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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, 2023**

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, 2023, together with comparative figures for the same period of 2022.

FINANCIAL HIGHLIGHTS

| | Six months ended June 30, 2023 (Unaudited) RMB'000 | Six months ended June 30, 2022 (Unaudited) RMB'000 | Period-to-period change |
|--|---|---|------------------------------------|
| Revenue | 255,610 | 209,965 | 21.7% |
| Gross profit | 201,249 | 164,175 | 22.6% |
| Loss before tax | (370,339) | (246,406) | 50.3% |
| Loss for the period | (366,215) | (239,668) | 52.8% |
| Loss attributable to owners of the parent | (350,188) | (199,933) | 75.2% |
| Loss per Share attributable to ordinary equity holders of the parent | | | |
| Basic and diluted | RMB(0.80) | RMB(0.46) | 73.9% |

INTERIM RESULTS

The Board is pleased to announce the unaudited condensed consolidated results of the Group for the six months ended June 30, 2023, as follows:

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

For the six months ended 30 June 2023

| | | 2023 | 2022 |
|--|--------------|-------------------------|-------------------------|
| | | (Unaudited) | (Unaudited) |
| | <i>Notes</i> | RMB'000 | RMB'000 |
| REVENUE | 4 | 255,610 | 209,965 |
| Cost of sales | | <u>(54,361)</u> | <u>(45,790)</u> |
| Gross profit | | 201,249 | 164,175 |
| Other income and gains | | 33,077 | 62,448 |
| Selling and distribution expenses | | (157,911) | (123,357) |
| Research and development costs | | (294,715) | (220,316) |
| Administrative expenses | | (77,893) | (54,746) |
| Other expenses | | (26,341) | (38,022) |
| Finance costs | | (31,185) | (18,400) |
| Impairment losses on financial assets, net | | (9,656) | (3,595) |
| Share of losses of: | | | |
| A joint venture | | (1,083) | (2,498) |
| Associates | | (5,881) | (12,095) |
| LOSS BEFORE TAX | 5 | (370,339) | (246,406) |
| Income tax credit | 6 | <u>4,124</u> | <u>6,738</u> |
| LOSS FOR THE PERIOD | | <u>(366,215)</u> | <u>(239,668)</u> |

| | <i>Note</i> | 2023 (Unaudited) RMB'000 | 2022 (Unaudited) RMB'000 |
|--|-------------|---|--------------------------------|
| OTHER COMPREHENSIVE INCOME/(LOSS) | | | |
| Other comprehensive income that may be reclassified to profit or loss in subsequent periods: | | | |
| Exchange differences on translation of foreign operations | | <u>56,146</u> | <u>70,987</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 |
| Income tax effect | | <u>–</u> | <u>(30)</u> |
| Net other comprehensive income that will not be reclassified to profit or loss in subsequent periods | | <u>–</u> | <u>4,458</u> |
| OTHER COMPREHENSIVE INCOME FOR THE PERIOD, NET OF TAX | | <u>56,146</u> | <u>75,445</u> |
| TOTAL COMPREHENSIVE LOSS FOR THE PERIOD | | <u>(310,069)</u> | <u>(164,223)</u> |
| Loss attributable to: | | | |
| Owners of the parent | | <u>(350,188)</u> | <u>(199,933)</u> |
| Non-controlling interests | | <u>(16,027)</u> | <u>(39,735)</u> |
| | | <u>(366,215)</u> | <u>(239,668)</u> |
| Total comprehensive loss attributable to: | | | |
| Owners of the parent | | <u>(295,344)</u> | <u>(125,312)</u> |
| Non-controlling interests | | <u>(14,725)</u> | <u>(38,911)</u> |
| | | <u>(310,069)</u> | <u>(164,223)</u> |
| LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT | | | |
| Basic and diluted | 8 | <u>RMB(0.80)</u> | <u>RMB(0.46)</u> |

INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

30 June 2023

| | | 30 June 2023 (Unaudited) RMB'000 | 31 December 2022 (Audited) RMB'000 |
|---|--------------|--|--|
| | <i>Notes</i> | | |
| NON-CURRENT ASSETS | | | |
| Property, plant and equipment | | 363,461 | 318,139 |
| Right-of-use assets | | 132,283 | 143,144 |
| Goodwill | | 1,276,312 | 1,238,535 |
| Other intangible assets | | 600,553 | 611,171 |
| Investment in a joint venture | | 5,314 | 2,728 |
| Investments in associates | | 66,786 | 70,283 |
| Deferred tax assets | | 13,554 | 9,941 |
| Equity investments designated at fair value through other comprehensive income | | 16,338 | 15,747 |
| Financial assets at fair value through profit or loss | | 414,448 | 388,322 |
| Prepayments, other receivables and other assets | | 4,301 | 15,855 |
| Total non-current assets | | 2,893,350 | 2,813,865 |
| CURRENT ASSETS | | | |
| Inventories | | 117,808 | 104,396 |
| Trade receivables | 9 | 401,622 | 303,388 |
| Prepayments, other receivables and other assets | | 128,428 | 119,868 |
| Due from directors | | – | 34,400 |
| Pledged deposits | | 5,204 | 27,487 |
| Cash and cash equivalents | | 1,453,165 | 1,879,431 |
| Total current assets | | 2,106,227 | 2,468,970 |
| CURRENT LIABILITIES | | | |
| Trade payables | 10 | 24,564 | 9,126 |
| Lease liabilities | | 23,181 | 23,457 |
| Other payables and accruals | | 253,009 | 227,590 |
| Interest-bearing bank borrowings | | 328,566 | 222,603 |
| Government grants | | 1,730 | 1,370 |
| Contract liabilities | | 2,215 | 2,952 |
| Tax payable | | 6 | 5,006 |
| Total current liabilities | | 633,271 | 492,104 |
| NET CURRENT ASSETS | | 1,472,956 | 1,976,866 |
| TOTAL ASSETS LESS CURRENT LIABILITIES | | 4,366,306 | 4,790,731 |

| | 30 June 2023 (Unaudited) RMB'000 | 31 December 2022 (Audited) RMB'000 |
|--|---|--|
| NON-CURRENT LIABILITIES | | |
| Interest-bearing bank borrowings | 450,115 | 573,379 |
| Other payables and accruals | 506,427 | 487,826 |
| Lease liabilities | 70,937 | 80,204 |
| Deferred tax liabilities | 16,035 | 17,411 |
| Government grants | 1,550 | 600 |
| | <hr/> | <hr/> |
| Total non-current liabilities | 1,045,064 | 1,159,420 |
| | <hr/> | <hr/> |
| Net assets | 3,321,242 | 3,631,311 |
| | <hr/> <hr/> | <hr/> <hr/> |
| EQUITY | | |
| Equity attributable to owners of the parent | | |
| Share capital | 441,012 | 441,012 |
| Reserves | 2,871,508 | 3,166,852 |
| | <hr/> | <hr/> |
| | 3,312,520 | 3,607,864 |
| | <hr/> | <hr/> |
| Non-controlling interests | 8,722 | 23,447 |
| | <hr/> | <hr/> |
| Total equity | 3,321,242 | 3,631,311 |
| | <hr/> <hr/> | <hr/> <hr/> |

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 2023, 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 2023 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 2022.

3. CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The International Accounting Standards Board has issued a number of amendments to International Financial Reporting Standards (“**IFRSs**”) that are first effective for the current accounting period of the Group. None of these developments have had a material effect on how the Group’s results and financial position for the current or prior periods have been prepared or presented in the interim financial report. IFRSs comprise International Financial Reporting Standards, IASs and Interpretations. The Group has not applied any new IFRSs that is not yet effective for the current accounting period. The directors of the Company (the “**Directors**”) anticipated that the application of these new IFRSs will have no material impact on the interim financial report.

