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杭州启明醫療器械股份有限公司  
**Venus Medtech (Hangzhou) Inc.**

(A joint stock company incorporated in the People's Republic of China with limited liability)  
 (Stock Code: 2500)

**ANNOUNCEMENT OF INTERIM RESULTS  
 FOR THE SIX MONTHS ENDED JUNE 30, 2022**

The board (the “**Board**”) of directors (the “**Director(s)**”) of Venus Medtech (Hangzhou) Inc. (the “**Company**”) is pleased to announce the unaudited consolidated interim results of the Company and its subsidiaries (together, the “**Group**”) for the six months ended June 30, 2022, together with comparative figures for the same period of 2021.

**FINANCIAL HIGHLIGHTS**

	<b>Six months ended June 30, 2022 (Unaudited) RMB'000</b>	<b>Six months ended June 30, 2021 (Unaudited) RMB'000</b>	<b>Period-to-period change</b>
Revenue	<b>209,965</b>	239,269	-12.2%
Gross Profit	<b>164,175</b>	188,088	-12.7%
Loss before tax	<b>(246,406)</b>	(117,211)	110.2%
Loss for the period	<b>(239,668)</b>	(117,215)	104.5%
Loss attributable to owners of the parent	<b>(199,933)</b>	(113,063)	76.8%
Loss per Share attributable to ordinary equity holders of the parent			
Basic and diluted	<b>RMB (0.46)</b>	RMB (0.26)	77.0%

## INTERIM RESULTS

The Board is pleased to announce the unaudited condensed consolidated results of the Group for the six months ended June 30, 2022, as follows:

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

For the six months ended June 30, 2022

	Notes	2022 (Unaudited) RMB'000	2021 (Unaudited) RMB'000
<b>REVENUE</b>	4	<b>209,965</b>	239,269
Cost of sales		<u>(45,790)</u>	<u>(51,181)</u>
Gross profit		<b>164,175</b>	188,088
Other income and gains		<b>62,448</b>	34,877
Selling and distribution expenses		<b>(123,357)</b>	(99,050)
Research and development costs		<b>(220,316)</b>	(104,328)
Administrative expenses		<b>(54,746)</b>	(44,792)
Other expenses		<b>(38,022)</b>	(81,304)
Finance costs		<b>(18,400)</b>	(984)
Impairment losses on financial assets, net		<b>(3,595)</b>	(3,195)
Share of losses of associates		<u><b>(14,593)</b></u>	<u>(6,523)</u>
<b>LOSS BEFORE TAX</b>	5	<b>(246,406)</b>	(117,211)
Income tax credit/(expense)	6	<u><b>6,738</b></u>	<u>(4)</u>
<b>LOSS FOR THE PERIOD</b>		<u><u><b>(239,668)</b></u></u>	<u><u>(117,215)</u></u>

	<i>Note</i>	<b>2022</b> <b>(Unaudited)</b> <b>RMB'000</b>	2021 (Unaudited) RMB'000
<b>OTHER COMPREHENSIVE INCOME/(LOSS)</b>			
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign operations		<u>70,987</u>	<u>(8,452)</u>
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:			
Equity investments designated at fair value through other comprehensive income:			
Changes in fair value		4,488	(116)
Income tax effect		<u>(30)</u>	<u>-</u>
Net other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods		<u>4,458</u>	<u>(116)</u>
<b>OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD, NET OF TAX</b>			
		<u>75,445</u>	<u>(8,568)</u>
<b>TOTAL COMPREHENSIVE LOSS FOR THE PERIOD</b>			
		<u>(164,223)</u>	<u>(125,783)</u>
Loss attributable to:			
Owners of the parent		(199,933)	(113,063)
Non-controlling interests		<u>(39,735)</u>	<u>(4,152)</u>
		<u>(239,668)</u>	<u>(117,215)</u>
Total comprehensive loss attributable to:			
Owners of the parent		(125,312)	(121,631)
Non-controlling interests		<u>(38,911)</u>	<u>(4,152)</u>
		<u>(164,223)</u>	<u>(125,783)</u>
<b>LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT</b>			
Basic and diluted	8	<u>RMB (0.46)</u>	<u>RMB (0.26)</u>

## INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

June 30, 2022

	<i>Notes</i>	<b>30 June 2022</b> <b>(Unaudited)</b> <b>RMB'000</b>	31 December 2021 <b>(Audited)</b> <b>RMB'000</b>
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment		258,092	142,237
Right-of-use assets		92,823	108,510
Goodwill		1,404,358	519,711
Other intangible assets		1,005,285	304,744
Investments in associates		71,801	76,184
Deferred tax assets		112,015	8,170
Equity investments designated at fair value through other comprehensive income		87,517	16,194
Financial assets at fair value through profit or loss		270,735	477,155
Prepayments, other receivables and other assets		23,566	16,930
		3,326,192	1,669,835
<b>TOTAL non-current assets</b>			
<b>CURRENT ASSETS</b>			
Inventories		106,331	90,519
Trade receivables	9	336,260	302,096
Prepayments, other receivables and other assets		124,674	89,232
Pledged deposits		4,778	2,563
Cash and cash equivalents		2,435,122	2,955,212
		3,007,165	3,439,622
<b>TOTAL current assets</b>			
<b>CURRENT LIABILITIES</b>			
Trade payables	10	29,306	8,751
Lease liabilities		12,560	17,727
Other payables and accruals		248,414	144,732
Interest-bearing bank borrowings		429,276	4,900
Government grants		14,993	14,993
Contract liabilities		4,387	2,845
Refund liabilities		15,015	14,106
Tax payable		8	480
		753,959	208,534
<b>TOTAL current liabilities</b>			
<b>NET CURRENT ASSETS</b>		<b>2,253,206</b>	3,231,088
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>		<b>5,579,398</b>	4,900,923

	<b>30 June 2022</b> <b>(Unaudited)</b> <b>RMB'000</b>	31 December 2021 <b>(Audited)</b> <b>RMB'000</b>
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>	<b>5,579,398</b>	4,900,923
<b>NON-CURRENT LIABILITIES</b>		
Interest-bearing bank borrowings	495,377	–
Other payables and accruals	367,811	167,480
Lease liabilities	38,741	48,148
Deferred tax liabilities	209,428	53,451
Government grants	420	–
Total non-current liabilities	<u>1,111,777</u>	<u>269,079</u>
Net assets	<u><b>4,467,621</b></u>	<u>4,631,844</u>
<b>EQUITY</b>		
<b>Equity attributable to owners of the parent</b>		
Share capital	441,012	441,012
Reserves	<u>3,979,306</u>	<u>4,104,618</u>
	<b>4,420,318</b>	4,545,630
Non-controlling interests	<u>47,303</u>	<u>86,214</u>
Total equity	<u><b>4,467,621</b></u>	<u>4,631,844</u>

## NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

### 1. CORPORATE INFORMATION

Venus Medtech (Hangzhou) Inc. (the “**Company**”) is a joint stock company with limited liability established in the People’s Republic of China (the “**PRC**”). The registered office of the Company is located at Room 311, 3/F, Block 2, No. 88, Jiangling Road, Binjiang District, Hangzhou, the PRC.

During the six months ended 30 June 2022, the Company and its subsidiaries (the “**Group**”) were principally engaged in the research and development, and the manufacturing and sale of bioprosthetic heart valves.

The Company was listed on the Main Board of The Stock Exchange of Hong Kong Limited on 10 December 2019.

### 2. BASIS OF PREPARATION

The interim condensed consolidated financial information for the six months ended 30 June 2022 has been prepared in accordance with International Accounting Standard (“**IAS**”) 34 *Interim Financial Reporting*. The interim condensed consolidated financial information does not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group’s annual consolidated financial statements for the year ended 31 December 2021.

### 3. CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The accounting policies adopted in the preparation of the interim condensed consolidated financial information are consistent with those applied in the preparation of the Group’s annual consolidated financial statements for the year ended 31 December 2021, except for the adoption of the following revised International Financial Reporting Standards (“**IFRSs**”) for the first time for the current period’s financial information.

