— at a point in time	<u><b>136,534</b></u>	<u>38,655</u>

## 5 EXPENSES BY NATURE

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Change of work in process and finished goods	(19,180)	(3,807)
Employee benefits expenses	171,277	107,425
Listing expenses	—	25,942
Service expenses for research and development	340,517	22,154
Raw materials and consumables used		
— Research and development expenses	33,731	22,944
— Cost of sales	26,878	7,362
Professional service fees	27,641	9,969
Meeting expenses	15,215	6,143
Advertisement fee	14,985	5,365
Depreciation of property, plant and equipment	14,170	10,849
Utilities and office expenses	12,314	8,993
Entertainment expense	10,391	8,202
Travelling and transportation expenses	10,283	4,980
Amortisation of intangible assets	9,698	6,472
Auditor's remuneration		
— Audit service	3,964	3,558
— Non-audit service	1,001	1,558
Depreciation of right-of-use assets	3,077	1,229
Depreciation of investment properties	541	928
Others	17,933	5,629
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Total cost of sales, selling and distribution expenses, administrative expenses and research and development expenses	<b>694,436</b>	<b>255,895</b>
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## 6 OTHER INCOME

	Year ended December 31,	
	2021	2020
	RMB'000	RMB'000
Rental income	747	762
Government grants	8,300	7,975
Gain from financial assets at fair value through profit or loss	680	—
Interest income on financial assets at fair value through profit or loss	—	3,698
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	<b>9,727</b>	<b>12,435</b>
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## 7 OTHER LOSSES — NET

	Year ended December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Foreign exchange losses — net	(48,139)	(198,312)
Losses on disposal of property, plant and equipment	(218)	(379)
Others	(2,269)	(221)
	<u>(50,626)</u>	<u>(198,912)</u>

## 8 FINANCE INCOME — NET

	Year ended December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
<b>Finance income:</b>		
Bank interest income	<u>24,771</u>	<u>33,604</u>
<b>Finance costs:</b>		
Exchange losses on financial instruments issued to investors	—	(22,926)
Interest expense on lease liabilities	(186)	(88)
Interest expense on borrowings from a related party	—	(3)
	<u>(186)</u>	<u>(23,017)</u>
<b>Finance income — net</b>	<u><b>24,585</b></u>	<u><b>10,587</b></u>

## 9 INCOME TAX EXPENSE

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

### (a) Cayman Islands

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains. In addition, upon payments of dividends by the Company to its shareholders, no Cayman Islands withholding tax is imposed.

### (b) Hong Kong

No provision for Hong Kong profits tax has been provided for at the rate of 16.5% or 8.25% as the Group has no estimated assessable profit.

(c) **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, enterprise engaging in research and development activities are entitled to claim 175% of their research and development expenses incurred as tax deductible expenses when determining their assessable profits for that year.

- (d) 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:

	Year ended December 31,	
	2021	2020
	RMB’000	RMB’000
Loss before income tax	<u>(574,216)</u>	<u>(2,068,656)</u>
Tax calculated at statutory tax rates applicable to each group entity	(63,468)	(68,097)
Tax effect of:		
Income tax settlement differences	8,014	—
Expenses not deductible for tax purpose ( <i>Note (i)</i> )	3,213	2,680
Super deduction for research and development expenses	(29,250)	(13,464)
Unrecognised tax losses carried forward ( <i>Note (ii)</i> )	<u>81,491</u>	<u>78,881</u>
Income tax expense	<u>—</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 recognised as deferred tax assets will be expired as follows:

*Tax losses carried forward*

	As at December 31,	
	2021	2020
	RMB'000	RMB'000
2023	2,402	2,402
2024	3,090	3,090
2025	4,363	4,363
2026	14,915	14,915
2027	37,126	37,126
2028	50,841	50,841
2029	122,350	128,878
2030	284,931	315,524
2031	325,967	—
	<u>845,985</u>	<u>557,139</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, 2021 and 2020.

	Year ended December 31,	
	2021	2020
Loss for the year and attributable to owners of the Company (RMB'000)	574,216	2,068,656
Weighted average number of ordinary shares in issue (thousand)	<u>661,656</u>	<u>466,994</u>
Basic loss per share (RMB)	<u>0.86</u>	<u>4.43</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, 2021, 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, 2021 and 2020, 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, 2021 and 2020 is the same as basic loss per share of the respective years.

## 11 DIVIDEND

No dividend has been paid or declared by the Company or the companies now comprising the Group during the year ended December 31, 2021 (2020: Nil).

## 12 TRADE AND OTHER PAYABLES

	As at December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables — third parties	54,168	8,125
Other payables — third parties	31,116	11,465
Staff salaries and welfare payables	24,490	11,324
Accrued taxes other than income tax	5,388	3,638
	<u>115,162</u>	<u>34,552</u>
Less: non-current portion	<u>—</u>	<u>—</u>
Current portion	<u>115,162</u>	<u>34,552</u>

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

	As at December 31,	
	2021	2020
	<i>RMB'000</i>	<i>RMB'000</i>
Within 1 year	54,003	8,120
Between 1 year and 2 years	160	5
Between 2 year and 5 years	5	—
	<u>54,168</u>	<u>8,125</u>