4. REVENUE

An analysis of revenue is as follows:

| | For the six months ended 30 June | |
|--|----------------------------------|----------------|
| | 2023 | 2022 |
| | (Unaudited) | (Unaudited) |
| | RMB’000 | RMB’000 |
| <i>Revenue from contracts with customers</i> | | |
| Sale of medical devices | <u>255,610</u> | <u>209,965</u> |

Disaggregated revenue information for revenue from contracts with customers

| | For the six months ended 30 June | |
|---|----------------------------------|----------------|
| | 2023 | 2022 |
| | (Unaudited) | (Unaudited) |
| | RMB’000 | RMB’000 |
| Geographical markets | | |
| Mainland China | 233,118 | 195,940 |
| Other countries/regions | <u>22,492</u> | <u>14,025</u> |
| Total revenue from contracts with customers | <u>255,610</u> | <u>209,965</u> |
| Timing of revenue recognition | | |
| Goods transferred at a point in time | <u>255,610</u> | <u>209,965</u> |

5. LOSS BEFORE TAX

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

| | For the six months ended 30 June | |
|---|----------------------------------|--------------------------------|
| | 2023 (Unaudited) RMB'000 | 2022 (Unaudited) RMB'000 |
| Cost of inventories sold | 52,975 | 44,082 |
| Impairment of trade receivables | 9,029 | 3,582 |
| Impairment of other receivables | 627 | 13 |
| Reversal of write-down of inventories to net realisable value | (467) | (2,227) |
| Loss on disposal of items of property, plant and equipment, net | 205 | 453 |
| Foreign exchange differences, net | (1,677) | (46,820) |

6. INCOME TAX CREDIT

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 24 December 2022 and was entitled to a preferential tax rate of 15% (2022: 15%).

Israel

Pursuant to the relevant tax laws of Israel, the corporate income tax was levied at 23% (2022: 23%) on the taxable income arising in Israel.

USA

Pursuant to the relevant tax laws of the USA, federal corporation income tax was levied at the rate of 21% (2022: 21%) on the taxable income arising in the USA.

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% (2022: 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 19% (2022: up to 15%) on the taxable income arising in the NL.

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

| | For the six months ended 30 June | |
|-----------------------|---|--------------------------------------|
| | 2023 | 2022 |
| | (Unaudited) RMB'000 | (Unaudited) RMB'000 |
| Current tax – PRC | | |
| Charge for the period | 1 | 65 |
| Current tax – Israel | | |
| Charge for the period | – | 23 |
| Current tax – USA | | |
| Charge for the period | – | 1 |
| Current tax – UK | | |
| Charge for the period | – | – |
| Current tax – NL | | |
| Charge for the period | 413 | – |
| Deferred tax | <u>(4,538)</u> | <u>(6,827)</u> |
| | <u>(4,124)</u> | <u>(6,738)</u> |

7. DIVIDEND

The Board does not recommend the payment of any dividend in respect for the six months ended 30 June 2023 (six months ended 30 June 2022: 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 437,897,443 (six months ended 30 June 2022: 436,986,462) in issue during the period.

The Group had no potentially dilutive ordinary shares in issue during the six months ended 30 June 2023 (six months ended 30 June 2022: Nil).

The calculation of basic loss per share is based on:

| | For the six months ended 30 June | |
|--|---|--------------------------------------|
| | 2023 | 2022 |
| | (Unaudited) RMB'000 | (Unaudited) RMB'000 |
| Loss | | |
| Loss attributable to ordinary equity holders of the parent | <u>350,188</u> | <u>199,933</u> |
| | | |
| | Number of shares | |
| | For the six months ended 30 June | |
| | 2023 | 2022 |
| | (Unaudited) | (Unaudited) |
| Shares | | |
| Weighted average number of shares in issue during the period | <u>437,897,443</u> | <u>436,986,462</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:

| | 30 June 2023 (Unaudited) RMB'000 | 31 December 2022 (Audited) RMB'000 |
|-----------------|---|--|
| Within 6 months | 248,708 | 164,808 |
| 7 to 12 months | 63,860 | 83,811 |
| 1 to 2 years | 83,602 | 54,429 |
| Over 2 years | 5,452 | 340 |
| | <u>401,622</u> | <u>303,388</u> |

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:

| | 30 June 2023 (Unaudited) RMB'000 | 31 December 2022 (Audited) RMB'000 |
|-----------------|---|--|
| Within 3 months | 23,696 | 8,980 |
| 3 to 6 months | 765 | 50 |
| 6 to 12 months | 47 | 65 |
| Over 12 months | 56 | 31 |
| | <u>24,564</u> | <u>9,126</u> |

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 integrate 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 diseases including the 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.