Amendments to IFRS 3	<i>Reference to the Conceptual Framework</i>
Amendments to IAS 16	<i>Property, Plant and Equipment: Proceeds before Intended Use</i>
Amendments to IAS 37	<i>Onerous Contracts – Cost of Fulfilling a Contract</i>
<i>Annual Improvements to IFRS Standards 2018-2020</i>	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41

The nature and impact of the revised IFRSs are described below:

- (a) Amendments to IFRS 3 replace a reference to the previous *Framework for the Preparation and Presentation of Financial Statements* with a reference to the *Conceptual Framework for Financial Reporting* issued in March 2018 without significantly changing its requirements. The amendments also add to IFRS 3 an exception to its recognition principle for an entity to refer to the Conceptual Framework to determine what constitutes an asset or a liability. The exception specifies that, for liabilities and contingent liabilities that would be within the scope of IAS 37 or IFRIC 21 if they were incurred separately rather than assumed in a business combination, an entity applying IFRS 3 should refer to IAS 37 or IFRIC 21 respectively instead of the Conceptual Framework. Furthermore, the amendments clarify that contingent assets do not qualify for recognition at the acquisition date. The Group has applied the amendments prospectively to business combinations that occurred on or after 1 January 2022. As there were no contingent assets, liabilities and contingent liabilities within the scope of the amendments arising in the business combination that occurred during the period, the amendments did not have any impact on the financial position and performance of the Group.
- (b) Amendments to IAS 16 prohibit an entity from deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced while bringing that asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Instead, an entity recognises the proceeds from selling any such items, and the cost of those items, in profit or loss. The Group has applied the amendments retrospectively to items of property, plant and equipment made available for use on or after 1 January 2021. Since there was no sale of items produced while making property, plant and equipment available for use on or after 1 January 2021, the amendments did not have any impact on the financial position or performance of the Group.

- (c) Amendments to IAS 37 clarify that for the purpose of assessing whether a contract is onerous under IAS 37, the cost of fulfilling the contract comprises the costs that relate directly to the contract. Costs that relate directly to a contract include both the incremental costs of fulfilling that contract (e.g., direct labour and materials) and an allocation of other costs that relate directly to fulfilling that contract (e.g., an allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract as well as contract management and supervision costs). General and administrative costs do not relate directly to a contract and are excluded unless they are explicitly chargeable to the counterparty under the contract. The Group has applied the amendments prospectively to contracts for which it has not yet fulfilled all its obligations at 1 January 2022 and no onerous contracts were identified. Therefore, the amendments did not have any impact on the financial position or performance of the Group.
- (d) *Annual Improvements to IFRS Standards 2018-2020* sets out amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41. Details of the amendments that are applicable to the Group are as follows:
- IFRS 9 *Financial Instruments*: clarifies the fees that an entity includes when assessing whether the terms of a new or modified financial liability are substantially different from the terms of the original financial liability. These fees include only those paid or received between the borrower and the lender, including fees paid or received by either the borrower or lender on the other's behalf. The Group has applied the amendment prospectively to financial liabilities that are modified or exchanged on or after 1 January 2022. As there was no modification of the Group's financial liabilities during the period, the amendment did not have any impact on the financial position or performance of the Group.
  - IFRS 16 *Leases*: removes the illustration of payments from the lessor relating to leasehold improvements in Illustrative Example 13 accompanying IFRS 16. This removes potential confusion regarding the treatment of lease incentives when applying IFRS 16.

#### 4. REVENUE

An analysis of revenue is as follows:

	<b>For the six months ended 30 June</b>	
	<b>2022</b>	2021
	<b>(Unaudited)</b>	(Unaudited)
	<b>RMB'000</b>	RMB'000
<i>Revenue from contracts with customers</i>		
Sale of medical devices	<b>209,965</b>	239,269

#### **Disaggregated revenue information for revenue from contracts with customers**

	<b>For the six months ended 30 June</b>	
	<b>2022</b>	2021
	<b>(Unaudited)</b>	(Unaudited)
	<b>RMB'000</b>	RMB'000
<b>Geographical markets</b>		
Mainland China	<b>195,940</b>	233,688
Other countries/regions	<b>14,025</b>	5,581
Total revenue from contracts with customers	<b>209,965</b>	239,269
<b>Timing of revenue recognition</b>		
Goods transferred at a point in time	<b>209,965</b>	239,269

## 5. LOSS BEFORE TAX

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

	For the six months ended 30 June	
	2022	2021
	(Unaudited) RMB'000	(Unaudited) RMB'000
Cost of inventories sold	44,082	48,794
Impairment of trade receivables	3,582	3,154
Impairment of other receivables	13	41
(Reversal of write-down)/write-down of inventories to net realisable value	(2,227)	731
Loss on disposal of items of property, plant and equipment, net	453	8
Foreign exchange differences, net	(46,820)	17,662
	<u>(46,820)</u>	<u>17,662</u>

## 6. INCOME TAX

### PRC

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations, the subsidiaries which operate in Mainland China are subject to corporate income tax at a rate of 25% on the taxable income. Preferential tax treatment is available to the Company, since it was recognised as a High and New Technology Enterprise on 4 December 2019 and was entitled to a preferential tax rate of 15% (2021: 15%).

### USA

Pursuant to the relevant tax laws of the USA, federal corporation income tax was levied at the rate of 21% (2021: 21%) on the taxable income arising in the USA.

### Israel

Pursuant to the relevant tax laws of Israel, the corporate income tax was levied at 23% (2021: 23%) on the taxable income arising in Israel.

### United Kingdom ("UK")

Pursuant to the relevant tax laws of the UK, the principal federal tax was levied at the rate of up to 19% (2021: up to 19%) on the taxable income arising in the UK.

### Netherlands ("NL")

Pursuant to the relevant tax laws of the NL, the corporate income tax was levied at the rate of up to 25% (2021: up to 25%) on the taxable income arising in the NL.



The income tax (credit)/expense of the Group during the period is analysed as follows:

	<b>For the six months ended 30 June</b>	
	<b>2022</b>	2021
	<b>(Unaudited)</b>	(Unaudited)
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
Current tax – PRC		
Charge for the period	65	1,125
Current tax – USA		
Charge for the period	1	14
Current tax – Israel		
Charge for the period	23	–
Current tax – UK		
Charge for the period	–	7
Current tax – NL		
Charge for the period	–	87
Deferred tax	<u>(6,827)</u>	<u>(1,229)</u>
	<u><u>(6,738)</u></u>	<u><u>4</u></u>

## 7. DIVIDEND

The Board does not recommend the payment of any dividend in respect for the six months ended 30 June 2022 (six months ended 30 June 2021: Nil).

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

The calculation of the basic loss per share amounts is based on the loss for the period attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 436,986,462 (six months ended 30 June 2021: 438,220,338) in issue during the period.

The Group had no potentially dilutive ordinary shares in issue during the six months ended 30 June 2022 (six months ended 30 June 2021: Nil).

The calculation of basic loss per share is based on:

	<b>For the six months ended 30 June</b>	
	<b>2022</b>	2021
	<b>(Unaudited)</b>	(Unaudited)
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
<b>Loss</b>		
Loss attributable to ordinary equity holders of the parent	<u><u>199,933</u></u>	<u><u>113,063</u></u>

	<b>Number of shares</b>	
	<b>For the six months ended 30 June</b>	
	<b>2022</b>	2021
	<b>(Unaudited)</b>	(Unaudited)
<b>Shares</b>		
Weighted average number of shares in issue during the period	<u><u>436,986,462</u></u>	<u><u>438,220,338</u></u>

## 9. TRADE RECEIVABLES

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

	<b>30 June 2022</b> <b>(Unaudited)</b> <b>RMB'000</b>	31 December 2021 <b>(Audited)</b> <b>RMB'000</b>
Within 6 months	<b>204,729</b>	184,308
7 to 12 months	<b>74,450</b>	92,884
1 to 2 years	<b>57,020</b>	24,664
Over 2 years	<b>61</b>	240
	<hr/> <b>336,260</b> <hr/>	<hr/> <b>302,096</b> <hr/>

## 10. TRADE PAYABLES

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

	<b>30 June 2022</b> <b>(Unaudited)</b> <b>RMB'000</b>	31 December 2021 <b>(Audited)</b> <b>RMB'000</b>
Within 3 months	<b>28,461</b>	7,812
3 to 6 months	<b>274</b>	685
6 to 12 months	<b>287</b>	172
Over 12 months	<b>284</b>	82
	<hr/> <b>29,306</b> <hr/>	<hr/> <b>8,751</b> <hr/>

## MANAGEMENT DISCUSSION AND ANALYSIS

### I. BUSINESS OVERVIEW

#### Overview

We are a global high-end innovative medical device manufacturer committed to developing and commercializing high-quality medical devices that benefit patients. Founded in 2009, the Company has grown into a global platform company integrating R&D, clinical development, manufacturing and commercialization.