## **MANAGEMENT DISCUSSION AND ANALYSIS**

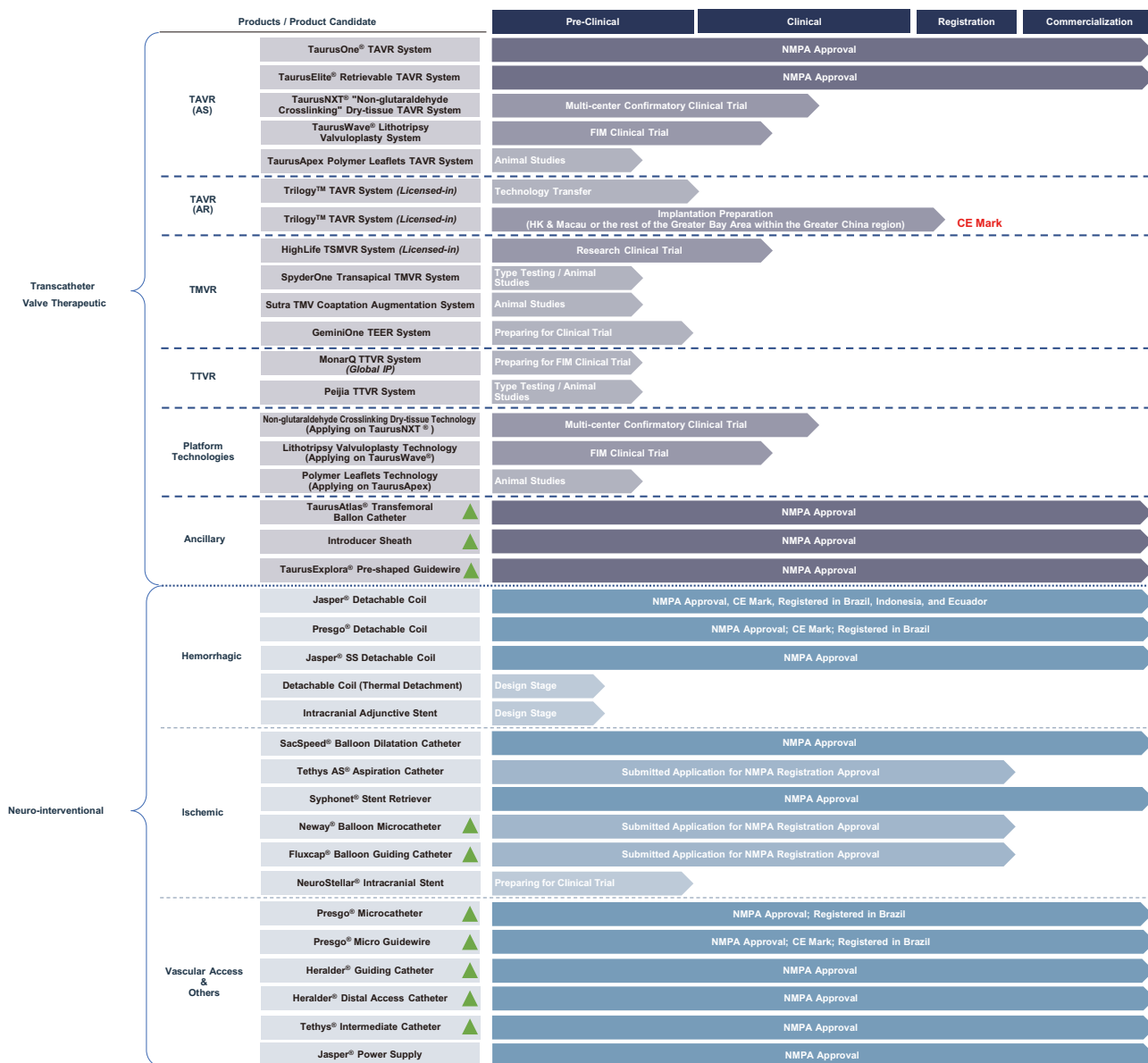
### **I. BUSINESS REVIEW**

#### **Overview**

We have built a med-tech 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 year ended December 31, 2021, we obtained registration approvals from NMPA for seven products, including TaurusOne® and TaurusElite®, the first and second generations of Transcatheter Aortic Valve Replacement (“TAVR”) devices. As of March 31, 2022, we have had 16 registered products and 16 product candidates at various development stages. The following chart summarizes the development status of our product portfolio as of March 31, 2022:



▲ Among our product candidates, these devices are exempted from clinical trial requirements in accordance with the Catalogue of Medical Device Exempted from Clinical Evaluation (《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, 2021, our revenue generated from the sales of transcatheter valve therapeutic products amounted to RMB41.9 million, compared to nil recorded during the year ended December 31, 2020.

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

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

TaurusOne® is our internally developed first-generation TAVR product, and is designed to treat aortic valve stenosis using a catheter-based approach. The PAV of TaurusOne® uses bovine pericardium, which is generally more durable and performs better in terms of hemodynamic profile than porcine pericardium.

We received the NMPA approval for TaurusOne® in April 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®, and yet it features a key upgrade in its delivery catheter system (“DCS”) that allows physicians to retrieve and reposition the PAV during the valve placement process if the initial release position is not ideal, further improving the safety of the TAVR procedure.

We received the NMPA approval for TaurusElite® in June 2021 and commercialized it in July 2021. For the year ended December 31, 2021, the sales from TaurusElite® comprised the majority of our sales of the Transcatheter Valve Therapeutic Business.

We have successfully achieved commercial implantation of TAVR products in 95 hospitals (equivalent to 102 centers) for the year ended December 31, 2021, benefiting from the increasing number of experienced physicians and hospitals, great user experience of our product, and our dedicated marketing and sales capabilities for TAVR products.



### ***TaurusNXT® — Third-Generation “Non-glutaraldehyde Crosslinking” Dry-tissue TAVR System***

TaurusNXT® is our internally developed third-generation TAVR system, and has significantly different product material and structure from TaurusOne® and TaurusElite®. TaurusNXT® incorporates our patented non-glutaraldehyde crosslinking tissue processing technology that removes the root cause of valve calcification, which is the number one cause of prosthetic valve degeneration. The technology is expected to greatly enhance the durability and biocompatibility of the PAV. Furthermore, comparing to the traditional dry tissue technology using glycerin, TaurusNXT® adopts a vacuum freeze-drying technology to maintain the physical integrity of the valve tissue while allowing the PAV to be pre-loaded onto the DCS. The DCS of TaurusNXT® is both retrievable and steerable, making it even 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® was completed in September 2021. We are currently carrying out the multi-center confirmatory clinical trial for TaurusNXT®.

