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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 ANNUAL RESULTS  
 FOR THE YEAR ENDED DECEMBER 31, 2022**

The board (the “**Board**”) of directors (the “**Director(s)**”) of Venus Medtech (Hangzhou) Inc. (the “**Company**”) is pleased to announce the audited consolidated results of the Company and its subsidiaries (together, the “**Group**”) for the year ended December 31, 2022 (the “**Reporting Period**”), together with audited comparative figures for the same period of 2021.

**FINANCIAL HIGHLIGHTS**

	Year ended December 31, 2022 <i>RMB'000</i>	Year ended December 31, 2021 <i>RMB'000</i>	Year-on-year change
Revenue	406,461	415,862	-2.3%
Gross Profit	313,998	324,344	-3.2%
Loss before tax	(1,156,344)	(377,555)	206.3%
Loss for the year	(1,122,042)	(371,394)	202.1%
Loss attributable to owners of the parent	(1,057,699)	(373,636)	183.1%
Loss per Share attributable to ordinary equity holders of the parent			
Basic and diluted	RMB(2.42)	RMB(0.85)	184.7%

## ANNUAL RESULTS

The Board is pleased to announce the audited condensed consolidated annual results of the Group for the year ended December 31, 2022 as follows:

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

	<i>Notes</i>	<b>2022</b> <b>RMB'000</b>	2021 <i>RMB'000</i>
<b>REVENUE</b>	4	<b>406,461</b>	415,862
Cost of sales		<u>(92,463)</u>	<u>(91,518)</u>
Gross profit		<b>313,998</b>	324,344
Other income and gains	4	<b>147,988</b>	307,147
Selling and distribution expenses		<b>(260,382)</b>	(216,067)
Research and development costs		<b>(527,451)</b>	(258,336)
Administrative expenses		<b>(192,178)</b>	(128,585)
Other expenses		<b>(557,781)</b>	(389,257)
Impairment losses on financial assets, net		<b>(21,972)</b>	(3,185)
Finance costs	6	<b>(44,623)</b>	(1,905)
Share of losses of:			
A joint venture		<b>(4,092)</b>	–
Associates		<u>(9,851)</u>	<u>(11,711)</u>
<b>LOSS BEFORE TAX</b>	5	<b>(1,156,344)</b>	(377,555)
Income tax credit	7	<u>34,302</u>	<u>6,161</u>
<b>LOSS FOR THE YEAR</b>		<u><b>(1,122,042)</b></u>	<u>(371,394)</u>
<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		<b>118,952</b>	(17,671)
Share of other comprehensive income of associates		<u>737</u>	<u>–</u>
Net other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods		<u><b>119,689</b></u>	<u>(17,671)</u>

	<i>Note</i>	<b>2022</b> <b>RMB'000</b>	2021 RMB'000
Other comprehensive (loss)/income 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		(787)	3,158
Income tax effect		<u>321</u>	<u>(568)</u>
Net other comprehensive (loss)/income that will not be reclassified to profit or loss in subsequent periods		<u>(466)</u>	<u>2,590</u>
<b>OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR, NET OF TAX</b>		<u><b>119,223</b></u>	<u>(15,081)</u>
<b>TOTAL COMPREHENSIVE LOSS FOR THE YEAR</b>		<u><b>(1,002,819)</b></u>	<u><b>(386,475)</b></u>
Loss attributable to:			
Owners of the parent		(1,057,699)	(373,636)
Non-controlling interests		<u>(64,343)</u>	<u>2,242</u>
		<u><b>(1,122,042)</b></u>	<u><b>(371,394)</b></u>
Total comprehensive loss attributable to:			
Owners of the parent		(940,052)	(388,578)
Non-controlling interests		<u>(62,767)</u>	<u>2,103</u>
		<u><b>(1,002,819)</b></u>	<u><b>(386,475)</b></u>
<b>LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT</b>			
Basic and diluted	9	<u><b>RMB(2.42)</b></u>	<u><b>RMB(0.85)</b></u>

## AUDITED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	<i>Note</i>	<b>2022</b>	2021
		<b>RMB'000</b>	<b>RMB'000</b>
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment		<b>318,139</b>	142,237
Right-of-use assets		<b>143,144</b>	108,510
Goodwill		<b>1,238,535</b>	519,711
Other intangible assets		<b>611,171</b>	304,744
Investment in a joint venture		<b>2,728</b>	–
Investments in associates		<b>70,283</b>	76,184
Deferred tax assets		<b>9,941</b>	8,170
Equity investments designated at fair value through other comprehensive income		<b>15,747</b>	16,194
Financial assets at fair value through profit or loss		<b>388,322</b>	477,155
Prepayments, other receivables and other assets		<b>15,855</b>	16,930
		<hr/>	<hr/>
Total non-current assets		<b>2,813,865</b>	1,669,835
<b>CURRENT ASSETS</b>			
Inventories		<b>104,396</b>	90,519
Trade receivables	<i>10</i>	<b>303,388</b>	302,096
Prepayments, other receivables and other assets		<b>119,868</b>	89,232
Due from directors		<b>34,400</b>	–
Pledged deposits		<b>27,487</b>	2,563
Cash and cash equivalents		<b>1,879,431</b>	2,955,212
		<hr/>	<hr/>
Total current assets		<b>2,468,970</b>	3,439,622

	<i>Notes</i>	<b>2022</b> <b>RMB'000</b>	2021 <i>RMB'000</i>
<b>CURRENT LIABILITIES</b>			
Trade payables	<i>11</i>	<b>9,126</b>	8,751
Lease liabilities		<b>23,457</b>	17,727
Other payables and accruals		<b>227,590</b>	144,732
Interest-bearing bank borrowings	<i>12</i>	<b>222,603</b>	4,900
Government grants		<b>1,370</b>	14,993
Contract liabilities		<b>2,952</b>	2,845
Refund liabilities		–	14,106
Tax payable		<b>5,006</b>	480
		<hr/>	<hr/>
Total current liabilities		<b>492,104</b>	208,534
		<hr/>	<hr/>
<b>NET CURRENT ASSETS</b>		<b>1,976,866</b>	3,231,088
		<hr/>	<hr/>
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>		<b>4,790,731</b>	4,900,923
		<hr/>	<hr/>
<b>NON-CURRENT LIABILITIES</b>			
Interest-bearing bank borrowings	<i>12</i>	<b>573,379</b>	–
Other payables and accruals		<b>487,826</b>	167,480
Lease liabilities		<b>80,204</b>	48,148
Deferred tax liabilities		<b>17,411</b>	53,451
Government grants		<b>600</b>	–
		<hr/>	<hr/>
Total non-current liabilities		<b>1,159,420</b>	269,079
		<hr/>	<hr/>
Net assets		<b>3,631,311</b>	4,631,844
		<hr/> <hr/>	<hr/> <hr/>
<b>EQUITY</b>			
<b>Equity attributable to owners of the parent</b>			
Share capital		<b>441,012</b>	441,012
Reserves		<b>3,166,852</b>	4,104,618
		<hr/>	<hr/>
		<b>3,607,864</b>	4,545,630
		<hr/>	<hr/>
Non-controlling interests		<b>23,447</b>	86,214
		<hr/>	<hr/>
Total equity		<b>3,631,311</b>	4,631,844
		<hr/> <hr/>	<hr/> <hr/>

## NOTES

### 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 year, the Group was 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 on 10 December 2019.