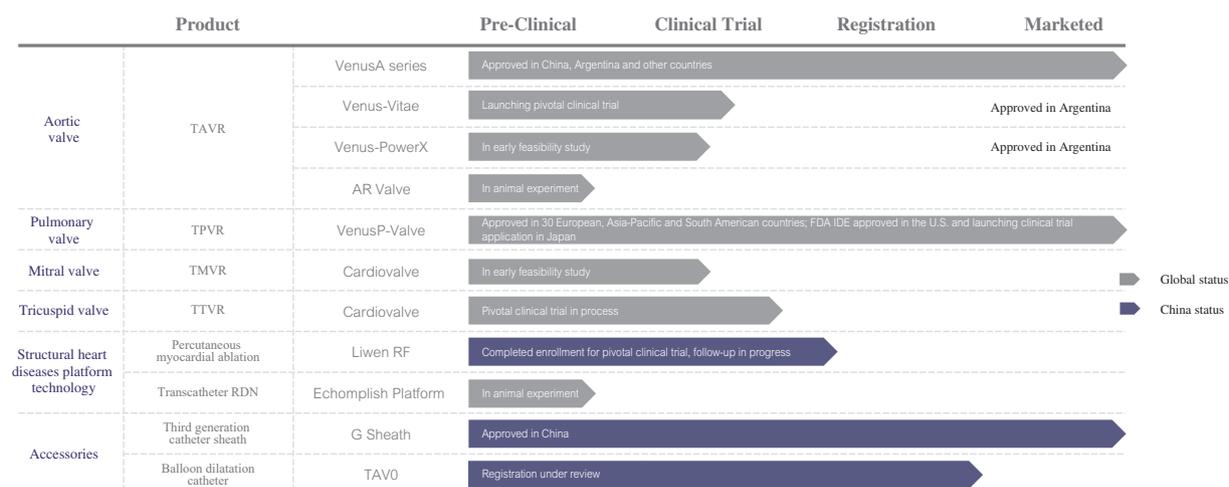
For the six months ended June 30, 2023 and up to the date of this announcement, the Company has achieved constant business progress and smooth globalization with a commitment to its long-standing strategic goals. During the Reporting Period, VenusP-Valve, which is our first independently developed product marketed in Europe and also the first self-expanding TPVR product approved in Europe, continued to benefit from our improving overseas channels for commercialization to enter 30 countries including the United Kingdom, Italy, Spain, Denmark, Greece, France, Germany, Poland and Switzerland, and has been included into medical insurance systems in countries such as Germany. In July 2023, VenusP-Valve was approved by the FDA for IDE application, allowing pivotal clinical trial to be conducted, thus becoming the first Chinese-made heart valve product approved for clinical study in the United States. Meanwhile, we continued to accelerate international multi-centered patient enrollment in pivotal clinical trial of Cardiovalve. 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 our core therapeutic area. We have commercialized three TAVR products, one TPVR product and one procedural accessory. Our products currently in clinical trials include next-generation TAVR products (Venus-Vitae and Venus-PowerX), one innovative medical device Cardiovalve which can be used for both TMVR and TTVR, and one product currently under animal experiment for the treatment of aortic regurgitation. Besides, we have two procedural accessories, launched catheter sheath product (G Sheath) and one balloon dilation catheter currently in the registration (TAV0), which are mainly used by physicians to facilitate TAVR procedures. For treatment of HCM, we have developed the world's first 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 approval for registration from the NMPA in April 2017, which marked the first NMPA approved TAVR commercialized product in China. VenusA-Plus received approval for registration 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 upgraded 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 for registration 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 21st Chinese Interventional Cardiology (CIT 2023), the eight-year follow-up results of VenusA-Valve were released. An 11-year follow-up has been completed for the first patient. The long track record of ultrasound data indicated consistently sound and stable metrics including peak valve velocity, average valve pressure difference and left ventricular ejection fraction. Furthermore, approximately 80% of the subjects had no or only minimal aortic regurgitation, fully validating the long-term safety and efficacy of VenusA-Valve. At the 9th China Valve (Hangzhou) Conference, the three-year follow-up results of VenusA-Plus were released. According to the results, there was no new case of cardiac death, and the subgroup results showed that VenusA-Plus achieved a good effect for patients with bicuspid aortic valve and tricuspid aortic valve demonstrating the sound clinical safety, efficacy and operability of VenusA-Plus. Chinese TAVR patients are characterized by a high proportion of bicuspid aortic valve and severe calcification of valve leaflets, while VenusA series products with strong radial force are particularly suitable for patients with severe bicuspid aortic valve.