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

### ***TaurusApex — Polymer Leaflets TAVR***

TaurusApex is our internally developed fourth-generation TAVR featuring the polymer leaflets instead of traditional bovine pericardium. Using multi-layer woven polymer material, TaurusApex may better mimic the features and hemodynamic performance of human’s native valves. By replacing bio-materials with long-lasting and stable polymer materials, TaurusApex could further improve durability and biocompatibility of the prosthetic valve. It could also significantly simplify the product manufacturing process and reduce the production cost. The development of TaurusApex is a significant step that we take to explore innovative solutions to improve the durability of the prosthetic valve. We are currently conducting animal studies 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 uses shockwave technology to remodel calcification on valve annulus and leaflets. After the treatment, the hemodynamics of the native valves could better fit the native annulus. 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. We are currently proceeding with FIM clinical trial for this product.

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

## ***Trilogy™ — Licensed-in TAVR Product for Aortic Regurgitation Indication***

We entered into a collaboration and license agreement, a service agreement and a stock purchase agreement with JenaValve, a US-based medical device company, in December 2021. Pursuant to the Agreements, JenaValve has granted us an exclusive license regarding Trilogy™ Heart Valve System for the treatment of AR and AS. We are entitled to develop, manufacture, and commercialize the product in the Greater China region and JenaValve agreed to provide services, assisting us to exploit the value of the product within the region. We also acquired certain shares of preferred stock of JenaValve, representing a minority equity investment in JenaValve. For further details, please also refer to our announcement dated January 14, 2022.

AR is one of the most common types of aortic valve diseases. According to Frost & Sullivan, there were approximately 27.0 million patients worldwide and 3.9 million patients in China in 2020, suffering from AR. As of the date of this announcement, Trilogy™ Heart Valve System is the first and the only transfemoral device of its kind to receive CE Mark approval for the treatment of both severe symptomatic AR and AS. It was also granted the Breakthrough Device Designation by the United States Food and Drug Administration.

We consider this transaction an important step to strengthen our TAVR pipeline by adding first-in-class aortic valve regurgitation treatment system, and hopes to benefit more patients in China by expanding indications to AR with clinically proven minimally invasive options. The transaction will enable us to have the most comprehensive TAVR pipeline covering major aortic valve diseases, compared to other players in China. We have initiated the technology transfer as of the date of this announcement. We are under implantation preparation of Trilogy™ in Hong Kong, Macau and the rest of the Greater Bay Area within the Greater China region.

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

Besides the above products, we have also been developing a balloon-expandable TAVR product, which is currently in the type testing stage.

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

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

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 mitral valve regurgitation, in December 2020. 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, a pioneer company focusing on TAVR 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 realize self-centering and self-alignment. This system separates the valve from its anchoring ring and delivers the two components through the femoral vein and femoral artery, respectively, through a simple three-step procedure. The 2-component design respectful 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.

The technology transfer was completed in the third quarter of 2021, and local manufacturing in China has been established. The first mitral valve replacement procedure using HighLife TSMVR device was completed by West China Hospital of Sichuan University in December 2021, which is also the first application of TSMVR technology in Asia. The product is currently in the process of research clinical trial, and we are expecting to initiate the confirmatory clinical trial in China in 2022.

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

### *GeminiOne — TEER System*

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 lock & unlock during the procedure, as well as multi-angular detachment that copes with a wider range of anatomy. GeminiOne is designed to treat mitral valve and tricuspid valve diseases. The product is currently in the pre-clinical evaluation stage, targeting the launch of clinical trial in 2022.

Dr. Saibal Kar, who is one of the early advocates for TEER technique and a world-leading doctor specializing in TEER procedure, is our medical consultant for GeminiOne.

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

### *Sutra — TMV Coaptation Augmentation System*

In April 2021, we entered into a stock purchase agreement with Sutra, a US-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 mitral valve regurgitation using a coaptation augmentation technology that targets only the posterior mitral valve leaflet. Sutra Hemi Valve is currently in the animal studies stage.

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

Besides the collaborations with our global partners, we have also been internally developing a transapical TMV replacement product, which is currently in the animal studies stage.

## **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 Medical Technologies, LLC (“**inQB8**”) in May 2021, a US-based medical technology incubator, 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 with the device development in partnership with us. MonarQ is currently in the pre-clinical evaluation stage, and we expect to carry out FIM clinical trial in 2022.

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

### **Platform Technologies**

We are committed to constantly explore platform technologies which can be applied to various therapies. As of March 31, 2022, we have three patented platform technologies, namely Non-glutaraldehyde Crosslinking Dry-tissue Technology, Polymer Leaflets Technology and Lithotripsy Valvuloplasty Technology.

Non-glutaraldehyde Crosslinking Dry-tissue Technology and Polymer Leaflets Technology are currently used in our third-generation TAVR product TaurusNXT<sup>®</sup> and our forth-generation TAVR product TaurusApex, respectively. These technologies can also be applied to other TAVR, TMVR or TTVR product candidates.

Lithotripsy Valvuloplasty Technology is our non-implant solution (currently used in TaurusWave<sup>®</sup>), to treat AS by remodeling the severe calcification. We are currently carrying out 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, 2021, our revenue generated from the sales of neurointerventional products amounted to RMB94.6 million, representing an increase of 144.7% from approximately RMB38.7 million recorded during the year ended December 31, 2020.

## **Hemorrhagic Products and Product Candidates**

For the year ended December 31, 2021, we generated a total revenue of RMB51.3 million from hemorrhagic products, representing an increase of 52.3% from approximately RMB33.7 million for the year ended December 31, 2020 and accounting for 54.2% of the total revenue of the Neurointerventional Business.