### 2.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards (“**IFRSs**”) issued by the International Accounting Standards Board and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention, except for equity investments designated at fair value through other comprehensive income and financial assets and liabilities at fair value through profit or loss which have been measured at fair value. These financial statements are presented in Renminbi (“**RMB**”) and all values are rounded to the nearest thousand except when otherwise indicated.

### 2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

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

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

### 2.3 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

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

Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> <sup>3</sup>
Amendments to IFRS 16	<i>Lease Liability in a Sale and Leaseback</i> <sup>2</sup>
IFRS 17	<i>Insurance Contracts</i> <sup>1</sup>
Amendments to IFRS 17	<i>Insurance Contracts</i> <sup>1,5</sup>
Amendment to IFRS 17	<i>Initial Application of IFRS 17 and IFRS 9 – Comparative Information</i> <sup>6</sup>
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current (the “<b>2020 Amendments</b>”)</i> <sup>2,4</sup>
Amendments to IAS 1	<i>Non-current Liabilities with Covenants (the “<b>2022 Amendments</b>”)</i> <sup>2</sup>
Amendments to IAS 1 and IFRS Practice Statement 2	<i>Disclosure of Accounting Policies</i> <sup>1</sup>
Amendments to IAS 8	<i>Definition of Accounting Estimates</i> <sup>1</sup>
Amendments to IAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction</i> <sup>1</sup>

<sup>1</sup> Effective for annual periods beginning on or after 1 January 2023

<sup>2</sup> Effective for annual periods beginning on or after 1 January 2024

<sup>3</sup> No mandatory effective date yet determined but available for adoption

- <sup>4</sup> As a consequence of the 2022 Amendments, the effective date of the 2020 Amendments was deferred to annual periods beginning on or after 1 January 2024
- <sup>5</sup> As a consequence of the amendments to IFRS 17 issued in June 2020, IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before 1 January 2023
- <sup>6</sup> An entity that chooses to apply the transition option relating to the classification overlay set out in this amendment shall apply it on initial application of IFRS 17

### 3. OPERATING SEGMENT INFORMATION

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

#### Geographical information

##### (a) Revenue from external customers

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Mainland China	354,567	405,346
Others	51,894	10,516
	<u>406,461</u>	<u>415,862</u>

The revenue information above is based on the locations of the customers.

##### (b) Non-current assets

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Mainland China	561,196	477,893
Israel	503,136	134,740
Hong Kong	66,584	–
USA	30,349	31,692
Netherlands	55	–
	<u>1,161,320</u>	<u>644,325</u>

The non-current asset information above is based on the locations of the assets and excludes goodwill, deferred tax assets and financial instruments.

#### Information about major customers

No revenue from the Group's sales to a single customer amounted to 10% or more of the Group's total revenue during the year (2021: Nil).

#### 4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
<i>Revenue from contracts with customers</i>		
Sale of medical devices	<u>406,461</u>	<u>415,862</u>

#### Revenue from contracts with customers

##### (a) *Disaggregated revenue information*

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
<b>Geographical markets</b>		
Mainland China	354,567	405,346
Others	<u>51,894</u>	<u>10,516</u>
Total revenue from contracts with customers	<u>406,461</u>	<u>415,862</u>

##### **Timing of revenue recognition**

Goods transferred at a point in time	<u>406,461</u>	<u>415,862</u>
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##### (b) *Performance obligations*

There was no revenue recognised during the year that was included in the contract liabilities at the beginning of the reporting period and recognised from performance obligations satisfied in previous periods.

The amounts of transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at 31 December are as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Amounts expected to be recognised as revenue:		
Within one year	<u>2,952</u>	<u>2,845</u>

The amounts of transaction prices allocated to the performance obligations are expected to be recognised as revenue within one year. The amounts disclosed above do not include variable consideration which is constrained.



	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
<b>Other income</b>		
Bank interest income	19,230	33,380
Other interest income	15,418	16,100
Government grants ( <i>note (a)</i> )	31,128	6,687
Others	485	1,918
	<u>66,261</u>	<u>58,085</u>
<b>Gains</b>		
Fair value adjustments of contingent considerations	–	239,048
Fair value gain on a derivative financial instrument	–	10,014
Foreign exchange gains, net	81,727	–
	<u>81,727</u>	<u>249,062</u>
	<u>147,988</u>	<u>307,147</u>

*Note:*

- (a) The government grants mainly represent incentives received from the local governments for the purpose of compensation for expenditure arising from research activities and clinical trial activities and awards for new valve product development and expenditure incurred on certain projects.

## 5. LOSS BEFORE TAX

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

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Cost of inventories sold	90,717	87,351
Research and development costs	527,451	258,336
Depreciation of property, plant and equipment	27,072	14,844
Depreciation of right-of-use assets	27,370	14,325
Amortisation of other intangible assets	57,910	22,452
Impairment of property, plant and equipment	4,197	–
Reversal of write-down of inventories to net realisable value	(202)	(1,434)
Impairment of other intangible assets	111,735	46,189
Impairment of goodwill	304,301	189,957
Government grants	(31,128)	(6,687)
Bank interest income	(19,230)	(33,380)
Other interest income	(15,418)	(16,100)
Loss on disposal of items of property, plant and equipment, net	130	18
Lease payments not included in the measurement of lease liabilities	1,883	1,932
Fair value gain on a derivative financial instrument	–	(10,014)
Fair value losses, net:		
Financial assets at fair value through profit or loss		
– mandatorily classified as such	189	656
Fair value adjustments of contingent considerations	55,549	(239,048)
Foreign exchange differences, net	(81,727)	31,716
	<u>                    </u>	<u>                    </u>

## 6. FINANCE COSTS

An analysis of finance costs is as follows:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Interest on bank loans	40,360	70
Interest on lease liabilities	5,402	1,835
	<u>                    </u>	<u>                    </u>
Total interest expense	45,762	1,905
Less: Interest capitalised	(1,139)	–
	<u>                    </u>	<u>                    </u>
	<u>44,623</u>	<u>1,905</u>

## **7. 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 in December 2022, and was entitled to a preferential tax rate of 15% during the year (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 during the year.