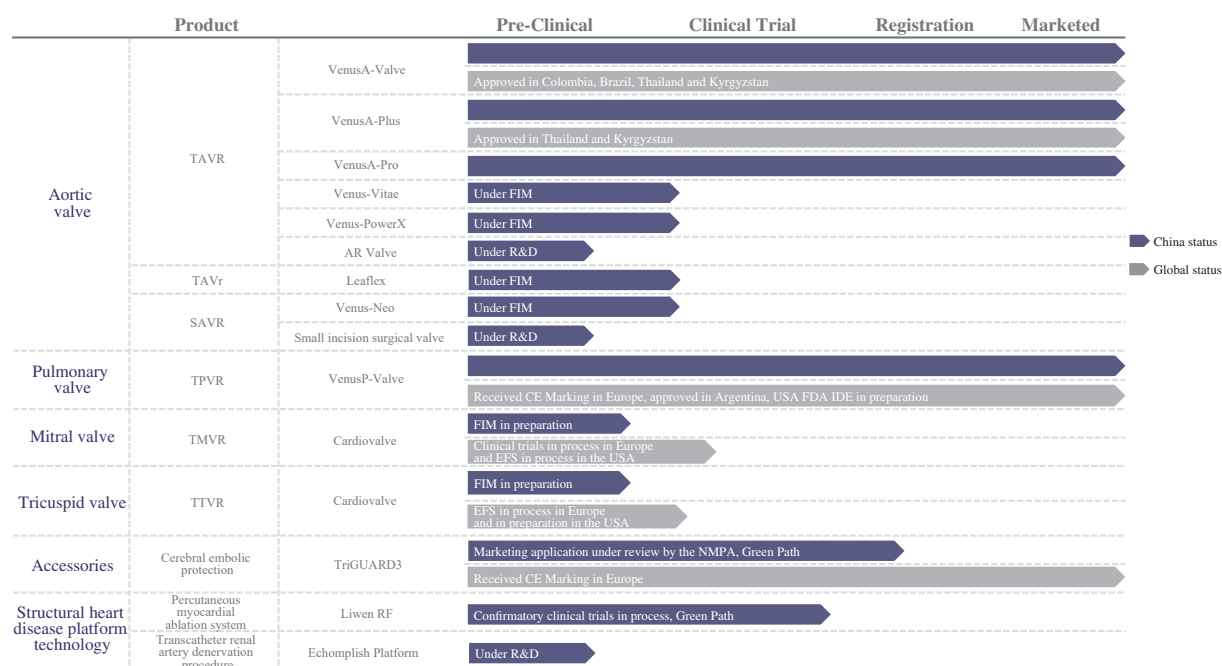
We have forged a product portfolio covering the interventional heart valve devices targeting valvular heart disease concerning aortic valve, pulmonary valve, mitral valve and tricuspid valve, ablation system for interventional treatment of HCM, renal artery denervation ablation system for interventional treatment of hypertension and other surgical accessory consumables, allowing us to provide overall solutions for the patients. In the future, we will focus on the fields of new materials, bionics, image fusion technology and digital sensing, and leverage constant innovations to better cover the entire therapeutic process of patients, so as to satisfy the needs of doctors and patient population.

For the six months ended June 30, 2022 and up to the date of this announcement, the Company efficiently implemented its global commercialization initiatives, achieved milestones in clinical development and registration of pipeline products, and has grown from a single-product company into a platform company with extended scale and enhanced competitiveness. VenusA-Valve, VenusA-Plus and our other TAVR products witnessed steady increase in sales, and continued to maintain a high proportion of market share; VenusA-Pro has been approved for marketing in China, which further enriched our TAVR product pipeline; VenusP-Valve, our independently developed pulmonary valve replacement product, has been approved for marketing in Europe and China; and our eight clinical trials conducted worldwide are in smooth progress, fully demonstrating our innovation capacity and R&D competence.

#### Our Products and Product Pipeline

As of the date of this announcement, the Company has successfully established a product pipeline consisting of 14 innovative medical devices, including three marketed TAVR products (VenusA-Valve, VenusA-Plus and VenusA-Pro), one marketed TPVR product (VenusP-Valve), two TAVR products in clinical stage (Venus-Vitae and Venus-PowerX), one aortic valve repair device in clinical stage (Leaflex), one TMVR and TTVR product in clinical stage (Cardiovalve), one surgical valve in clinical stage (Venus-Neo), one small incision surgical valve in R&D stage, one HCM ablation system in clinical stage (Liwen RF), one RDN system in R&D stage, one marketed valvuloplasty balloon products (V8 and TAV8) and one marketed cerebral embolic protection device (TriGUARD3).

The following chart summarizes the development status of our products and product candidates as of the date of this announcement:



### ***VenusA-Valve, VenusA-Plus and VenusA-Pro – TAVR Products***

We currently have three TAVR products on the market, VenusA-Valve, VenusA-Plus and VenusA-Pro. VenusA-Valve is our first-generation TAVR system, which is used to treat severe AS. VenusA-Valve received marketing approval from the NMPA in April 2017, which marked the first NMPA approved TAVR product marketed in China. Moreover, VenusA-Valve has been approved for marketing in Colombia, Brazil, Thailand and Kyrgyzstan, and has been registered and approved for marketing in Argentina in July 2022.

VenusA-Plus is the second generation TAVR system. While maintaining the strong radial force of the first generation valve, VenusA-Plus introduces the functions of retrievability and repositioning, which may reduce the complexity of procedures and significantly shorten the learning cycle of surgeons. VenusA-Plus was approved by NMPA for marketing in November 2020, and was China’s first approved retrievable TAVR product. Besides, VenusA-Plus has been approved for marketing in Thailand and Kyrgyzstan.

VenusA-Pro is an upgrade of VenusA-Plus. In addition to maintaining the strong radial force, it improves the cross-aortic arch performance with the novel capsule cavity head made of super-elastic material, which therefore enhances the controllability in procedures, and brings more benefits to patients. VenusA-Pro was approved by the NMPA for marketing in May 2022, making the Company the first domestic enterprise with three TAVR products. Our extensive product pipeline offers better treatment options to surgeons and patients, and also facilitates us to maintain our leading market position.

Our TAVR products have been implanted in over 10,000 clinical applications, and the Company is the first company with over 10,000 implants of TAVR products in the industry. At the 20th Chinese Interventional Cardiology (CIT) 2022, the seven-year follow-up results of VenusA-Valve were released, which showed that at the seventh year after implantation of VenusA-Valve, there were 12 cardiac death events, accounting for 13.6%; and incidence of stroke, as the major safety endpoint, is 6.7% at the seventh year. According to the ultrasound data, the peak valve velocity, average valve pressure difference and left ventricular ejection fraction are significantly improved immediately after implantation of VenusA-Valve, and are maintained in a sound and stable condition. In addition, the effective orifice area of VenusA-Valve is kept at above 1.2 cm<sup>2</sup> on average. All of these validate the long-term safety and efficacy of VenusA-Valve, and provides constant benefits to surviving patients.

At the 8th China Valve (Hangzhou) Conference, the two-year follow-up results of VenusA-Plus were released. Of the 54 patients who finished the follow-up via phone calls and 25 who returned to hospitals for follow-up, there was no new case of cardiac death within two years from implantation of VenusA-Plus, and the subgroup results showed that, VenusA-Plus achieves a good effect for patients with bicuspid aortic valve and trileaflet, and demonstrates the sound clinical safety, efficacy and operability of VenusA-Plus.

For the six months ended June 30, 2022, the sales revenue of TAVR products was RMB196.6 million, representing a decrease of 16.2% from RMB234.7 million for the six months ended June 30, 2021.

#### ***VenusP-Valve – TPVR Product***

VenusP-Valve, our independently developed transcatheter pulmonary valve system, received the CE MDR Marking on April 8 and was approved for commercialization. It is designed to treat patients suffering moderate to severe pulmonary regurgitation with or without RVOT stenosis. It is the first self-expanding TPVR product approved for marketing in Europe, and also the first Class III implantable cardiovascular device approved under new CE MDR regulations. In addition, VenusP-Valve was approved for marketing by the NMPA on July 11 for the treatment of patients with severe pulmonary regurgitation (≥3+) with native RVOT. As the first TPVR product approved to be marketed in China, VenusP-Valve filled the gap in clinical demands. In the same month, VenusP-Valve was approved for marketing in Argentina.

Uniquely designed with both flared ends, VenusP-Valve provides stable anchoring and easy delivery, with no need for pre-stenting before the procedure. It is available in a variety of specifications with extensive applicability, and extends coverage to patients with broadened RVOT, thus satisfying the needs of more than 85% patient population in clinical application. Since the first clinical operation in 2013 performed by Academician Ge Junbo, director of the Department of Cardiology from Zhongshan Hospital Fudan University, VenusP-Valve has been used in clinical application for 10 years, including nearly 300 cases for humanitarian aid covering 20 countries and regions across Asia, Europe, North America and South America.