***Detachable Coils:*** we received the NMPA approval for the Jasper<sup>®</sup> SS Detachable Coil in June 2021, making it our third NMPA approved detachable coil. The detachment process for Jasper<sup>®</sup> SS Detachable Coil is the same as for Jasper<sup>®</sup> Detachable Coil, our first-generation detachable coil, whereas Jasper<sup>®</sup> SS Detachable Coil is much softer in order to address further clinical needs during the fill and finish processes of a cerebral aneurysm endovascular coiling procedure. We are also in the process of developing our third-generation detachable coil (thermal detachment).

***Intracranial Adjunctive Stent:*** Intracranial Adjunctive Stent is indicated for use with neurovascular embolization coils in the treatment of intracranial aneurysms. Stent-assist coil embolization allows endovascular treatment of complex shaped and wide necked intracranial aneurysms.

## **Ischemic Products and Product Candidates**

For the year ended December 31, 2021, we generated a total revenue of RMB19.5 million from ischemic products, representing an increase of 596.2% from approximately RMB2.8 million for the year ended December 31, 2020 and accounting for 20.6% of the total revenue of the Neurointerventional Business.

***Syphonet<sup>®</sup> Stent Retriever*** (formerly named as Shenyi<sup>®</sup> in English): Syphonet<sup>®</sup> Stent Retriever is our major product candidate designed for removing thrombus in intracranial vessels in a mechanical thrombectomy procedure for patients with acute ischemic stroke. 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. The stent is also designed with 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, facilitating physicians with better visual guidance. The Syphonet<sup>®</sup> Stent Retriever has various specifications, all compatible with 0.017-inch microcatheter. The compatibility feature will improve the success rate of deployment and reduce procedure time. We received the NMPA approval for the registration application for Syphonet<sup>®</sup> Stent Retriever in February 2022, making it our eleventh NMPA approved neurointerventional product.



***Tethys AS® Aspiration Catheter:*** our Tethys AS® Aspiration Catheter is specially designed for direct-aspiration in mechanical thrombectomy. It features a softer distal tip which allows the device to pass through the tortuous vessels easily. The 0.071-inch wide lumen increases the suction force. Meanwhile, the double layer design with outer braids and inner coils shows high compressive strength and helps maintain lumen integrity. The device improves the recanalization rate and reduces the procedure time for better clinical outcomes. We have submitted the application of Tethys AS® Aspiration Catheter for NMPA Approval as of March 31, 2022 and expect to receive the regulatory approval within 2022.

***Fluxcap® Balloon Guiding Catheter:*** Fluxcap® Balloon Guiding Catheter offers a multi-faceted approach for clot retrieval by creating proximal flow arrest, reducing embolic burden during endovascular treatment of acute ischemic stroke. We have submitted the application of Fluxcap® Balloon Guiding Catheter for NMPA Approval as of March 31, 2022 and expect to receive the regulatory approval within 2022.

With the successive launch of Syphonet® Stent Retriever, Tethys AS® Aspiration Catheter and Fluxcap® Balloon Guiding Catheter this year, we will be 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 manifestations of patients.

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

***Neway® Balloon Microcatheter:*** Neway® Balloon Microcatheter is an innovative combination of balloon dilation catheter and microcatheter. It is used for dilating stenosis to help with intracranial blood supply in intracranial angioplasty procedure, while providing the channel for intracranial stent placement or other medical devices immediately after. The unique design can improve the safety of the procedure and significantly reduce procedure steps and time. We have submitted the application of Neway® Balloon Microcatheter for NMPA Approval as of March 31, 2022 and expect to receive the regulatory approval within 2022.

## **Vascular Access Products**

For the year ended December 31, 2021, we generated a total revenue of RMB23.5 million from vascular access products, representing an increase of 1,094.3% from approximately RMB2.0 million for the year ended December 31, 2020 and accounting for 24.9% of the total revenue of the Neurointerventional Business.

***Tethys® Intermediate Catheter:*** our Tethys® Intermediate Catheter assists the delivery of diagnostic devices and/or treatment devices to the neurovascular system and peripheral vascular system, and is applicable in various procedures, including aneurysm embolization procedures, mechanical thrombectomy procedures and ICAD procedures.



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

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

**Research & Development**

Both in-house innovation and business development opportunities are crucial to our R&D efforts. Our core R&D team is led by Dr. Yi Zhang, our chairman of the Board and chief executive officer, Mr. Kongrong Pan, our chief operating officer and Dr. Jian Fong Tan, our chief technology officer. Each of them is an industry veteran with an impressive academic and professional background, has previously worked in managerial positions at various leading players in the medical device sector.

We have also developed deep relationship with global leaders in both the transcatheter valve therapeutic and neurointerventional domains, including world-class scientists, physicians and industry practitioners. Besides licensing in edging technologies, we have also been building up our overseas R&D capabilities through close collaboration:

We are Sutra’s second largest shareholder after the founder, and has right of first offer if Sutra proposes to offer or sell any new securities, subject to certain customary exceptions. Sutra will share the R&D facilities with the Company in the United States, and will also assist us in expanding R&D presence in North America. The founding team of Sutra is composed of professionals with extensive experience in both academia and industry.

inQB8 will serve as a project incubation center in partnership with us. The arrangement constitutes a 50–50 ownership of the incubator between the Company and inQB8. Under the partnership, in the joint development of novel products and solutions in the structural heart field, we will have exclusive privileges and rights to these technologies globally. The founding team of inQB8 has multidisciplinary backgrounds in medtech and engineering. Before founding inQB8, the team founded **CardiAQ Valve Technologies (“CardiAQ”)**. **CardiAQ** developed the world’s first transcatheter TMVR system and was later acquired by Edwards Lifesciences.

We have established close working relationship with world-class consultants, who provide consultancy 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 also served as the chairman or the core team member in many premier transcatheter valve therapeutics conferences, including TVT, PCR London Valves and PCR-CIT China Chengdu Valves. He is actively involved in our overseas business development, product promotion and clinical trials, including clinical trial and tech transfer of HighLife as well as clinical trial of TaurusWave®.