### **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 during the year.

### **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 during the year.

### **Netherlands (“NL”)**

Pursuant to the relevant tax laws of the NL, the corporate income tax was levied at the rate of up to 15% (2021: up to 15%) on the taxable income arising in the NL during the year.

The income tax credit of the Group during the year is analysed as follows:

	<b>2022</b> <b>RMB'000</b>	2021 <b>RMB'000</b>
Current – PRC		
Charge for the year	<b>1,707</b>	1,601
Current – USA		
Charge for the year	<b>949</b>	17
Overprovision in prior years	–	(773)
Current – Israel		
Charge for the year	<b>428</b>	361
Current – UK		
Charge for the year	–	6
Current – NL		
Charge for the year	<b>188</b>	181
Current – Netherlands		
Credit for the year	<b>(203)</b>	–
Deferred	<b>(37,371)</b>	(7,554)
	<b>(34,302)</b>	(6,161)

## 8. DIVIDEND

No dividend has been paid or declared by the Company during the year (2021: Nil).

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

The calculation of the basic loss per share amount is based on the loss attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 437,897,443 (2021: 438,577,016) in issue during the year, as adjusted to reflect the shares purchased in 2021 which were treated as treasury shares.

The Group had no potentially dilutive ordinary shares in issue during the years ended 31 December 2022 and 2021.

The calculation of basic loss per share is based on:

	<b>2022</b> <b>RMB'000</b>	2021 <b>RMB'000</b>
Loss		
Loss attributable to ordinary equity holders of the parent	<b>(1,057,699)</b>	(373,636)
	<b>Number of shares</b>	
	<b>2022</b>	2021
Shares		
Weighted average number of shares in issue during the year	<b>437,897,443</b>	438,577,016

## 10. TRADE RECEIVABLES

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Trade receivables	316,486	308,639
Impairment	(13,098)	(6,543)
	<u>303,388</u>	<u>302,096</u>

The Group's trading terms with its customers are mainly on credit. The credit period is generally six months to one year. Each customer has a maximum credit limit. The Group seeks to maintain strict control over its outstanding receivables. Overdue balances are reviewed regularly by senior management. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

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

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Within 6 months	164,808	184,308
7 to 12 months	83,811	92,884
1 to 2 years	54,429	24,664
Over 2 years	340	240
	<u>303,388</u>	<u>302,096</u>

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

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
At beginning of year	6,543	3,667
Impairment losses, net	6,555	3,067
Amount written off as uncollectible	-	(191)
At end of year	<u>13,098</u>	<u>6,543</u>

## 11. 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:

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Within 3 months	8,980	7,812
3 to 6 months	50	685
6 to 12 months	65	172
Over 12 months	31	82
	<u>9,126</u>	<u>8,751</u>

Trade payables are non-interest-bearing and are normally settled on 30-day terms.

## 12. INTEREST-BEARING BANK BORROWINGS

	Effective interest rate (%)	Maturity	2022 RMB'000	2021 RMB'000
<b>Current</b>				
Bank loans – unsecured	1-year LPR* plus 0.45%	2023	100,115	–
Current portion of long-term bank loan – secured US\$90,000,000 bank loan	LIBOR* plus 3.65%	2023	122,488	–
Current portion of long-term bank loan – secured	1-year LPR plus 0.60%	2022	–	4,400
Bank loans – unsecured	1-year LPR plus 2.15%	2022	–	500
			222,603	4,900
<b>Non-Current</b>				
Bank loan – secured US\$90,000,000 bank loan	LIBOR plus 3.65%	2024-2025	501,451	–
Bank loans – secured	5-year LPR minus 0.10%	2026-2036	61,915	–
Bank loans – secured	5-year LPR minus 0.15%	2026-2037	10,013	–
			573,379	–
			795,982	4,900

\* Loan Prime Rate in Mainland China (“LPR”) and London Interbank Offered Rate (“LIBOR”)

## MANAGEMENT DISCUSSION AND ANALYSIS

### I. BUSINESS OVERVIEW

#### Overview

Founded in 2009, we have grown into a global platform company engaged in innovative medical devices that integrates R&D, clinical development, manufacturing and commercialization. Our vision is to become a global leader in interventional therapy for structural heart diseases, providing effective treatment options for major diseases that seriously threaten human health where current treatment methods are inaccessible.

We have developed a product portfolio covering the interventional heart valve devices for valvular heart disease including aortic valve, pulmonic 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 accessory consumables, allowing us to provide overall solutions for the doctors and 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, and satisfy the needs of doctors and patients population.

Throughout 2022 and up to the date of this announcement, the Company has achieved constant breakthroughs in business operations with a commitment to its long-standing strategic goals, including, in particular, significant progress in overseas operations amid its smooth globalization paces. During the Reporting Period, VenusP-Valve became our first independently developed product marketed in Europe, and also the first self-expanding TPVR product approved in Europe. Backed by our improving overseas channels for commercialization, VenusP-Valve has recorded strong sales of RMB40.9 million since its launch in April 2022. Meanwhile, the Company successfully completed the acquisition of Cardiovalve, an international technology leader in heart valve devices, and expedited its core products to enter international multi-centered confirmatory clinical trials. Besides, Venus-Vitae and Venus-PowerX, our independently developed innovative products, are under smooth international multi-centered clinical study as planned.

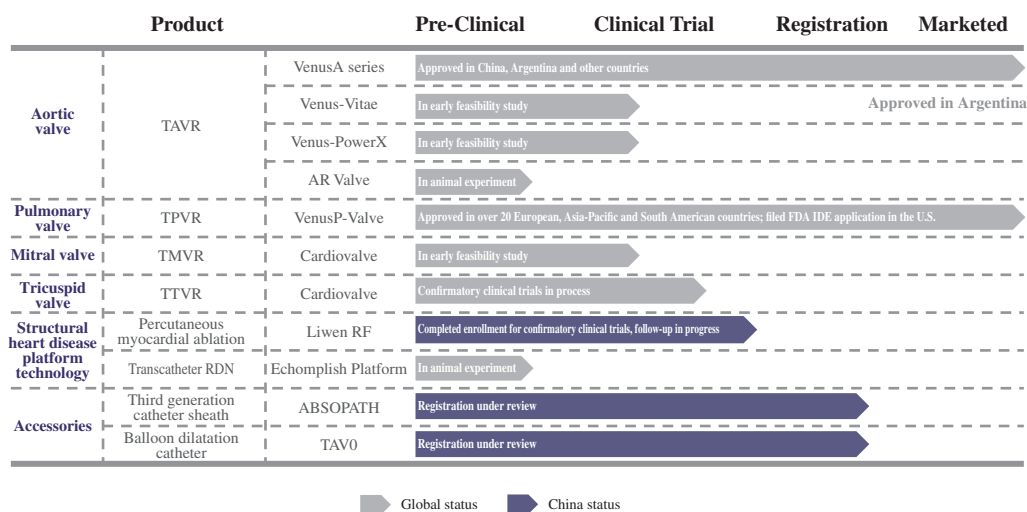
#### Our Products and Product Pipeline

As of the date of this announcement, the Company has successfully established a product pipeline consisting of 12 innovative medical devices, covering the fields of heart valve diseases, HCM and hypertension.