For the six months ended June 30, 2023, sales revenue from VenusA series products was RMB229.8 million, representing an increase of 16.9% from RMB196.6 million for the six months ended June 30, 2022.

VenusP-Valve – TPVR Product

VenusP-Valve, our independently developed transcatheter pulmonary valve system, obtained 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.

VenusP-Valve was approved for registration 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 been marketed in over one-fifth of the countries along the “Belt and Road” initiative, and has entered in 30 countries and regions including Britain, Italy, Spain, Denmark, Greece, France, Germany, Poland and Switzerland. Leveraging its professional and efficient overseas marketing team, the Company achieved strong sales performance for VenusP-Valve.

VenusP-Valve is highly recognized among experts and physicians worldwide because of excellent long-term safety and effectiveness. The three-year follow-up data of VenusP-Valve showed that the procedure 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 trivial or less perivalvular leak and 95.38% subjects had mild or less tricuspid regurgitation; and the proportion of subjects of New York Heart Association (NYHA) classification Class III decreased significantly 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 five-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.

Currently, we are expediting PROTEUS pivotal clinical trials on VenusP-Valve in the United States and Japan. In July 2023, we obtained approval from the FDA for IDE application. We will initiate clinical trials at over ten centers simultaneously in the U.S. and Japan through the Japan-US Harmonization By Doing project, with a total of 60 patients estimated to be enrolled.

For the six months ended June 30, 2023, the sales revenue of VenusP-Valve was RMB25.2 million, representing an increase of RMB16.1 million from RMB9.1 million for the six months ended June 30, 2022.

Venus-Vitae – New Generation TAVR Product

Venus-Vitae, our self-developed new generation TAVR system, the first balloon-expandable dry tissue product, is about to enter SMART-ALIGN global pivotal clinical trials.

Venus-Vitae adopted Venus-Endura dry tissue technology, which leverages advanced anti-calcification technology to improve the durability of the valve, and three-dimensional force controlled dehydration technology without glutaraldehyde for preservation. 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 wire-lock technology, thus locking the valve during transporting and balloon expanding. The wire-lock technology, steerable 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 adaptive active anti-PVL Seadapt skirt with high compression ratio, self-expansion and high resilience, which can adjust its height adaptively to fill the perivalvular space and promote the combination of vascular tissue and skirt. In December 2022, Venus-Vitae was approved for registration in Argentina. We will conduct international multi-centered clinical trials in countries and regions such as Europe and Canada, to expedite the approval of Venus-Vitae in global market.

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

Venus-PowerX – New Generation TAVR Product

Venus-PowerX, our self-developed new generation TAVR system, the world's first self-expanding dry tissue product, is currently under early feasibility study stage and is about to enter global pivotal clinical trials.

Venus-PowerX is the new generation pre-loaded dry tissue valve product. It adopts the Venus-Endura technology, which leverages advanced anti-calcification technology to improve the durability of the valve, and three-dimensional force controlled dehydration technology without glutaraldehyde for preservation. 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 releasable and 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 adaptive active anti-PVL Seadapt skirt with high compression ratio, self-expansion and high resilience, which can adjust its height adaptively to fill the perivalvular space and promote the combination of vascular tissue and skirt. In May 2023, Venus-PowerX was approved for registration in Argentina. We will conduct international multi-centered clinical trials in countries and regions such as Europe, to expedite the approval of Venus-PowerX in global market.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET VENUS-POWERX 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 stage for mitral regurgitation and in pivotal clinical trial for the treatment of patients with tricuspid regurgitation.

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 of Cardiovalve has been going smoothly. The TARGET CE pivotal clinical trials, since started by Cardiovalve in November 2022, have extended to more than 20 centers in Germany, Italy and Canada. As at August 31, 2023, rapid progress has been made with over 40 patients enrolled. We will carry forward the clinical trials of Cardiovalve, to seek earlier approvals for marketing in global market.