Dr. Saibal Kar became our consultant in September 2021. He is a world-leading doctor well-known for his research and achievements in the field of structured 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 Inc., Boston Scientific, and Abbott Vascular. He worked as a principal investigator in a couple of multicenter studies and randomized studies for MitraClip. Dr. Saibal Kar is currently advising the R&D of our TEER product, GeminiOne.

In October 2021, Suzhou SITRI Interventional Medtech Institute (“IMI”), an innovation incubation and investment platform dedicated in the field of vascular interventional medical devices, was established. The IMI was proposed and funded by us together 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 through 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, 2021, we had an in-house R&D team of 110 employees dedicated to the research and development of our transcatheter valve therapeutic products and neurointerventional products, accounting for 16.0% of our total number of employees. As of December 31, 2021, we had a robust intellectual property portfolio, consisting of a total of 81 registered patents and 39 patents under application.

As of the date of this announcement, TaurusNXT® was formally accepted by the Special Review and Approval Procedure for Innovative Medical Devices of NMPA, and will enjoy advantages including expedited approval, as well as favorable policy support and market access. As of the date of this announcement, we have the highest number of medical devices accepted by the Special Review and Approval Procedure among Chinese listed transcatheter valve therapeutic peers, which once again proved our strong R&D capabilities and innovativeness of our product pipeline.

## **Manufacturing**

We manufacture, assemble and examine our products at our two production facilities. One is located in our self-owned properties in Suzhou, Jiangsu province, and another is located in leased properties in Shanghai. During the year ended December 31, 2021, we manufactured our 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 our leased properties in Shanghai with a total area of 1,188.4 sq.m. Since we obtained the Contract Manufacturing License (委託生產許可) to manufacture our Jasper<sup>®</sup> Detachable Coil in our Suzhou production facility, under the Jiangsu Pilot Marketing Authorization Holder (MAH) System (江蘇醫療器械註冊人制度試點), we relocated part of the Jasper<sup>®</sup> Detachable Coil's production to Suzhou and manufactured the product at both sites. For our Neurointerventional Business, we currently manufacture our Jasper<sup>®</sup> Detachable Coil, Herald<sup>®</sup> Guiding Catheter, Tethys<sup>®</sup> Intermediate Catheter, SacSpeed<sup>®</sup> Balloon Dilatation Catheter, Jasper<sup>®</sup> SS Detachable Coil, Herald<sup>®</sup> Distal Access Catheter, and Syphonet<sup>®</sup> Retriever Stent in our Suzhou facility.

For our Transcatheter Valve Therapeutic Business, we have five NMPA approved products as of March 31, 2022, including our first-and second-generation TAVR products, guidewire, introducer sheath, and balloon aortic valvuloplasty catheter, all of which are manufactured or will be manufactured in our Suzhou facility. Our Suzhou facility is also equipped with multiple production lines dedicated to TaurusNXT<sup>®</sup>, TaurusWave<sup>®</sup>, and other transcatheter valve therapeutic product candidates.

## **Commercialization**

As of December 31, 2021, we had an expanded sales and marketing team of 157 employees, with 55 of whom dedicated to the sales and marketing of our neurointerventional products and 102 focusing on the sales and marketing of our transcatheter valve therapeutic products.

For our Transcatheter Valve Therapeutic Business, we have built an in-house sales and marketing team with professional background and experience in the innovative medical device industry. We have established an effective sales and marketing team structure that matches the innovative nature of TAVR products, comprised of

- Product specialists, who collaborate with R&D team to align product roadmap with the lifecycle of product portfolio to address unmet clinical needs
- Marketing specialists, who promote brand awareness, market education & exposure to KOLs/hospitals
- Clinical support specialists, who provide seamless technical support and intensive involvement to ensure best patient outcomes

- Frontline sales, who stay connected with physicians and hospitals to complete sales procedure
- Apart from above sales and marketing personnels, we are also equipped with a group of medical department specialists, who provide patient assessment and full support to clinical needs

Accurate product positioning and superior product performance, all-around marketing and sales support as well as high-touch sales model are three key building blocks for accelerated commercialization of our TAVR products. For the year ended December 31, 2021, we have achieved commercial implantation of TAVR products in 95 hospitals (equivalent to 102 centers) which includes 3 of the Top 4 centers and 29 of the Top 40 centers. We will strengthen our research cooperation with TOP/KA hospitals in 2022 and size up the sales team for more coverage and adoption of our TAVR products.

For our Neurointerventional Business, we have an experienced and professional sales team which has built a long term cooperation relationship with seasoned distributors. For the year ended December 31, 2021, we had 143 distributors, covering over approximately 1,700 hospitals nationwide. We will continually build on our sales team and distributor coverage in response to 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 Delta variant and Omicron variant successively in 2021. Despite of the social restrictions imposed, our product sales, financial condition and results of procedures were not adversely impacted. Our revenue for the year ended December 31, 2021 increased by 253.2% to RMB136.5 million from RMB38.7 million for the year ended December 31, 2020. We will continue to enhance remedial measures in line with the government's requirements in response to the ongoing situation.

### **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. The construction of our new headquarter in Suzhou covering a total area of 86,000 sq.m started in November 2021, which marks our dedication towards the next decade of development.

For our Transcatheter Valve Therapeutic Business, our sales and marketing team will focus on the commercialization of TaurusOne<sup>®</sup> and TaurusElite<sup>®</sup>. In addition, we will actively launch clinical trials for a number of our pre-clinical stage product candidates and facilitate the progress of those that are currently in the clinical stage. We will carry out the technology transfer of Trilogy<sup>™</sup> from JenaValve and subsequent clinical trial. We are also in preparation of the implantations of Trilogy<sup>™</sup> in Hong Kong, Macau and the rest of the Greater Bay Area within the Greater China region.