Since receiving the CE MDR Marking in the European Union (EU), the Company has delivered the first batch of VenusP-Valve products to the European market on May 7, and VenusP-Valve has been used for commercial purposes in several regions of the Europe for multiple times. In May, it was approved by the FDA for two cases of humanitarian use in the United States, which were successfully completed in June and August, respectively. In addition, a meeting of IDE clinical investigators for VenusP-Valve has been held in the United States, and VenusP-Valve was qualified for the Japan-US Harmonization By doing project with clinical trials proposed to be launched in both United States and Japan, so as to speed up the registration and marketing in both countries.

As the world's first China-made self-expanding valve product approved for marketing in the EU, VenusP-Valve is highly recognized among experts and doctors worldwide because of its clinical data with excellent long-term safety and effectiveness. The three-year follow-up data of VenusP-Valve published at the 2022 Catheter Interventions in Congenital, Structural and Valvular Heart Disease (CSI) showed that the success rate of 64 patients undergoing TPVR surgery reached 100%, and the mortality and re-operation rate were 0%; no patients suffered moderate or severe pulmonary regurgitation; 96.87% subjects only had mild symptoms of perivalvular leak and tricuspid regurgitation; and the proportion of subjects of New York Heart Association (NYHA) classification Class III decreased from 8.06% before procedure to 1.69%. In addition, the five-year follow-up of VenusP-Valve has been completed in China. The results showed that the 5-year post-surgery mortality rate was only 3.64%, pulmonary regurgitation was greatly reduced, incidence of severe pulmonary regurgitation dropped from 54.5% to 0% and incidence of moderate to severe pulmonary regurgitation dropped from 36.4% to 2.22%, which demonstrated significantly improved right ventricular function and hemodynamic function, and validated the long-term safety and effectiveness of VenusP-Valve.

For the six months ended June 30, 2022, the sales revenue of VenusP-Valve derived overseas was RMB9.1 million (six months ended June 30, 2021: Nil).

#### ***Venus-PowerX – New Generation TAVR Product***

The Venus-PowerX product, a new generation TAVR system independently developed by the Company, is the world's first self-expanding dry tissue valve product. Currently, it is under FIM clinical trials.

Venus-PowerX is the only 100% retrievable valve in clinical stage currently available in the world. It adopts the wire-controlled design, which permits it to be retrieved after complete release, and therefore excels in terms of safety compared with products designed with traditional approaches for release and retrieval. Venus-PowerX is equipped with the world's first self-adaptable active anti-paravalvular leak technology which is based on the proprietary expandable polymer, which will not cause problems such as increased delivery size triggered by physical skirt or skirt damage from retrieving valve, and effectively resist paravalvular leak. In addition, the unique preloaded dry tissue technology and anti-calcification technology increase the durability of the valve. With smaller size and one third less in height than the second generation products, it boasts precise positioning and steerable performance. We will conduct clinical trials of Venus-PowerX in international markets such as Europe and the U.S., and promote the approval of Venus-PowerX for marketing in the global market.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET VENUS-POWERX SUCCESSFULLY.**

### ***Venus-Vitae – New Generation TAVR Product***

The Venus-Vitae product, the world’s first balloon-expanding dry tissue product and a new generation of TAVR system independently developed by the Company, is currently under FIM clinical trials.

Compared with similar products, Venus-Vitae leverages advanced anti-calcification technology to improve valve durability. Its specially designed dry tissue, without aldehyde residue, allows pre-assembly, which not only improves safety, but also facilitates clinical application, storage and transportation. In addition, its unique patented valve lock wire design ensures that the valve does not shift on the balloon catheter. The product, which is designed with supra-annular prosthesis, complemented by short frame and smaller diameter delivery system, has better cross-aortic arch capability. We will launch clinical trials in Europe, USA and other international markets, and facilitate Venus-Vitae to receive marketing approval around the globe.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET VENUS-VITAE SUCCESSFULLY.**

### ***Cardiovalve – New Generation TMVR/TTVR Product***

The acquisition of Cardiovalve Ltd. (“**Cardiovalve**”), a company engaged in innovative transcatheter interventional replacement products for patients suffering from mitral or tricuspid regurgitation has been completed on January 25, 2022 (the “**Acquisition**”) and Cardiovalve has become a wholly-owned subsidiary of the Company.

Cardiovalve system is a transcatheter valve replacement system for patients suffering from mitral regurgitation and tricuspid regurgitation. Compared with similar products, its transfemoral approach significantly improves the safety of treatment and its 55 mm annuli is suitable for about 95% of the patient population. Meanwhile, its unique short frame design lowers the risk of LVOT obstruction. At present, the Cardiovalve system is undergoing multi-center clinical trials in the United States and Europe, and the initial clinical results are promising. Its indication for treatment of mitral regurgitation has entered clinical study in Europe and approved for an early feasibility study in the U.S.. Furthermore, its indication for treatment of tricuspid regurgitation received “Breakthrough Device Designation” by the FDA in January 2020 and obtained approval for early feasibility study. Cardiovalve is the first company approved by the FDA to conduct early feasibility study on indications of mitral regurgitation and tricuspid regurgitation.

Upon the Acquisition, the Company continued to promote its clinical research in Europe and the United States, and at the same time accelerated its clinical development, registration and marketing in the domestic market. Since completion of the Acquisition, the patient enrollment in clinical trials of Cardiovalve in mitral valve and tricuspid valve goes smoothly in Europe, and the device was highly recognized among doctors overseas. According to the data released at the TVT 2022 – Structural Heart Summit held on June 9 in the United States, three patients undergoing tricuspid valve replacement with the Cardiovalve system did not experience any regurgitation immediately after and within 30 days from the procedure, and one of them did not experience regurgitation even in six months after the procedure. Easy to operate and highly repeatable, Cardiovalve can be controlled in three steps: positioning, anchoring and release. Short learning period of surgeons is conducive to the popularization of the device. Domestically, Cardiovalve showcased at renowned academic conferences including China Valve (Hangzhou) 2022 and the 16th Oriental Congress of Cardiology (OCC 2022), where we shared the experience of TMVR and TTVR procedures and demonstrated the unique advantages of Cardiovalve to promote the development of domestic technology and lay a solid foundation for clinical trials in China.

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

***Venus-Neo – Surgical Valve***

Venus-Neo, a new-generation expandable dry valve product independently developed by the Company, successfully completed the first FIM clinical application in Union Hospital Tongji Medical College of Huazhong University of Science and Technology on April 12, and is currently under FIM clinical trials. The other product, the small incision surgical valve, which is implanted through small incision in median sternum or between ribs and therefore contributes to quick recovery and is less invasive, is currently under animal study.

As the Company's first surgical bioprosthetic valve product, Venus-Neo adopts the supra-annular design with bovine pericardium tissue as the valve leaflet. Leveraging optimized valve design and unique anti-calcification drying technology, it can be stored in a liquid-free environment, and contains no aldehyde residue, which enhances safety and is convenient for clinical use, storage and transportation. In addition, Venus-Neo's valve stent adopts expandable design, thereby providing a better choice for patients who need to receive valve-in-valve procedures in the future.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET VENUS-NEO SUCCESSFULLY.**

***TriGUARD3 – CEP device***

TriGUARD3, the cerebral embolic protection device, can protect brain completely through covering the whole ascending aorta. It is the only CEP device designed to cover the whole ascending aorta (covering the innominate artery, left carotid artery and subclavian artery). It can greatly minimize the risk of brain damage and prevent cerebral embolism during TAVR and other structural heart disease surgeries.

TriGUARD3 obtained the CE Marking from the EU on March 4, 2020 for commercialization in Europe. In October 2021, NMPA has officially accepted the marketing application of TriGUARD3 submitted by the Company, and it is currently under review.



For the six months ended June 30, 2022, the sales revenue of TriGUARD3 was RMB3.8 million (six months ended June 30, 2021: RMB4.2 million).

### ***Leaflex – Aortic Valve Repair Product***

Leaflex is a non-implant catheter-based solution for AS treatment. It scores the calcification within the leaflets from the aortic side, and the ventricular side of leaflets remains basically intact without tearing the ventricular tissue of leaflets, so as to achieve complete movement, restore the mobility of leaflets and improve valve hemodynamics, thereby improving flow access and reducing the gradient across the valve. The Leaflex procedure is simple without implantation, and the hospitalization length-of-stay is short.

Leaflex can be used not only for young patients who may be too young for TAVR, but also for future valve-in-valve procedures of aortic valve after TAVR implantation, so as to provide lifetime management of AS at a lower cost than replacement. In September 2020, we completed the cooperative transaction with Pi-Cardia, and introduced Leaflex products into the Chinese market. It is currently under FIM clinical study. Pi-cardia has commenced clinical trials in Europe.