Interventional treatment of heart valve diseases is one of our core therapeutic areas. We have commercialized three TAVR products and one TPVR product. Our products currently in clinical trials include TAVR products (Venus-Vitae and Venus-PowerX), as well as one TMVR and TTVR product (Cardiovalve). We also have one product candidate currently under animal experiment for the treatment of aortic regurgitation. In addition, we have two accessories currently in the registration, namely ABSOPATH catheter sheath and TAV0 balloon dilation catheter, which are mainly used by physicians in conjunction with VenusA series products in TAVR procedures.

For treatment of HCM, we have developed the globally innovative Liwen RF ablation system. We also have developed the renal artery denervation (RDN) ablation system, an innovative device in interventional therapy for hypertension.

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



### ***VenusA Series-TAVR Products***

We currently have three marketed TAVR products, namely, VenusA-Valve, VenusA-Plus and VenusA-Pro. VenusA-Valve received marketing approval from the NMPA in April 2017, which marked the first NMPA approved TAVR product in China. VenusA-Plus received marketing approval from the NMPA in November 2020, which is the first retrievable TAVR product approved in China. 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 curve of surgeons.

VenusA-Pro, an upgrade version of VenusA-Plus, ensures radial force while providing improved cross-aortic arch performance with its capsule head made of super-elastic material, therefore enhancing the operability in procedures. Its commissural alignment marks help to give adequate protection to coronary artery. VenusA-Pro was approved by the NMPA in May 2022, making the Company the first domestic enterprise with three TAVR products. Our extensive product pipeline offers better treatment options to physicians and patients, and also enables us to maintain our leading market position.



As the earliest commercialized product in China, VenusA series products have the longest follow-up track record among peers, and their medium to long-term safety and efficacy have been sufficiently verified. At the 20th Chinese Interventional Cardiology (CIT) 2022, the seven-year follow-up results of VenusA-Valve were released. The data showed that at the seventh year after implantation of VenusA-Valve, there were 12 cardiac death events, accounting for 13.6%. At the 8th China Valve (Hangzhou) Conference, the two-year follow-up results of VenusA-Plus were released. 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 valve and tricuspid valve, demonstrating the sound clinical safety, efficacy and operability of VenusA-Plus. Chinese TAVR patients are characterized by a high proportion of bicuspid valve (representing approximately 40% of the total number of TAVR patients) and severe calcification of valve leaflets, while VenusA series products with strong radial force are suitable for patients with severe bicuspid aortic valve.

For the year ended December 31, 2022, sales revenue from VenusA series products was RMB358.1 million, representing a decrease of 11.6% from RMB405.3 million for the year ended December 31, 2021.

### ***VenusP-Valve – TPVR Product***

VenusP-Valve, our independently developed transcatheter pulmonary valve system, received the CE MDR in April 2022 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 in Europe, and also the first Class III implantable cardiovascular device approved under new CE MDR regulations. In addition, VenusP-Valve was approved by the NMPA in July 2022 for the treatment of patients with severe pulmonary regurgitation ( $\geq 3+$ ) with native RVOT. As the first TPVR product approved in China, VenusP-Valve filled the gap in clinical demands. In the same month, VenusP-Valve was approved in Argentina. As of the date of this announcement, our VenusP-Valve has entered in more than 20 countries and regions including Britain, Italy, Spain, Denmark, Greece, France, Germany, Poland and Switzerland. Leveraging its efficient overseas marketing efforts, the Company achieved strong sales performance for VenusP-Valve.

VenusP-Valve is highly recognized among experts and doctors worldwide because of 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 reached 100%, and the mortality and re-operation rate were 0%; no patients suffered moderate or severe pulmonary regurgitation; 96.87% subjects had mild symptoms of perivalvular leak and 95.38% subject had mild tricuspid regurgitation; and the proportion of subjects of New York Heart Association (NYHA) classification Class III decreased from 7.69% before procedure to 1.67%; and those of Class I surged from 27.69% before procedure to 90%. In addition, according to the five-year follow-up of patients receiving VenusP-Valve implantation in China, the 5-year post-procedure 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.

At present, we are accelerating the confirmatory clinical study of VenusP-Valve in the United States and Japan. IDE investigators meeting for VenusP-Valve was held in the United States, and we will initiate clinical trials both in the United States and Japan through the Japan-US Harmonization By Doing project. In March 2023, we submitted to the FDA an Investigational Device Exemption (IDE) application in the United States.

For the year ended December 31, 2022, sales revenue of VenusP-Valve was RMB40.9 million (for the year ended December 31, 2021: nil).

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

Venus-PowerX, the world's first self-expanding dry-tissue valve product and the new generation TAVR system independently developed by us, is currently under early feasibility study.

Venus-PowerX is the new generation pre-loaded dry-tissue valve product. It adopts the Venus-Endura biomembrane, which leverages advanced anti-calcification technology to improve the durability of the valve, and three-dimensional force controlled dehydration technology without the use of glutaraldehyde for preservation. Therefore, while enhancing safety, Venus-PowerX also boasts convenience for clinical application, preservation and transportation. Its pre-loaded dry tissue technology can significantly reduce operation preparation time. Venus-PowerX is the only completely 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. It is also equipped with the world's first adoptive active anti-PVL skirt made of polymer materials with highly compressible and self-expanding performance, which can promote the combination of vascular tissue and skirt through the growth and filling of cells in the void. We will conduct international multi-centered clinical trials in regions such as Europe and China, to expedite the approval of Venus-PowerX in 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 balloon-expandable dry-tissue product and a new generation of TAVR system independently developed by the Company, is currently under early feasibility study.

Venus-Endura biomembrane is adopted for Venus-Vitae, which leverages advanced anti-calcification technology to improve the durability of the valve, and three-dimensional force controlled dehydration technology without the use of glutaraldehyde for preservation. Therefore, while enhancing safety, Venus-Vitae also boasts convenience for clinical application, preservation and transportation. In addition, its delivery system is uniquely designed with the patented lock-wire technology, thus lock the valve during transporting and balloon expanding. The lock-wire technology, bending adjustment function, balloon coaxial rotation function and axial fine adjustment function maximize the controllability for physicians, and fill in the gap in the market where similar products are not equipped with commissures alignment delivery system. It is also equipped with the world's first adoptive active anti-PVL skirt made of polymer materials with highly compressible and self-expanding performance, which can promote the combination of vascular tissue and skirt through the growth and filling of cells in the void. Venus-Vitae has been approved in Argentina in December 2022. We will conduct international multi-centered clinical trials in countries and regions such as Europe, Canada and China, to expedite the approval of Venus-Vitae in global market.