For our Neurointerventional Business, we intend to keep the sales growth momentum through further penetration of our existing products, and commercially launch new products currently in the pipeline. In particular, we received the NMPA approval of Syphonet<sup>®</sup> Stent Retriever in February 2022 and we expect to receive NMPA approval for a number of other ischemic products this year, including Tethys AS<sup>®</sup> Aspiration Catheter, Fluxcap<sup>®</sup> Balloon Guiding Catheter and Neway<sup>®</sup> Balloon Microcatheter. Our dedicated sales team will make efforts to commercialize these products once approved.

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

## **II. FINANCIAL REVIEW**

For the year ended December 31, 2021, the Group recorded a revenue of RMB136.5 million, as compared to RMB38.7 million for the year ended December 31, 2020, representing an increase of 253.2% in total revenue as compared with 2020; and a net loss of RMB574.2 million, as compared to RMB2,068.7 million for the same period in 2020.

The net loss for the year ended December 31, 2021 was mainly due to the increase of research and development expenses. The Group made upfront and milestone payments in relation to four BD projects in 2021, resulting in RMB314.6 million of one-time expensing R&D payments.

The net loss for the year ended December 31, 2020 was mainly due to fair value loss of RMB1,675.5 million attributable to financial instruments and foreign exchange losses of RMB221.2 million. The fair value loss of financial instruments is a non-cash item, and there will be no further gains or losses on fair value changes upon the closing of the global offering in 2020.

## Revenue

For the year ended December 31, 2021, the Group's revenue was RMB136.5 million, representing an increase of 253.2% compared to RMB38.7 million for the year ended December 31, 2020. The increase in revenue was primarily attributable to: (i) commercialization of the first generation TAVR product TaurusOne® and the second generation retrievable TAVR product TaurusElite®, of which the revenue was RMB41.9 million; (ii) increased sales revenue of detachable coils and other existing neuro-interventional products including SacSpeed® Balloon Dilatation Catheter; and (iii) commercialization of multiple new neuro-interventional products including Tethys® Intermediate Catheter and Jasper® SS Detachable Coil. The revenue from Neurointerventional Business was RMB94.6 million for the year ended December 31, 2021, representing an increase of 144.7% as compared to RMB38.7 million for the year ended December 31, 2020.

With the new additions to our ischemic and vascular access products, our revenue from the Neurointerventional Business has been further diversified. The following table sets forth the components of revenue from neuro-interventional products for the period indicated.

	Year ended December 31,			
	2021		2020	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
Hemorrhagic	<b>51,293</b>	<b>54.2</b>	33,684	87.1
Ischemic	<b>19,465</b>	<b>20.6</b>	2,796	7.2
Vascular Access	<b>23,539</b>	<b>24.9</b>	1,971	5.1
Others	<b>296</b>	<b>0.3</b>	204	0.6
Total	<b><u>94,593</u></b>	<b><u>100.0</u></b>	<b><u>38,655</u></b>	<b><u>100.0</u></b>

## Cost of Sales

For the year ended December 31, 2021, the Group's cost of sales was RMB40.9 million, representing a 204.3% of increase as compared to RMB13.4 million for the year ended December 31, 2020, primarily attributed to (i) new products launched from both Transcatheter Valve Therapeutic Business and Neurointerventional Business in the Reporting Period; and (ii) the increased sales volume of the existing products from the Neurointerventional Business.



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

As a result of the foregoing factors, the Group's gross profit increased by 279.2% from RMB25.2 million for the year ended December 31, 2020 to RMB95.7 million for the year ended December 31, 2021, which was in line with the increase of revenue. Gross profit margin is calculated as gross profit divided by revenue and multiplying the result by 100%. The Group's gross profit margin increased to 70.1% for the year ended December 31, 2021, as compared to 65.3% for the year ended December 31, 2020, primarily attributed to the launch of new products of Transcatheter Valve Therapeutic Business and Neurointerventional Business, which have a higher margin compared with existing products.

## **Selling and Distribution Expenses**

Selling and distribution expenses increased by 341.4% from RMB21.1 million for the year ended December 31, 2020 to RMB93.3 million for the year ended December 31, 2021. Such increase was primarily attributable to (i) the increase in market education, development of multi-sales channels, and sales promotion which was in line with the increase of sales revenue during the year of 2021; and (ii) the increase in staff costs.

## **Administrative Expenses**

Administrative expenses decreased by 3.0% from RMB118.0 million for the year ended December 31, 2020 to RMB114.4 million for the year ended December 31, 2021. The decrease was mainly attributed to (i) the decrease in listing fee; and (ii) the decrease in the amortization of share-based compensation expenses.

## **Research and Development Expenses**

Research and development expense increased by 331.4% from RMB103.4 million for the year ended December 31, 2020 to RMB445.9 million for the year ended December 31, 2021. Such increase was primarily attributable to (i) the one-time expensing BD payments of RMB314.6 million for TMVR and TTVR products; (ii) the increase in staff costs; and (iii) the increase in expenses in the on-going research and development projects.



For the year ended December 31, 2021, research and development expenses in Transcatheter Valve Therapeutic Business and Neurointerventional Business amounted to RMB394.2 million and RMB51.7 million, respectively. The increase in the research and development expenses Transcatheter Valve Therapeutic Business was mainly due to the upfront and milestone payments in relation to four BD projects in 2021. This resulted in RMB314.6 million of one-time expensing R&D payments. The following table sets forth the components of research and development expenses for the year indicated.

	<b>Year ended December 31,</b>			
	<b>2021</b>		<b>2020</b>	
	<i><b>RMB'000</b></i>	<i><b>%</b></i>	<i><b>RMB'000</b></i>	<i><b>%</b></i>
Service expenses for research and development	<b>340,517</b>	<b>76.4</b>	21,325	20.6
Employee benefits expenses	<b>60,117</b>	<b>13.5</b>	49,399	47.8
Raw materials and consumables used	<b>33,731</b>	<b>7.6</b>	22,731	22.0
Depreciation and amortization	<b>5,253</b>	<b>1.2</b>	5,183	5.0
Other	<b>6,261</b>	<b>1.3</b>	4,727	4.6
Total	<b><u>445,879</u></b>	<b><u>100.0</u></b>	<b><u>103,365</u></b>	<b><u>100.0</u></b>

### **Other Income**

Other income decreased from RMB12.4 million for the year ended December 31, 2020 to RMB9.7 million for the year ended December 31, 2021. The decrease was mainly attributable to the decrease in investment income from bank wealth management products.