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

### ***Liwen RF – Ablation System***

Liwen RF ablation system, independently developed by Nuocheng Medical, a wholly-owned subsidiary of the Company, is an innovative device for the treatment of HCM. In November 2021, the Company completed acquisition of Nuocheng Medical and accelerated the clinical research progress of Liwen RF in China. At present, Liwen RF is in multi-center clinical trial across China.

Liwen RF adopts the international novel operation treatment through ventricular septum under the guidance of ultrasound and boasts the technical advantages of minimally invasive, accurate positioning, unrestricted by target blood vessels, significantly reducing ventricular septum thickness, and mitigating complications such as conduction system damage. The device not only achieves dehydration and necrosis of hypertrophic myocardial cells, but also blocks the blood supply to hypertrophic myocardial tissue, thereby achieving long-term prognosis. It offers a safe, effective, accurate and minimally invasive innovative treatment strategy for HCM. We propose to conduct clinical trials in Europe, and promote the approval of Liwen RF in the international market.

According to the 144 completed exploratory clinical trials of Liwen RF ablation system, and the comparison results with traditional surgical gold standard surgeries, the success rate of surgeries with Liwen RF ablation system reaches 88% with no mortality after one year of surgery, and the clinical manifestations, cardiac function and quality of life of patients are significantly improved. Besides, it is obviously superior to surgical operation and alcohol ablation, which effectively validates its safety, effectiveness and advanced performance. Liwen RF ablation system passed NMPA's Application for Special Approval Procedure on Innovative Medical Devices in August, and was admitted to the special review process, which fully demonstrated its novelty.

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

### ***Renal artery denervation (“RDN”) product***

On June 30, 2021, the Company established a 51% owned subsidiary, Renaly Ltd, with Israeli high-tech company, Healium, to introduce the new generation of innovative devices for RDN from Healium, and conduct R&D, production and commercialization of RDN products worldwide. It is currently under animal study.

Its exclusive Dual-Mode Ultrasound Technology Platform can realize non-contact continuous ablation treatment with real-time ultrasound imaging, significantly reducing the occurrence of various problems such as insufficient nerve ablation or vascular damage caused by uncontrollable ablation. The delivery of accurate and efficient ablation shifts the treatment paradigm to more predictable outcomes and simplifies the procedure flow to ultimately improve the safety and efficacy of ablation procedures. Professor Martin B. Leon, a member of our Global Advisory Board and his team will serve as the global PI of the product.

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

### ***R&D innovation***

In the broad market of structural heart diseases, the Company is committed to solving clinical pain points, increases R&D investment, deeply engages in the field of structural heart diseases, makes constant innovations, and continues to accumulate technical experience, striving to bring innovative products to the market, and consolidate its leading position in the field of valves. In the field of aortic valves, the Company’s latest generation of dry valve TAVR products, PowerX, Vitae and Venus-Neo, the surgical valve product, which are in clinical stage, adopt advanced anti-calcification treatment technology to extend valve durability, further improve and simplify transcatheter aortic valve replacement procedure. In the field of pulmonary valve products, VenusP-Valve has been successively approved for marketing in Europe and China, and the Company has included patients with congenital heart disease into the target patients. Interventional therapy in mitral and tricuspid valve fields will be our new growth drivers in the future. The Company’s Cardiovalve, the world’s leading product in interventional treatment of mitral and tricuspid valve diseases, has commenced clinical trials in Europe and the United States, and is expected to enter clinical trials in China during the year.

The Company’s R&D platform continues to fledge. The Company has established a global R&D innovation platform through independent R&D and external cooperation. Our three R&D centers are located in Hangzhou, China, Caesarea, Israel, and California, USA, and comprise of members with professional experience and innovative capacity at home and abroad. In March, the Company established Venus Medical Global Heart Valve Innovation Center in Israel, tapping into Israel’s innovative talents and culture to improve the Company’s global innovation system and product layout. The Global Heart Valve Innovation Center will be committed to incubating breakthrough innovative treatment technologies, further improving the global innovation system and product layout, focusing on the research and development of a new generation of aortic regurgitation treatment technology using Cardiovalve technology platform and the application of digital health technology in valve system, and transferring the technology to China and other regions in the world at an appropriate time. The Company’s research and development achievements receive numerous recognitions and rewards, and are listed in national key projects. In May, the “Research and Development of New Pre-installed Interventional Heart Valve System” project led by the Company passed the inspection and acceptance of China Biotechnology Development Center with an excellent rating in terms of performance. This marked the second time for the Company to pass inspection and acceptance with brilliant results following undertaking the “National Science and Technology Support Program-Novel Biological Heart Valve System Development Project” of the Ministry of Science and Technology.

In addition to internal innovation, we also constantly expand and enrich product pipeline through external investment and cooperation, which covers innovative frontier areas such as hypertrophic cardiomyopathy and resistant hypertension, so as to broaden business layout in structural heart diseases, enrich innovative device pipeline, improve innovative device research and clinical application, speed up research and development and transformation of innovative technologies and products, and extend presence to emerging areas leveraging international leading new technologies to achieve technological leadership.

For the six months ended June 30, 2021 and 2022, our R&D expenses were RMB104.3 million and RMB220.3 million, respectively.

### ***Intellectual Properties***

The Company attaches great importance to intellectual property protection. Leveraging its strong R&D capability, as of June 30, 2022, the Company had a total of 786 patents and patents under applications, including 319 authorized invention patents. We had 305 patents under application and authorized in the PRC, including 182 issued patents; and 452 patents under application and authorized overseas, including 259 authorized patents. We had 29 PCT applications. Our global IP portfolio mainly covers China, the U.S., Europe, Japan, Canada, Russia, India, Brazil and other countries.

### ***Manufacturing***

We have an approximately 3,500 sq.m. facility in Hangzhou and an approximately 816 sq.m. facility in Israel for manufacturing our heart valve products and product candidates. Our manufacturing facilities comply with the GMP requirements in the U.S., the EU and the PRC and follow rigorous manufacturing and quality control standards to ensure high product quality and safety standards. The Company maintains strong synergy between R&D and production, and focuses on the management process of whole product life cycle. In the process of launching R&D for new products, it will pay due consideration to the convenience of production and optimizes product design to improve production efficiency and product quality. The Company continuously strengthens the production capacity and production management level, establishes and improves advanced quality management system and refines production system. We conduct all the key valve manufacturing procedures in-house. Over the years, we have accumulated expertise and know-how in manufacturing heart valve products, which sets a solid foundation for our long-term growth. In order to meet the demand of gradual commercialization of products in our product pipeline, the Company has formulated the stage-by-stage capacity planning for different product development cycles, gradually improved and upgraded the large-scale commercial production capacity based on a sound quality management system, expanded capacity and improved the economies of scale while maintaining high quality standards. Meanwhile, the Company makes prior arrangement in production technics and cost control to lay a solid foundation for the commercialization of the Company's products in different countries and regions.

### ***Quality system***

The Company has established a quality management system that meets the requirements of GMP of the NMPA of the PRC, Quality System Regulation of the FDA of the U.S., MDR of EU, BGMP of ANVISA of Brazil, ISO13485 and other regulations and standards, and carries out quality control in the whole life cycle of products from R&D to post-marketing sales. The Company develops and maintains a quality management system with high standards and strict requirements to ensure the quality of its products. In 2019 and 2021, the Company was invited to the first and third experience exchange meeting regarding national medical device production quality management standards. This year, the Company introduced and shared experiences with national medical device enterprises as an outstanding representative in Beijing. As the COVID-19 remains challenging globally, the Company accepted and successfully passed the remote and on-site quality system audit under the new MDR regulation by the EU Notified Body this year, and facilitated pulmonary valve products to obtain CE Marking. In addition, the Company was elected as Hangzhou Medical Device Inspector Training Base, providing a platform for theoretical knowledge and practical operation for inspector training.

### ***Commercialization***

We will continue to strengthen the construction and integration of professional, branded and digital marketing systems. We have established domestic specialized marketing teams, overseas marketing teams focusing on European and Latin American markets, and sales support systems regarding clinical medicine, market access and brand promotion targeting specific regions and countries.

As of June 30, 2022, we have established a sales team in China comprising of nearly 260 personnel, covering 375 tertiary hospitals, who provide a strong foundation for constant sales increase. The Company adopts an independent marketing model, and has established a largest marketing team and in-house logistics supply chain team in the industry. Through professional communication and medical promotion of the marketing team, our in-house supply chain proactively responds to customers' needs and improves the penetration into Chinese market. In order to improve the standardized diagnosis and treatment services for patients with AS in China, the Company adopts digital means to launch education, and conducts public welfare assistance, community care and other activities, so as to realize the whole-process management of patients from treatment to rehabilitation. Our independently developed VenusA-Pro was approved for marketing in China in May and VenusP-Valve was approved for marketing in China in July. As the only Company in the market with three TAVR products and one TPVR product, our rich product pipeline provides doctors and patients with more and better choices of treatment, enhances the brand influence of the Company and facilitates to consolidate our leading position in China.