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

***Cardiovalve – TMVR/TTVR Product***

Cardiovalve, a wholly-owned subsidiary of the Company, has independently developed the mitral valve and tricuspid valve replacement products. Currently, Cardiovalve is in early feasibility study for TMVR and in confirmatory clinical trials for TTVR.

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 annular is suitable for about 95% patient population. Meanwhile, its unique short frame design lowers the risk of LVOT obstruction.

Since completion of the Acquisition, the patient enrollment in TMVR and TTVR clinical trials of Cardiovalve has been going smoothly with a rapid progress in Europe. In November 2022, Cardiovalve started a TARGET CE confirmatory clinical trial. So far, sound progress has been made with ongoing multi-centered patient enrollment in countries including Germany, where more than 10 patients have been enrolled. We will carry forward international multi-centered clinical trials in countries and regions including Europe and China, to expedite the approval of Cardiovalve for marketing in global market.

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

***Liwen RF – Ablation System***

Hangzhou Nuocheng Medical Technology Co., Ltd. (杭州諾誠醫療科技有限公司), a wholly-owned subsidiary of the Company, has independently developed Liwen RF ablation system, an innovative device for treatment of HOCM. In March 2023, we completed the enrollment of all patients to confirmatory clinical trials for Liwen RF, and entered the follow-up stage in China. Among the current follow-up comprising 38 patients after six months from the procedure, the success rate reaches 92.11% (35/38), representing a significant improvement compared to alcohol ablation. As for the clinical endpoint, the maximum ventricular septal thickness decreased to an average of 17.08 mm (25.61% lower than that before the procedure), and the post-procedure pressure gradient of the left ventricular outflow tract decreased to 16.31 mmHg (76.25% lower than that before the procedure). Both of these two important indicators improved significantly compared to those before the procedure, and showed a trend of continuous improvement.

Liwen RF 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 HOCM. We propose to conduct clinical trials in Europe, and accelerate the approval of Liwen RF in the global market.

According to the 144 completed exploratory clinical trials of Liwen RF ablation system, compared with traditional gold standard surgeries, the success rate with Liwen RF ablation system reaches 88% with no mortality after one year, and the clinical manifestations, cardiac function and quality of life of patients are significantly improved. It is significantly better than surgical operation and alcohol septal ablation, which effectively validates its safety, effectiveness and advanced performance. In August 2022, the product was approved for special review through the special examination and approval of the National Medical Products Administration for innovative medical devices 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.**

***RDN ablation system***

The Company has introduced the new generation RDN innovative device developed by Healium, an Israeli high-tech company. It is currently in animal experiment.

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 new generation of dry-tissue valve TAVR products, Venus-PowerX and Venus-Vitae, which are in clinical stage, adopt advanced anti-calcification technology to extend valve durability, further improve and simplify the procedure of TAVR. In the field of pulmonary valve products, VenusP-Valve has been successively approved 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.

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, Tel Aviv, Israel and Irvine, California, USA, and comprise of members with professional experience and innovative capacity at home and abroad. In March 2022, the Company established Venus 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-loaded Interventional Heart Valve System" project led by the Company passed the inspection of China National Center for Biotechnology Development with an excellent rating in terms of performance. This marked the second time for the Company to pass inspection 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 HCM 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 years ended December 31, 2021 and 2022, our R&D expenses were RMB258.3 million and RMB527.5 million, respectively.

### **Intellectual Properties**

The Company attaches great importance to intellectual property protection. Leveraging its strong R&D capability, as of March 31, 2022 the Company had a total of 832 patents and patents under applications, including 366 authorized invention patents. We had 343 patents under application and authorized in the PRC, including 212 authorized patents; and 469 patents under application and authorized overseas, including 293 authorized patents. We had 21 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 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. To support our rapid business growth, our Venus Medtech Life and Health Industrial Park on Binpu Road, Binjiang District, Hangzhou with a planned site area of approximately 206,400 square meters is under construction, laying the solid foundation for rapid increase in production capacity in future periods.

### ***Quality system***

The Company has established an international quality management system in accordance with ISO13485, GMP of NMPA in China, QSR of FDA in the United States, MDR of EU, RDC of ANVISA in Brazil, MDSAP and other regulations and standards. As of the date of this announcement, the Company has obtained ISO13485 system certificate, MDR system certificate of EU, production licenses in China and Brazil, and is also a training base unit for medical device inspectors in Hangzhou. Leveraging the establishment and maintenance of a high-standard and strict quality management system, the Company imposes quality control on products throughout the life cycle from R&D to marketing, so as to ensure the quality of products. In 2022, despite the severe challenges from the COVID-19 pandemic, the Company accepted the MDR supervision and audit of the Notified Body through a combination of online and on-site means, and successfully passed the inspection. Meanwhile, the Company applied for the MDSAP system certification and successfully passed the online and on-site audit, and is expected to obtain the MDSAP system certificate in April 2023. In addition, the Company has also established a digital and refined quality system through proactive participating in and completing the safety intelligence supervision “black box” project of Zhejiang Medical Products Administration, the management intelligence supervision platform of Hangzhou Market Supervision Administration, and the key transcatheter replacement system for the “14th Five-year” period and other intelligence regulation projects.

### ***Commercialization***

As of December 31, 2022, we have established a sales team in China comprising nearly 260 members, covering 400 Class III hospitals, to provide a strong foundation for sustainable sales growth. The Company has established the largest sales and marketing team in the industry as well as an in-house logistics supply chain team, to provide professional and comprehensive medical solutions for doctors and patients. We took an active part in international and domestic academic conferences to carry forward our academic education and promotion efforts. During the year, we launched a total of 52 meetings under our independent five major brand conferences, involving 476 experts and a total of 240,000 viewers. Besides, we participated in more than 40 academic activities such as symposiums, live procedure broadcasts and training workshops, involving over 1,200 experts, including more than 30 online meetings with a total of 700,000 viewers. In order to improve the standardized diagnosis and treatment services for patients with AS in China, we have established a comprehensive and multi-dimensional program to publicize knowledge about valve diseases, through channels such as expert television interviews, webcasts, new media, free treatment events and educational sessions for patients. We carried out a series of tour seminars on TAVR to educate primary-level hospitals about disease treatment. By strengthening ultrasound diagnosis training, we improved the diagnostic ability of ultrasound physicians for valve diseases. Through these efforts, we aim to realize the whole-process management of patients from treatment to rehabilitation. Our independently developed VenusA-Pro was approved in China in May and VenusP-Valve was approved in China in July. As the only company in the market with three TAVR products and one TPVR product, our rich product pipeline provides physicians and patients with more and better choices of treatment, enhances the brand influence of the Company and helps to consolidate our leading position in China.