### **Finance Income**

Finance Income decreased from RMB33.6 million for the year ended December 31, 2020 to RMB24.8 million for the year ended December 31, 2021. The decrease was mainly due to lower amount of term deposits and the lower interest rate of bank deposit.

### **Finance Costs**

Finance costs decreased from RMB23.0 million for the year ended December 31, 2020 to RMB0.2 million for the year ended December 31, 2021. For the year ended December 31, 2020, the Group recorded foreign exchange losses amounted to RMB22.9 million on preferred shares.

## **Gearing Ratio**

Gearing ratio is calculated by dividing total liabilities by total equity and multiplying the result by 100%. As at December 31, 2021, the gearing ratio of the Group increased to 4.79% from 2.42% as at December 31, 2020.

## **Net Current Assets**

The Group's net current asset as at December 31, 2021 was RMB2,307.7 million, as compared to RMB2,499.7 million as at December 31, 2020.

## **Capital Management**

The primary goal of the Group's capital management is to maintain the Group's stability and growth, safeguard its normal operations and maximize shareholders' value. The Group reviews and manages its capital structure on a regular basis, and makes timely adjustments to it in light of changes in economic conditions.

## **Liquidity and Financial Resources**

As at December 31, 2021, the Group's total cash and cash equivalents amounted to approximately RMB2,296.1 million, representing an decrease of 6.6% as compared to RMB2,458.2 million as at December 31, 2020. The management is confident that the Group's financial resources is sufficient for its daily operations.

As at December 31, 2021, the current assets of the Group were RMB2,426.4 million, including cash and cash equivalents of RMB2,296.1 million, the inventories of RMB66.1 million and other current assets of RMB64.2 million.

As at December 31, 2021, the current liabilities of the Group were RMB118.7 million, including trade and other payables of RMB115.2 million and other current liabilities of RMB3.5 million.

As at December 31, 2021, the Group did not have any borrowings.

We rely on capital contributions by our shareholders as the major sources of liquidity. We also generate cash from our sales revenue 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, improving cost control and operating efficiency as well as accelerating the turnover of trade receivables by tightening our credit policy.

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

### **Capital Expenditure**

For the Reporting Period, the Group's total capital expenditure amounted to approximately RMB201.3 million, which was mainly used in (i) construction of building; (ii) acquisition of equipment and machinery; and (iii) technologies.

### **Significant Investment**

As at December 31, 2021, the Group's had RMB227.4 million unlisted equity investments measured at fair value through profit or loss.

### **Contingent Liabilities**

As at December 31, 2021, the Group did not have any significant contingent liabilities.

### **Material Acquisitions and Disposals**

As at December 31, 2021, the Group did not conduct any material acquisitions and disposals.

### **Charge on Assets**

As at December 31, 2021, the Group did not have any pledged asset.

### **Foreign Exchange Exposure**

The Group has transactional currency exposures. Certain of cash and cash equivalents and financial assets at fair value through profit or loss are dominated in foreign currencies and are exposed to foreign currency risk. Management of the Group monitors foreign exchange exposure and will enter into forward exchange settlement agreements with financial institutions to lock exchange rate risks should the need arise.

### **Future Plans for Material Investments and Capital Asset**

The Group had not authorized any plan for the material investments or acquisition of capital asset as of the date of this announcement.

## 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 were 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 table below sets forth the utilisation of the net proceeds from the Global Offering and the unused amount as at December 31, 2021:

Business objective as stated in the Prospectus	Percentage to total amount %	Net proceeds HK\$ million	Utilised amount as at December 31, 2021 HK\$ million	Unutilised amount as at December 31, 2021 HK\$ million	Expected timeline for unutilised amount
Development and commercialization of our Core Product and other major product candidates	65	1,682.18	183.33	1,498.85	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	205.14	53.66	Yr2025
Strengthen our research and development capabilities to enrich our product pipeline	8	207.04	39.57	167.47	Yr2024
Expand our product portfolio or intellectual property portfolio through potential strategic acquisitions, investments, partnerships and licensing opportunities	10	258.80	157.97	100.83	Yr2022
Working capital and other general corporate purposes	7	181.16	128.08	53.08	Yr2024
<b>Total</b>	<b>100</b>	<b>2,587.98</b>	<b>714.09</b>	<b>1,873.89</b>	

As at December 31, 2021, net proceeds from the Global Offering not yet utilized were deposited with certain licensed banks in Hong Kong or the PRC.

On January 22, 2021, the Company entered into the Placing Agreement with the Morgan Stanley & Co. International plc, pursuant to which the Company appointed Morgan Stanley & Co. International plc as its placing agent to procure not 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 Placing Shares represented approximately 5.3% of the existing issued share capital of the Company as at 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 not less than six Placees. The net proceeds from the Placing were approximately HK\$971.48 million. The table below sets forth the utilisation of the net proceeds from the Placing and the unused amount as at December 31, 2021:

<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 HK\$ million</b>	<b>Utilised amount as at December 31, 2021 HK\$ million</b>	<b>Unutilised amount as at December 31, 2021 HK\$ million</b>	<b>Expected timeline for unutilised 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)	100	971.48	610.21	361.27	Yr2025
To fund potential product licensing and possible merger and acquisition opportunities in other areas including tricuspid valve replacement and repair treatment					
To fund ongoing technology transfer, product development, and research and development, across the Group					
For other general corporate purposes					
<b>Total</b>	<b>100</b>	<b>971.48</b>	<b>610.21</b>	<b>361.27</b>	

As at December 31, 2021, 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, 2021, the Group had 689 employees, who were all based in China. The total employee benefits expenses of our Group, which consist of (i) wages, salaries and bonuses, (ii) social security costs and housing benefits, (iii) employee welfare and (iv) share-based compensation expenses, for the year ended December 31, 2021 were approximately RMB171.3 million.