Revenue from our new products has been on constant rise, and the proportion of revenue derived from the overseas market continues to increase, suggesting an improved revenue structure. As of June 30, 2022, VenusP-Valve was approved for marketing in the EU in April, and it is the first self-expanding TPVR product approved for marketing in Europe. This is another important milestone after TriGUARD3 entered the European market, and also marked the Company's commercial coverage extending to the mainstream market in Europe. At present, our overseas commercialization teams comprise professionals across Germany, France, Britain and other countries and regions. In terms of digital channel, we further enrich the global marketing strategies and methods through product launches, online seminars, online customer training and other activities, and continue to expand the global market. In the TAVR field, the Company further improved its product registration and market access capabilities in Southeast Asia, Central Asia, Latin America and other regions, and gradually established contact with doctors and hospitals through agents in the local area to continuously expand our brand influence.

## **Impact of COVID-19**

During the first half of 2022, persistent rage of COVID-19 in Shanghai and several other regions across China posed certain adverse impact on the Company's business operations in China, and there still remains uncertainty as to the impact of COVID-19 both at home and overseas in future. The potential impacts of COVID-19 on the Company's business operations include but are not limited to sales of products, recruitment and engagement of clinical subjects, product registration and approval, and procurement of raw materials. The Company will continue to keep abreast of COVID-19 developments and make prior arrangements to guarantee the safety of our employees and smooth progress of various projects.

## **II. FINANCIAL REVIEW**

### **Overview**

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

### **Revenue**

During the Reporting Period, all of our revenue was generated from sales of medical devices. Since its commercialization in August 2017, sales of VenusA-Valve have comprised the major portion of our revenue, and are expected to account for a substantial portion of our sales in the near future. VenusP-Valve received the CE MDR Marking in the EU on April 8, 2022, and was approved by the NMPA for marketing on July 11, 2022.

The Group's revenue for the six months ended June 30, 2022 was RMB210.0 million, representing a decrease of 12.2% compared to RMB239.3 million for the six months ended June 30, 2021. The decrease was primarily attributable to the negative impact of COVID-19. For the six months ended June 30, 2022, revenue from sales of VenusA-Valve and VenusA-Plus accounted for 93.7% of our total revenue, as compared to 98.1% for the six months ended June 30, 2021.

The following table sets forth a breakdown of our revenue by product:

<b>Revenue</b>	<b>Six months ended June 30, 2022 (Unaudited)</b>		<b>Six months ended June 30, 2021 (Unaudited)</b>	
	<b>RMB'000</b>	<b>Proportion</b>	<b>RMB'000</b>	<b>Proportion</b>
VenusA-Valve/VenusA-Plus	<b>196,573</b>	<b>93.7%</b>	234,699	98.1%
VenusP-Valve	<b>9,110</b>	<b>4.3%</b>	–	0.0%
TriGUARD3	<b>3,803</b>	<b>1.8%</b>	4,160	1.7%
Others	<b>479</b>	<b>0.2%</b>	410	0.2%
<b>Total</b>	<b><u>209,965</u></b>	<b><u>100%</u></b>	<b><u>239,269</u></b>	<b><u>100%</u></b>

### **Cost of Sales**

The cost of sales for VenusA-Valve/VenusA-Plus, VenusP-Valve and TriGUARD3 primarily consists of staff costs, raw material costs, depreciation and amortization, utility costs and others.

The Group's cost of sales for the six months ended June 30, 2022 was RMB45.8 million, representing a decrease of 10.5% compared to RMB51.2 million for the six months ended June 30, 2021. The decrease was in line with the change in sales revenue for the same period of 2022.

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

As a result of the aforementioned factors, the gross profit of the Group decreased by 12.7% from RMB188.1 million for the six months ended June 30, 2021 to RMB164.2 million for the six months ended June 30, 2022. Gross profit margin is calculated as gross profit divided by revenue. For the six months ended June 30, 2021 and 2022, the Group's gross profit margin was 78.6% and 78.2%, respectively.

### **Other Income and Gains**

The Group's other income and gains for the six months ended June 30, 2022 was RMB62.4 million, representing an increase of 78.8% compared to RMB34.9 million for the six months ended June 30, 2021, primarily attributable to the increase in government grants and foreign exchange gains as compared with the corresponding period of last year.

## Selling and Distribution Expenses

The Group's selling and distribution expenses for the six months ended June 30, 2022 was RMB123.4 million, representing an increase of 24.5% compared to RMB99.1 million for the six months ended June 30, 2021. The increase was mainly due to the growth of staff cost resulting from the increased number of sales personnel and increase in investment in market exploration and promotion.

## R&D Costs

The Group's R&D costs for the six months ended June 30, 2022 was RMB220.3 million, representing an increase of 111.2% compared to RMB104.3 million for the six months ended June 30, 2021. The increase was primarily attributable to completion of acquisition of Cardiovalve during the Reporting Period, leading to a corresponding increase in R&D expenses, as well as an increase in staff cost due to the expansion of the R&D team.

The following table sets forth a breakdown of R&D costs:

	<b>Six months ended June 30, 2022 (Unaudited) RMB'000</b>	Six months ended June 30, 2021 (Unaudited) RMB'000
Staff cost	71,468	30,686
Raw material cost	33,804	13,762
Third-party contracting cost	2,029	4,237
Intellectual property expenses	10,457	8,851
Clinical trial expenses	18,855	18,430
Depreciation and amortization	42,916	11,527
Others	40,787	16,835
	<u>220,316</u>	<u>104,328</u>

### **Administrative Expenses**

The Group's administrative expenses for the six months ended June 30, 2022 was RMB54.7 million, representing an increase of 22.1% compared to RMB44.8 million for the six months ended June 30, 2021. The increase was primarily attributable to the increase in the number of employees to support the operating requirements resulting from our business growth.

### **Other Expenses**

The Group's other expenses for the six months ended June 30, 2022 was RMB38.0 million, representing a decrease of 53.3% compared to RMB81.3 million for the six months ended June 30, 2021. The decrease was primarily due to decrease in donations during the Reporting Period.

### **Finance Costs**

The Group's finance costs for the six months ended June 30, 2022 was RMB18.4 million, representing an increase of RMB17.4 million compared to RMB1.0 million for the six months ended June 30, 2021. The increase was primarily attributable to the increase in interest expenses on bank borrowings during the Reporting Period.

### **Impairment Losses on Financial Assets, Net**

The Group's impairment losses on financial assets, net, for the six months ended June 30, 2022 was RMB3.6 million, representing an increase of 12.5% compared to RMB3.2 million for the six months ended June 30, 2021. The increase was primarily attributable to our maintenance of a flexible strategy over credit term management as affected by COVID-19, leading to an increase in provision for impairment allowance of certain trade receivables as a result of the increase in aging of trade receivables.

### **Share of Losses of Associates**

The Group's share of losses of associates for the six months ended June 30, 2022 was RMB14.6 million, representing an increase of 124.6% from RMB6.5 million for the six months ended June 30, 2021. The increase was primarily attributable to losses incurred by the associates during the Reporting Period.

### **Income Tax**

The Group's income tax credit for the six months ended June 30, 2022 was RMB6.7 million as compared to income tax expense of RMB4,000 for the six months ended June 30, 2021. The tax credit for the Reporting Period was primarily attributable to the deferred tax credited to profit or loss, which was related to the fair value adjustments arising from acquisition of subsidiaries.



## **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. To maintain or realign our capital structure, the Group may raise capital by way of bank loans or issuance of equity or convertible bonds.

## **Liquidity and Financial Resources**

The Group's cash and cash equivalents as at June 30, 2022 were RMB2,435.1 million, representing a decrease of 17.6% compared to RMB2,955.2 million as at December 31, 2021. The decrease was primarily attributable to the increase in R&D and operating expenses and investments.

We rely on capital contributions by our Shareholders and bank loans as the major sources of liquidity. We also generate cash from our sales revenue of existing commercialized products, including VenusA-Valve, VenusA-Plus, VenusP-Valve and TriGUARD3. 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 and accelerating the turnover of trade receivables by tightening our credit policy.

## **Borrowings and Gearing Ratio**

As at June 30, 2022, the Group's interest-bearing bank borrowings were RMB924.7 million (December 31, 2021: RMB4.9 million).