Revenue from overseas market recorded a constant rise, suggesting an improvement in our revenue structure. As of December 31, 2022, revenue from the overseas market amounted to RMB51.2 million, accounting for 12.6% of total revenue, primarily attributable to the approved marketing of VenusP-Valve in EU in April. At present, we have a professional commercialization team and supply chain in the overseas market, who sells our products to over 20 countries and regions including Germany, France and Britain. 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 the COVID-19 Pandemic***

The outbreak and spread of the COVID-19 pandemic had a significant adverse impact on global economy. During the Reporting Period, government authorities exercised strict lockdown measures to control the spread of COVID-19. China's epidemic controls had a significant negative impact on patient visits and educational activities of physicians, and hence the sales volume of TAVR products.

In early December 2022, Chinese government announced 10 optimized measures against COVID-19, leading to easier restrictions and controls over the epidemic. We do not expect significant adverse impact from the COVID-19 pandemic on heart valve procedures in China in 2023, and the industry is gradually picking up.

Given the uncertainties of the pandemic, we will maintain a close eye on its progress, and take proactive countermeasures to minimize the impact from the pandemic on our business operations.

## 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 year ended December 31, 2022 was RMB406.5 million, representing a decrease of 2.3% compared to RMB415.9 million for the year ended December 31, 2021. The decrease was primarily attributable to the negative impact of COVID-19. For the year ended December 31, 2022, sales revenue from VenusA series products accounted for 88.1% of our total revenue, as compared to 97.4% for the year ended December 31, 2021.

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

Revenue	Year ended December 31, 2022		Year ended December 31, 2021	
	RMB'000	Proportion	RMB'000	Proportion
VenusA series products	358,066	88.1%	405,346	97.4%
VenusP-Valve	40,867	10.1%	—	—
Others	7,528	1.8%	10,516	2.6%
Total	<u>406,461</u>	<u>100%</u>	<u>415,862</u>	<u>100%</u>

### Cost of Sales

The cost of sales primarily consists of staff costs, raw material costs, depreciation and amortization, utility costs and others.



The Group's cost of sales for the year ended December 31, 2022 was RMB92.5 million, representing an increase of 1.1% compared to RMB91.5 million for the year ended December 31, 2021. The increase was primarily attributable to an increase in overseas transportation costs, driven by the increasing proportion of revenue from overseas regions as a result of our continuous efforts in expanding global market during the year.

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

As a result of the aforementioned factors, the gross profit of the Group decreased by 3.2% from RMB324.3 million for the year ended December 31, 2021 to RMB314.0 million for the year ended December 31, 2022. Gross profit margin is calculated as gross profit divided by revenue. The gross profit margin of the Group decreased from 78.0% for the year ended December 31, 2021 to 77.2% for the year ended December 31, 2022, primarily attributable to a slight decline in product unit price for the purpose of marketing.

### **Other Income and Gains**

The Group's other income and gains for the year ended December 31, 2022 was RMB148.0 million, representing a decrease of 51.8% compared to RMB307.1 million for the year ended December 31, 2021. The change was primarily related to fair value adjustments to the contingent consideration payable for acquisitions last year.

### **Selling and Distribution Expenses**

The Group's selling and distribution expenses for the year ended December 31, 2022 was RMB260.4 million, representing an increase of 20.5% compared to RMB216.1 million for the year ended December 31, 2021. The increase was primarily attributable to an increase in overseas market development costs, as a result of our continuous efforts in expanding global market during the year.

### **R&D Costs**

The Group's R&D costs for the year ended December 31, 2022 was RMB527.5 million, representing an increase of 104.2% compared to RMB258.3 million for the year ended December 31, 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.

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

	Year ended December 31, 2022 (RMB'000)	Year ended December 31, 2021 (RMB'000)
Staff costs	148,605	78,942
Raw material costs	96,279	38,062
R&D service expenses	68,267	32,537
Intellectual property expenses	27,907	6,189
Clinical trial expenses	55,683	54,160
Depreciation and amortization	74,783	26,810
Others	55,927	21,636
	<u>527,451</u>	<u>258,336</u>

### Administrative Expenses

The Group's administrative expenses for the year ended December 31, 2022 was RMB192.2 million, representing an increase of 49.5% compared to RMB128.6 million for the year ended December 31, 2021. The increase was primarily attributable to the increase in overseas administrative expenses and merger and acquisition expenses following the completion of acquisition of Cardiovalve during the Reporting Period.

### Other Expenses

The Group's other expenses for the year ended December 31, 2022 was RMB557.8 million, representing an increase of 43.3% as compared to RMB389.3 million for the year ended December 31, 2021. The increase was primarily attributable to the impairment losses provided for certain intangible assets and goodwill of a total of RMB416.0 million by the Company during the Reporting Period (for the year ended December 31, 2021: RMB236.1 million).

The application of TriGUARD3, the core product of Keystone, for FDA 510(k) clearance in the USA was suspended in September 2021. During the Reporting Period, profitability generated by Keystone and its subsidiaries was lower than expected, and had a negative impact on the Group's profit. Besides, the management considered that such companies would experience deterioration in performance going ahead. Therefore, the management resolved to terminate business operations in Keystone Heart Ltd. and its subsidiaries during the year. Meanwhile, in November 2022, the marketing application of TriGUARD3 filed with the China National Medical Products Administration (the "NMPA") was suspended, leading to a further decline in its value-in-use. As of December 31, 2022, the management has reassessed the significant assumptions used in testing goodwill impairment, and considered that the recoverable amount was approximate to nil, which led to a decrease in the carrying amount of goodwill of Keystone and its subsidiaries to nil.

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

The Group's impairment losses on financial assets, net, for the year ended December 31, 2022 was RMB22.0 million, representing a change of RMB18.8 million compared to the impairment losses of RMB3.2 million for the year ended December 31, 2021. The increase was primarily attributable to impairment provision of trade receivables following operation termination in Keystone Heart Ltd. and its subsidiaries during the Reporting Period.

### **Finance Costs**

The Group's finance costs for the year ended December 31, 2022 was RMB44.6 million, representing an increase of RMB42.7 million compared to RMB1.9 million for the year ended December 31, 2021. The increase was primarily attributable to the increase in interest expenses on bank borrowings during the Reporting Period.