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 and training programs for our management staff and other employees to upgrade their skills and knowledge continuously. We provide our employees with regular feedback as well as internal and external training in various areas, such as product knowledge, project development and team building. We also assess our employees based on their performance to determine their 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**

In January 2022, all terms relating to the agreements with JenaValve became effective.

Save as disclosed above, there is no material subsequent event undertaken by the Company or by the Group after the Reporting Period and up to the date of this announcement.

## **FINAL DIVIDEND**

The Board has resolved not to declare any final dividend for the Reporting Period (year ended December 31, 2020: 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 of the Company 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. Yi 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. Yi Zhang is in charge of overall management, business, strategic development and scientific research and development of the 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 the 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. Yi Zhang), four non-executive Directors and four independent non-executive Directors, and therefore has a strong independent element in its composition.

On June 21, 2021, Mr. Wayne Wu resigned as an independent non-executive Director, and ceased to be the member of the Audit Committee and Nomination Committee and the chairman of the Remuneration Committee. On September 20, 2021, (i) Mr. Huacheng Wei was appointed as an independent non-executive Director, a member of the Audit Committee, the Remuneration Committee and the Nomination Committee; and (ii) Mr. Robert Ralph Parks was appointed as the chairman of Remuneration Committee.

Accordingly, during the period from June 21, 2021 to September 19, 2021, the Company did not meet the following requirements of the Listing Rules and the CG Code:

1. Rules 3.10A of the Listing Rules with regard to proportion of independent non-executive Directors on the Board;
2. Rule 3.25 of the Listing Rules, Rules with regard to the membership and composition of the Remuneration Committee; and
3. Code provision A.5.1 of the then CG Code (which has been amended as Rule 3.27A of the Listing Rules since January 1, 2022) with regard to the membership and composition of the Nomination Committee.



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, 2021.

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, 2021. 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, 2021.

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

On January 29, 2021, the Company allotted and issued a total of 33,800,000 new Shares by the way of Placing at the placing price of HK\$29.38 per Placing Share in accordance with terms and conditions of the Placing Agreement.

On December 7, 2021, the Company granted share options to certain employees to subscribe for a total of 7,801,386 Shares, subject to and upon the terms and conditions of the Share Option Scheme.

As of December 31, 2021, the trustee of the RSU Scheme has purchased an aggregate of 3,881,000 Shares (representing approximately 0.5781% of the total issued share capital of the Company) under the RSU Scheme.



As of December 31, 2021, a total of 104,493 Shares (representing approximately 0.0156% of the total issued share capital of the Company) have been granted to two independent non-executive Directors, namely Dr. Stephen Newman Oesterle and Mr. Robert Ralph Parks, under the RSU Scheme.

As of December 31, 2021, a total of 136,434 Shares (representing approximately 0.0203% of the total issued share capital of the Company) have been granted to an external consultant of the Group under the RSU Scheme.

Save as 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, 2021.

## **REVIEW OF FINANCIAL INFORMATION**

### **Audit Committee**

The Company has established the Audit Committee with written terms of reference in accordance with the Listing Rules. As of the date of this announcement, the Audit Committee comprises a non-executive Director, namely Mr. Jifeng Guan, and three independent non-executive Directors, namely, Mr. Huacheng Wei, Mr. Wai Ming Yip and Mr. Robert Ralph Parks. Mr. Wai Ming Yip is the chairman of the Audit Committee.

The Audit Committee has discussed with the Company's management and reviewed the audited consolidated financial statements of the Group for the Reporting Period.

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

The figures in respect of the Group's consolidated statement of comprehensive loss, consolidated balance sheet and the related notes thereto for the year ended December 31, 2021 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**

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

## **DEFINITIONS**

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

“a research jointly published by Academician Runlin Gao and Professor Zengwu Wang”	a research paper named as “Current status and etiology of valvular heart disease in China: a population-based survey” published by Academician Runlin Gao and Professor Zengwu Wang et al. from Fuwai Hospital through BMC Cardiovasc Disord in 2021
“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
“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
“confirmatory 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
“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®
“DCS”	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
“feasibility clinical trial”	a clinical trial of a medical device product designed to preliminarily demonstrate the safety of such product as used in human patients (in conjunction with the performance of a therapeutic procedure)

“FIM”	First-in-man, a stage of clinical trial
“Frost & Sullivan”	a research & consulting firm which specialized in producing industry research reports
“Fuwai Hospital”	Fuwai Hospital Chinese Academy of Medical Sciences
“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
“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
“JenaValve”	JenaValve Technology, Inc., a US-based medical device company
“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
“MS”	mitral stenosis
“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
“Nomination Committee”	the nomination committee of the Board
“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
“Preferred Shares”	has the meaning as ascribed to it under the Prospectus
“Prospectus”	the prospectus of the Company dated May 5, 2020, in relation to the Global Offering
“Remuneration Committee”	the remuneration committee of the Board
“Reporting Period”	the year ended December 31, 2021
“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 Option Scheme”	the share option scheme conditionally adopted by the Company on April 28, 2020, a summary of the principal terms of which is set forth in the paragraph headed “Appendix IV — Statutory and General Information — D. Share Incentive Schemes” in the Prospectus
“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
“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
“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“U.S. dollars”, “US\$” or “USD”	United States dollars, the lawful currency of the United States
“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
“we”, “us” or “our”	the Company and, unless the context indicates otherwise, its subsidiaries
“%”	per cent

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

Hong Kong, March 31, 2022

*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.*