The gearing ratio (calculated by dividing the sum of borrowings and lease liabilities by total equity) of the Group as at June 30, 2022 was 21.8%, representing an increase of 1,353.3% as compared to 1.5% as at December 31, 2021.

## **Net Current Assets**

The Group's net current assets, as at June 30, 2022 were RMB2,253.2 million, representing a decrease of 30.3% compared to net current assets of RMB3,231.1 million as at December 31, 2021.

## **Foreign Exchange Exposure**

We have transactional currency exposures. Certain of our bank balances, other receivables, other financial assets, other payables and other financial liabilities are dominated in foreign currencies and are exposed to foreign currency risk. We currently do not have a foreign currency hedging policy. However, our management monitors foreign exchange exposure and will consider appropriate hedging measures in the future should the need arise.

## **Significant Investments**

During the Reporting Period, we did not hold any significant investments.

## **Material Acquisitions and Disposals**

We entered into certain agreements with Mitraltech Holdings Ltd., the parent company of Cardiovalve, and other certain parties to acquire the 100% share capital and corresponding interests of Cardiovalve at a consideration (subject to certain adjustment) of US\$266 million on December 7, 2021 (the “**Acquisition**”), by way of acquisition of equity interests in its parent company Mitraltech Holdings Ltd. and subscription of convertible loan. This completion of the Acquisition has taken place on January 25, 2022 and Cardiovalve has become an indirect wholly-owned subsidiary of the Company. For details, please refer to the announcement made by the Company dated on January 26, 2022.

Saved as disclosed above, during the Reporting Period, we did not have any other material acquisitions or disposals of subsidiaries, associates and joint ventures of the Company.

## **Capital Expenditure**

For the six months ended June 30, 2022, the Group’s total capital expenditure amounted to approximately RMB1,202.7 million, which was used for (i) amounts paid to acquire a subsidiary; (ii) purchase of items of property, plant and equipment; (iii) purchase of equity investment designated at fair value through other comprehensive income; and (iv) purchase of other intangible assets.

## **Charge on Assets**

Certain of the Group’s loans amounted to RMB774.5 million were secured by mortgages or pledges over our assets. The mortgaged or pledged assets include equity interests of certain subsidiaries, leasehold land, time deposits, etc.

## **Contingent Liabilities**

As at June 30, 2022, except for the contingent consideration payable for acquisition of subsidiaries, we did not have any contingent liabilities.

## **Employees and Remuneration Policies**

As of June 30, 2022, we had 1,039 employees in total.

Among the 1,039 employees, 901 of our employees are stationed in China, and 138 of our employees are stationed overseas primarily in the U.S. and Israel. In compliance with the applicable labor laws, we enter into individual employment contracts with our employees covering matters such as wages, bonuses, employee benefits, workplace safety, confidentiality obligations, non-competition and grounds for termination. These employment contracts typically have terms of three to five years.

To remain competitive in the labor market, we provide various incentives and benefits to our employees. We invest in continuing education and training programs, including internal and external training, for our management staff and other employees to upgrade their skills and knowledge. We also provide competitive salaries, project and stock incentive plans to our employees especially key employees.

## **Future Investment Plans and Expected Funding**

The Group will continue to expand its markets in the PRC and globally in order to tap its internal potential and maximize Shareholders' interest. The Group will continue to grow through self-development, mergers and acquisitions, and other means. We will employ a combination of financing channels to finance capital expenditures, including but not limit to internal funds and bank loans. Currently, the bank credit lines available to the Group are adequate.

## **III. PROSPECTS**

During the first half of the year, we successfully commercialized VenusP-Valve in Europe, and completed the acquisition of Cardiovalve, thereby achieving the globalized layout in terms of mitral valve and tricuspid valve interventional therapies and further promoting our globalization strategy. In the domestic market, we are committed to generating profitability, striving for quality growth and maintaining a stable gross profit. In the second half of 2022, we will continue to focus on the unmet medical needs, dedicate ourselves to the globalization-driven strategies, concentrate on the fields of treatment for structural heart diseases, and leverage our first-mover advantages to expedite sales in the global market and speed up multi-center clinical trials conducted worldwide. Besides, we will seek to increase the number of TAVR procedures in domestic mid-to-high-end hospitals, aiming to enhance commercial margin.

### **Accelerate Globalization Pace**

Following the approval of VenusP-Valve for commercialization in the EU, supported by our existing international production capacity and quality system certification, we will facilitate our domestic production lines to receive quality system certification overseas, so as to lay a solid foundation for commercialization of domestically-made devices in the international market. Meanwhile, we will continue to expedite clinical study of VenusP-Valve in the USA and Japan, enhance our overseas clinical development and innovative device registration capabilities. In terms of commercialization, we will make unremitting efforts to promote the global sales of VenusP-Valve, extend the coverage to more hospitals in different countries and regions worldwide. In addition, we will establish a training system for overseas teams leveraging internal and external academic resources, respect and tap into the advantages and capabilities of local talents, and leverage the expertise of local sales professionals with extensive experience. In terms of market access, we will comply with local laws and regulations, learn about access policies of different countries and regions, strive to make breakthroughs in medical insurance, Diagnosis Related Group (DRG), bidding and hospital access procedures, and continue to venture into the international market.

### **Maintain Quality Marketing Growth**

COVID-19 has a long-term negative impact on the number of domestic TAVR procedures. As present, we are exposed to challenges such as enhancing the commercial profitability and promoting quality growth of TAVR products. Against such backdrop, we will continue to tap into our first-mover advantages, enhance establishment and integration of our marketing system, step up academic popularization and doctor education in key hospitals with our profound expertise, clinical resources and well-established product portfolio, increase the number of surgeries in mid-to-high-end hospitals, search far and deep for hospital potentials, and improve the profitability of our TAVR business. Meanwhile, we will continue to launch post-marketing clinical trials, and accumulate more clinical data to provide sufficient support for inclusion of our products in medical insurance and other access. We will also proactively cultivate ties and communicate with medical insurance departments to explore innovative payment methods such as payment by medical insurance and commercial insurance.

## CORPORATE GOVERNANCE AND OTHER INFORMATION

### Interim Dividend

The Board does not recommend the payment of interim dividend for the six months ended June 30, 2022 to the shareholders (six months ended June 30, 2021: Nil).

### Use of Proceeds

#### **(1) Use of Proceeds from the Initial Global Offering**

The net proceeds received by the Company from its initial global offering (including the full exercise of the over-allotment option) amounted to HK\$2,846.0 million (equivalent to RMB2,558.0 million) (after deducting the underwriting commissions and other estimated expenses in connection with the initial global offering and exercise of the over-allotment option).

As of June 30, 2022, the Company has used (i) RMB559.37 million for payment of expenses incurred by the core products of the Company; (ii) RMB687.75 million for payment of expenses incurred by other product candidates of the Company; (iii) RMB383.4 million to finance internal research and development and/or potential acquisition for the purpose of complementing our product portfolio; and (iv) RMB255.8 million for replenishment of working capital and other general corporate purposes. The Company intends to use the net proceeds that had not been utilized as of June 30, 2022 in the same manner and proportion as set out in the Prospectus under the section headed “Future Plans and Use of Proceeds”. For details of the breakdown of the use of proceeds, please refer to the 2022 interim report of the Company to be published in due course.

#### **(2) Use of Proceeds from the September 2020 Placing**

The net proceeds received by the Company from the placing of an aggregate of 18,500,000 new H Shares in September 2020 were approximately HK\$1,173.0 million (equivalent to RMB1,034.01 million) (after deducting the expenses of the placing).

Pursuant to the announcement made by the Company dated March 14, 2022, the Company made the clarification of the intended purposes of the proceeds from the September 2020 Placing. As of June 30, 2022, the Company has used (i) RMB471.30 million for investments in upstream and downstream companies and (ii) RMB562.71 million for working capital and other general corporate purposes, in order to facilitate the long-term strategic development of the Company. As of June 30, 2022, all proceeds of the September 2020 Placing have been used up in line with the intended purpose. For details of the breakdown of the use of proceeds, please refer to the 2022 interim report of the Company to be published in due course.

### **(3) Use of Proceeds from the January 2021 Placing**

Pursuant to the announcement made by the Company on March 14, 2022, the Company changed the use of proceeds from the January 2021 Placing (the “**Changed Use of Proceeds**”) and as at March 14, 2022, the unutilized proceeds from the January 2021 Placing amounted to approximately RMB986.81 million. In relation to the Changed Use of Proceeds, as of June 30, 2022, the Company has used (i) RMB143.07 million for Expanded Development and Research; (ii) RMB49.6 million for Investments; and (iii) RMB196.56 million for General Working Capital. The Company expects that the unutilized proceeds allocated to Expanded Development and Research to be used by December 31, 2023 and the proceeds allocated to unutilized Investments and General Working Capital to be used by December 31, 2022. Save as defined herein, the capitalized terms in this sub-section shall have the same meanings as defined in the announcement of the Company dated March 14, 2022. For details of the breakdown of the use of proceeds, please refer to the 2022 interim report of the Company to be published in due course.