### **Share of Loss in Investments in Associates and Joint Ventures Accounted for Using the Equity Method**

For the year ended December 31, 2022, the Group's share of loss in investments in associates and joint ventures accounted for using the equity method was RMB13.9 million, representing an increase of 18.8% from share of loss of RMB11.7 million for the year ended December 31, 2021, which was due to loss incurred in companies invested in by us during the Reporting Period.

### **Income Tax**

The Group's income tax credit for the year ended December 31, 2022 was RMB34.3 million, representing an increase of RMB28.1 million compared to the income tax credit of RMB6.2 million for the year ended December 31, 2021. The tax credit recorded during the Reporting Period was primarily attributable to the deferred tax (related to the fair value adjustment for acquisition of a subsidiary) included in profit or loss.

### **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 December 31, 2022 were RMB1,879.4 million, representing a decrease of 36.4% compared to RMB2,955.2 million for the year ended 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. 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**

The Group's total borrowings, including interest-bearing borrowings, as at December 31, 2022 were RMB796.0 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 December 31, 2022 was 24.8% (December 31, 2021: 1.5%).

### **Net Current Assets**

The Group's net current assets, as at December 31, 2022 were RMB1,976.9 million, representing a decrease of 38.8% 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**

As at December 31, 2022, 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 of the Acquisition, 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 year ended December 31, 2022, the Group's total capital expenditure amounted to approximately RMB1,090.4 million, which was used in (i) increase in the amount paid related to investment in a joint venture; (ii) the amount paid related to acquisition of a subsidiary; (iii) purchase of items of property, plant and equipment; (iv) purchase of financial assets at fair value through profit or loss; and (v) purchase of other intangible assets.

## Charge on Assets

Certain of the Group's loans amounted to RMB695.9 million were secured by mortgages or pledges over our assets. The mortgaged or pledged assets include leasehold land and term deposits of certain subsidiaries.

## Contingent Liabilities

As at December 31, 2022, except for the contingent consideration payables recognised for acquisition of subsidiaries, we did not have any contingent liabilities.

## Subsequent Events

On March 28, 2023, Hangzhou Qihao Equity Investment Co., Ltd. (杭州啓皓股權投資有限公司) (an indirect wholly-owned subsidiary of the Company), Hangzhou Broncus Medical Co., Ltd. (杭州堃博生物科技有限公司), and Hangzhou Linzhuo Industrial Fund Co., Ltd. (杭州臨卓產業基金有限公司), each as a limited partner, and Hangzhou Yingzhiqin Private Equity Management Co., Ltd. (杭州盈智勤私募基金管理有限公司), as a general partner, entered into a partnership agreement for the establishment of Hangzhou Yingzhiqin I Equity Investment Partnership (Limited Partnership)(杭州盈智勤壹號股權投資合夥企業(有限合夥)) to jointly participate in the investment therein, pursuant to which Hangzhou Broncus Medical Co., Ltd. (杭州堃博生物科技有限公司) agreed to subscribe for RMB125 million, which represent approximately 24.75% of the total capital contribution to Hangzhou Yingzhiqin I Equity Investment Partnership (Limited Partnership)(杭州盈智勤壹號股權投資合夥企業(有限合夥)), whereas, Hangzhou Qihao Equity Investment Co., Ltd.\* (杭州啓皓股權投資有限公司) agreed to subscribe for RMB125 million, which represent approximately 24.75% of the total capital contribution to Hangzhou Yingzhiqin I Equity Investment Partnership (Limited Partnership)(杭州盈智勤壹號股權投資合夥企業(有限合夥)). For details of this transaction, please refer to the announcement made by the Company on March 29, 2023.

## **Employees and Remuneration Policies**

As of December 31, 2022, we had 1,028 employees in total.

Among the 1,028 employees, 871 of our employees are stationed in China, and 157 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**

Committed to our vision of becoming a global leader in interventional therapy for structural heart diseases, we upheld the long-term strategies of “pursuing globalization and generating profitability” in 2022, expedited the promotion and clinical application of our innovative technologies in the global markets, established globally competitive business operation teams leveraging the marketing of our innovative products such as VenusP-Valve, and secured strong sales performance. In the domestic market, we focused on seeking profitability to drive our quality development, and facilitated our innovative products to achieve breakthroughs in clinical trials, registration and market access, in a bid to lay the foundation for our sustainable and steady growth.

### **Accelerate Globalization Pace**

Following the approved marketing and sales of VenusP-Valve in the EU, we will constantly establish and improve the international manufacture capabilities and quality system, aiming to lay a solid foundation for launching domestically-produced devices in the global market. Cardiovalve, our innovative device, has witnessed increasing penetration in global clinical applications, and attracted a number of experienced professionals to join clinical trials. Venus-PowerX and Venus-Vitae, a new generation of aortic valve products, have achieved smooth progress in global clinical trials, and are highly recognized by doctors. The Company has been pressing ahead with its globalization strategy. Meanwhile, we will launch the confirmatory clinical study of VenusP-Valve in the USA and Japan, and enhance our overseas clinical development and innovative device registration capabilities, endeavoring to establish presence in more countries and markets. In terms of commercialization, we will make unremitting efforts to promote the global sales of VenusP-Valve, and expect to enter in more than 50 countries and regions during the year, and strive for strong and sustainable sales increase. In terms of market access, we will comply with local laws and regulations, learn about access policies of different countries and regions, endeavor to make breakthroughs in medical insurance, bidding and hospital access procedures, and continue to venture into the international market. We will also proactively participate in international medical conferences and industry exhibitions in the field of cardiology, facilitate doctors to obtain an understanding of and get familiar with our products, so as to enhance our global brand influence.

## **Maintain Quality Marketing Growth**

In recent years, COVID-19 has had an on-going negative impact on the number of domestic heart valve interventional procedures. As present, the industry is exposed to the critical challenges of enhancing the commercial profitability of TAVR procedures and promoting sustainable and quality development. 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 surgeries the number of procedures in mid-to-high-end hospitals, develop 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.

Looking into 2023, we will remain committed to the unmet medical needs, uphold our globalization strategy with a focus on the field of structural heart diseases, leverage our first-mover advantages, expedite sales and marketing in the global market, facilitate the progress of international multi-center clinical study, and increase the number of surgeries with our products in domestic mid-to-high-end hospitals, in an endeavor to improve our profitability.

## **CORPORATE GOVERNANCE AND OTHER INFORMATION**

### **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. During the year ended December 31, 2022, the Company has strictly complied with the provisions of the Corporate Governance Code.

### **Compliance with the Model Code**

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 set out in Appendix 10 to the Listing Rules. The Company has made specific enquiries to all Directors and Supervisors concerning their compliance with the Model Code. All Directors and Supervisors confirmed that they had strictly observed all standards set out in our Company's code of conduct regarding Directors' and Supervisors' securities transactions during the year ended December 31, 2022.

The Company's employees, who are likely to be in possession of inside information of the Company, have also been subject to the code of conduct regarding Directors' and Supervisors' securities transactions of the Company. No incident of non-compliance of code of conduct regarding Directors' and Supervisors' securities transactions by the employees was noted by the Company during the year ended December 31, 2022.

### **Purchase, Sale or Redemption of Listed Securities**

There was no purchase, sale and redemption of any listed securities of the Company by the Company or any of its subsidiaries during the year ended December 31, 2022.

## 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 exercise of the initial global offering and the over-allotment option).

For the year ended December 31, 2022, the Company has used (i) RMB716.50 million for payment of expenses incurred by the core products of the Company; (ii) RMB712.74 million for payment of expenses incurred by other product candidates of the Company; (iii) RMB383.40 million to finance internal research and development or potential acquisition for the purpose complementing our product portfolio; and (iv) RMB255.80 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 December 31, 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 annual 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 aggregated of 18,500,000 new H Shares taken place 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 December 31, 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 December 31, 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 annual 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 December 31, 2022, the Company has used (i) RMB296.43 million for Expanded Development and Research; (ii) RMB49.6 million for Investments; and (iii) RMB214.63 million for General Working Capital. The Board expects that the unutilized proceeds allocated to Expanded Development and Research to be used by December 31, 2023 and the unutilized proceeds allocated to 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 annual report of the Company to be published in due course.



## **Audit Committee**

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

The Audit Committee has considered and reviewed the accounting principles and practices adopted by the Company and the Group and discussed matters in relation to internal control and financial reporting with the management. The Audit Committee considers that the annual financial results for the year ended 31 December 2022 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

## **Auditor**

The financial information set out in this announcement does not constitute the Group’s audited accounts for the year ended December 31, 2022, but represents an extract from the consolidated financial statements for the year ended December 31, 2022 which have been audited by the auditor of the Company, Ernst & Young, in accordance with Hong Kong Standards on Auditing issued by the Hong Kong Institute of Certified Public Accountants.

## **FINAL DIVIDEND**

The Board has resolved not to recommend the payment of a final dividend for the year ended December 31, 2022 (2021: Nil).

## **ANNUAL GENERAL MEETING**

A circular containing more details of the 2022 annual general meeting including closure of register of members and record date will be despatched to the Shareholders in due course.

## **FURTHER ANNOUNCEMENTS**

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)).

The annual report for the year ended December 31, 2022 of the Company containing all the information required by the Listing Rules will be despatched to the Shareholders and published on the websites of the Stock Exchange and the Company in due course.

## DEFINITIONS

“ABOSOPATH”	third generation catheter sheath
“AS”	aortic stenosis
“Audit Committee”	the audit committee of the Board
“Board”	the board of directors of the Company
“Cardiovalve”	Cardiovalve Ltd. (formerly known as Mitraltech Ltd.), a private company incorporated under the laws of Israel, which is a wholly-owned subsidiary of the Target Company
“CE Marking”	a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area
“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
“Closing”	the closing of the Share Purchase in accordance with the terms and conditions of the Share Purchase Agreement
“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)
“Company-Owned Equity”	the 799,443 Series C Preferred Shares that the Company currently indirectly holds through its wholly-owned subsidiary, Keystone
“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
“CSRC”	the China Securities Regulatory Commission

“Director(s)”	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”	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
“H Share Registrar”	Computershare Hong Kong Investor Services Limited
“HCM”	hypertrophic cardiomyopathy
“Healium”	Healium Medical Ltd, a high- tech company in Israeli
“HK\$”	Hong Kong dollars, the lawful currency of Hong Kong
“HOCM”	hypertrophic obstructive cardiomyopathy
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“IASB”	the International Accounting Standards Board
“IFRS”	International Financial Reporting Standards
“Keystone”	Keystone Heart Ltd. (a wholly owned subsidiary of the Company which as of the date of this announcement, owns 799,433 Series C Preferred Shares of the Target Company) and its subsidiaries
“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

“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 to the Listing Rules
“NL”	the Netherland
“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”	the principal investigator
“Purchaser”	Athena Medtech Holding Ltd, a private company incorporated under the laws of Israel and wholly-owned by Venus HK, which is in turn wholly-owned by the Company
“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
“Renaly”	Renaly Ltd, a 51% owned subsidiary established by the Company and Healium
“Reporting Period”	the one-year period from January 1, 2022 to December 31, 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 pulmonic artery
“RVOTD”	the dysfunction of RVOT
“Selling Shareholders’ Representative”	MTH Shareholder Representative LLC, a Delaware limited liability company
“Series C Preferred Shares”	the Series C preferred shares of the Target Company
“Share Purchase”	the purchase of all of the issued and outstanding shares of the Target Company (other than the Company-Owned Equity) by the Purchaser from the Target Company Selling Shareholders, pursuant to the terms and conditions of the Share Purchase Agreement

“Share Purchase Agreement”	the Share Purchase Agreement, dated as of December 7, 2022, entered into among the Company, the Purchaser, the Target Company, the Target Company Selling Shareholders and the Selling Shareholders’ Representative
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“Supervisor(s)”	member(s) of the supervisory committee of the Company
“Target Company”	Mitraltech Holdings Ltd., a private company incorporated under the laws of Israel
“Target Company Selling Shareholders”	the existing shareholders of the Target Company, other than Keystone
“TAV0”	TAV0 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 openchest 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 pulmonic stenosis, an opening in the interventricular septum, malposition of the aorta over both ventricles, and hypertrophy of the right ventricle
“TPVR”	transcatheter pulmonic valve replacement, a catheter-based technique to implant a new pulmonic valve in a minimally invasive procedure that does not involve open-chest surgery
“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
“UK”	the United Kingdom
“U.S.” or “the USA”	the United States of America, its territories and possessions, any state of the United States and the District of Columbia

“V8”	V8, one of our balloon transluminal aortic valvuloplasty catheter system products
“Venus HK”	Venus Medtech (Hong Kong) Limited, a company incorporated in Hong Kong and a wholly-owned subsidiary of the Company
“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-Pro”	VenusA-Pro System, one of our TAVR products
“VenusA series”	VenusA-Valve, VenusA-Plus and VenusA-Pro
“VenusA-Valve”	VenusA-Valve System, one of our TAVR products
“VenusP-Valve”	VenusP-Valve System, our TPVR product candidate

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

Hong Kong, March 31, 2023

*As at the date of this announcement, the executive Directors are Mr. Min Frank Zeng, Mr. Zhenjun Zi and Ms. Meirong Liu; the non-executive Director is Mr. Ao Zhang; and the independent non-executive Directors are Mr. Ting Yuk Anthony Wu, Mr. Wan Yee Joseph Lau and Mr. Chi Wai Suen.*