### **Purchase, Sale or Redemption of the Company’s Listed Securities**

The Group did not purchase, sell or redeem any of the Company’s listed securities during the six months ended June 30, 2022.

### **Subsequent Events**

The Company is not aware of any material subsequent events from June 30, 2022 to the date of this announcement.

### **Model Code for Securities Transactions**

The Company has adopted a code of conduct regarding Directors’ and Supervisors’ securities transactions on terms no less exacting than the required standard set out in the Model Code in Appendix 10 to the Listing Rules. Specific enquiries have been made to all the Directors and Supervisors, and they have confirmed that they have complied with the Company’s code of conduct regarding Directors’ and Supervisors’ securities transactions during the six months ended June 30, 2022.

The Company’s employees, who are likely to be in possession of inside information of the Company, have also been subject to the Model Code for securities transactions. No incident of non-compliance of the Model Code by the employees was noted by the Company during the six months ended June 30, 2022.

### **Compliance with the Corporate Governance Code**

The Company has adopted and applied the principles and code provisions as set out in the Corporate Governance Code contained in Appendix 14 to the Listing Rules. During the six months ended June 30, 2022, the Company has complied with the mandatory code provisions in the Corporate Governance Code.

## **Audit Committee**

The Audit committee has three members comprising all independent non-executive Directors, being Mr. Chi Wai Suen (chairman), Mr. Wan Yee Joseph Lau and Mr. Ting Yuk Anthony Wu, with terms of reference in compliance with Rule 3.21 of the Listing Rules.

The Audit Committee has considered and reviewed the accounting principles and practices adopted by the Group and has discussed matters in relation to internal controls, risk management and financial reporting with the management, including the review of the unaudited condensed consolidated interim financial results of the Group for the six months ended June 30, 2022. The Audit Committee considers that the interim financial results for the six months ended June 30, 2022 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made. The Company's independent auditor has not performed a review of these condensed consolidated financial information prepared in accordance with the relevant accounting standards.

## **Publication of Interim Results Announcement and Interim Report**

This announcement is published on the websites of the Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company ([www.venusmedtech.com](http://www.venusmedtech.com)), respectively.

The interim report containing all the information required by Appendix 16 to the Listing Rules will be despatched to the Shareholders and published on the websites of the Stock Exchange and the Company in due course, respectively.

## **DEFINITIONS**

“ANVISA”	Brazil’s National Health Surveillance Agency
“AS”	Aortic Stenosis
“Audit Committee”	the audit committee of the Board
“BGMP”	Brazil Good Manufacture Practice
“Board”	the board of directors of the Company
“CE Marking”	a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area
“CEP”	cerebral embolic protection, the function of the devices designed to capture or deflect emboli traveling to the brain during TAVR procedures in order to protect the supra-aortic vessels from embolic debris
“cGMP”	Current Good Manufacture Practice
“China” or “the PRC”	the People’s Republic of China, excluding, for the purpose of this announcement, Hong Kong, Macau Special Administrative Region and Taiwan

“CIT”	Chinese Interventional Therapeutics
“Company”	Venus Medtech (Hangzhou) Inc. (杭州啓明醫療器械股份有限公司), a limited liability company incorporated in the PRC on July 3, 2009 and converted into a joint stock limited liability company incorporated in the PRC on November 29, 2018, whose H Shares are listed on the Hong Kong Stock Exchange (Stock Code: 2500)
“Corporate Governance Code”	the Corporate Governance Code set out in Appendix 14 to the Listing Rules
“COVID-19”	an infectious disease caused by a newly discovered coronavirus, the outbreak of which began in December 2019
“Directors”	the director(s) of the Company
“EU”	the European Union
“FDA”	U.S. Food and Drug Administration
“FIM”	First In Man
“GMP”	good manufacturing practices, the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification
“Group” or “we/our/us”	the Company and its subsidiaries
“H Share(s)”	the overseas listed foreign shares with a nominal value of RMB1.00 each in the share capital of the Company, which are listed on the Hong Kong Stock Exchange and subscribed for and traded in Hong Kong dollars
“HCM”	hypertrophic cardiomyopathy
“HK\$”	Hong Kong dollars, the lawful currency of Hong Kong
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“IDE”	Investigation Device Exemption
“IFRS”	International Financial Reporting Standards
“InterValve”	InterValve Medical Inc., a company incorporated in Delaware, the U.S., on November 18, 2016 and is indirectly wholly-owned by the Company as of the date of announcement

“Keystone”	Keystone Heart Ltd. and its subsidiaries
“KOLs”	acronym for Key Opinion Leaders who are doctors that influence their peers’ medical practice, including but not limited to prescribing behavior
“Listing Rules”	the Rules governing the Listing of Securities on the Stock Exchange, as amended or supplemented from time to time
“LVOT”	left ventricular outflow tract, the anatomic structure through which the left ventricular stroke volume passes towards the aorta
“MDR”	Regulation (EU) 2017/745
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 to the Listing Rules
“NMPA”	National Medical Products Administration (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局)
“PI”	principle investigator
“Prospectus”	the prospectus published by the Company on November 28, 2019 in relation to its Hong Kong public offering
“R&D”	research and development
“RDN”	renal artery denervation
“Reporting Period”	the six months period from January 1, 2022 to June 30, 2022
“RMB” or “Renminbi”	Renminbi Yuan, the lawful currency of China
“RVOT”	right ventricular outflow tract, an infundibular extension of the ventricular cavity which connects to the pulmonary artery
“RVOTD”	the dysfunction of RVOT
“Shareholder(s)”	holders of shares of the Company
“SPVR”	surgical pulmonary valve replacement, a treatment of RVOTD through open-chest surgery
“Stock Exchange”	The Stock Exchange of Hong Kong Limited



“Supervisor(s)”	member(s) of the supervisory committee of the Company
“TAP treatment”	Transannular patching, a type of treatment for ToF that involves closing the ventricular septal defect and placing atransannular patch (a patch across the pulmonary valve connective tissue to enlarge the pulmonary annulus), which helps blood flow from the pulmonary valve
“TAV8”	TAV8 Balloon Aortic Valvuloplasty Catheter, one of our balloon transluminal aortic valvuloplasty catheter system products
“TAVR”	transcatheter aortic heart valve replacement, a catheter-based technique to implant a new aortic valve in a minimally invasive procedure that does not involve open-chest surgery to correct severe aortic stenosis
“TMVR”	transcatheter mitral valve replacement, catheter-based technique to implant a new mitral valve in a minimally invasive procedure that does not involve open-chest surgery
“ToF”	tetralogy of fallot, a congenital abnormality of the heart characterized by pulmonary stenosis, an opening in the interventricular septum, malposition of the aorta over both ventricles, and hypertrophy of the right ventricle
“TPVR”	transcatheter pulmonary valve replacement, a catheter-based technique to implant a new pulmonary valve in a minimally invasive procedure that does not involve open-chest surgery
“TriGUARD3”	TriGUARD3 Cerebral Embolic Protection Device, our CEP product candidate
“TTVR”	transcatheter tricuspid valve replacement, a catheter-based technique to implant a new tricuspid valve in a minimally invasive procedure that does not involve open-chest surgery
“U.S.” or “USA”	the United States of America, its territories and possessions, any state of the United States and the District of Columbia
“US\$”	United States dollars, the lawful currency of the United States of America
“V8”	V8, one of our balloon transluminal aortic valvuloplasty catheter system products
“Venus-PowerX”	Venus PowerX Valve, one of our TAVR product candidates
“Venus-Vitae”	Venus Vitae Valve, one of our TAVR product candidates

“VenusA-Plus”	VenusA-Plus System, one of our TAVR products
“VenusA-Valve”	VenusA-Valve System, our TAVR product
“VenusP-Valve”	VenusP-Valve System, our TPVR product

By Order of the Board  
**Venus Medtech (Hangzhou) Inc.**  
**Min Frank Zeng**  
*Chairman of the Board*

Hangzhou, August 31, 2022

*As at the date of this announcement, the executive Directors are Mr. Min Frank Zeng, Mr. Zhenjun Zi and Mr. Lim Hou-Sen (Lin Haosheng); the non-executive Director is Ms. Nisa Bernice Wing-Yu Leung; and the independent non-executive Directors are Mr. Ting Yuk Anthony Wu, Mr. Wan Yee Joseph Lau and Mr. Chi Wai Suen.*