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

Liwen RF – Ablation System

Nuocheng Medical, a wholly-owned subsidiary of the Company, has independently developed Liwen RF ablation system, an innovative medical device for treatment of patients with HOCM. In March 2023, we completed the enrollment of all patients to pivotal clinical trial for Liwen RF, and entered the follow-up stage in China. As of July 25, 2023, among the current follow-up comprising 79 patients after six months from the procedure, the success rate reaches 86.1% (68/79), representing a significant improvement compared to alcohol ablation. As for the clinical endpoint, the maximum ventricular septal thickness decreased from 23.36 mm to an average of 17.23 mm (26.2% lower than that before the procedure), and the post-procedure pressure gradient of the left ventricular outflow tract in resting state decreased from 72.86 mmHg to 22.44 mmHg (69.2% 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 gains 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.

According to the 144 previously completed exploratory clinical trial of Liwen RF ablation system, the success rate with Liwen RF ablation system reached 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 NMPA for innovative medical devices and was admitted to the special review process.

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

RDN ablation system

The Company established Renaly, a joint venture with Healium, an Israeli high-tech company to introduce the new generation RDN innovative device. 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.

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 terms of aortic valves, the Company's new generation of dry tissue TAVR products, Venus-Vitae and Venus-PowerX, 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 extend presence to overseas countries, 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, witnessed remarkable progress in clinical trials.

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 Medtech 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.

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 six months ended June 30, 2023 and 2022, our R&D expenses were RMB294.7 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 August 31, 2023 the Company had a total of 896 patents and patents under applications, including 397 authorized invention patents. We had 373 patents under application and authorized in the PRC, including 235 authorized patents; and 492 patents under application and authorized overseas, including 314 authorized patents. We had 31 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 square meters 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, ISO/IEC17025 and other regulations and standards. As of the date of this announcement, the Company has obtained ISO13485 system certificate, MDR system certificate of EU, MDSAP quality system certificate (covering the regulatory requirements of quality systems of the United States, Japan, Canada, Australia and Brazil), China production license, Brazil BGMPC certificate, CNAS laboratory accreditation certificate, 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. We obtained the MDSAP system certificate in May for the first time. 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 June 30, 2023, we have established a sales team in China comprising nearly 260 members, covering more than 420 Class III hospitals, to provide a strong foundation for sustainable sales growth. The Company has established a professional sales and marketing team 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. In order to improve the standardized diagnosis and treatment services for patients with AS in China, we have established a multi-dimensional program to publicize knowledge about valve diseases, through multiple channels such as co-holding of 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. 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.

We have established a professional commercialization team and supply chain in the overseas market, selling our products to 30 countries and regions including Germany, France and the United Kingdom. In August 2023, we appointed Shakeel Osman as the head of international congenital heart disease business for steering our pulmonary valve operations in the world (except mainland China), as a part of our efforts to improve our overseas marketing system and expedite overseas commercialization. In terms of digital channel, we further enriched the global marketing strategies and methods through product launches, online seminars, online training and other activities, and continued 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 physicians and hospitals through distributors to continuously expand sales and our brand influence.

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 continue 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, 2023 was RMB255.6 million, representing an increase of 21.7% compared to RMB210.0 million for the six months ended June 30, 2022. The increase was primarily attributable to continuous marketing promotion of VenusA series products and enhanced penetration of VenusP-Valve in the overseas market during the Reporting Period. For the six months ended June 30, 2023, revenue from sales of VenusA series products accounted for 89.9% of our total revenue, as compared to 93.7% for the six months ended June 30, 2022.

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

| Revenue | Six months ended June 30, 2023 (Unaudited) | | Six months ended June 30, 2022 (Unaudited) | |
|------------------------|---|-------------|---|-------------|
| | RMB'000 | Proportion | RMB'000 | Proportion |
| VenusA series products | 229,802 | 89.9% | 196,573 | 93.7% |
| VenusP-Valve | 25,194 | 9.9% | 9,110 | 4.3% |
| Others | 614 | 0.2% | 4,282 | 2.0% |
| Total | <u>255,610</u> | <u>100%</u> | <u>209,965</u> | <u>100%</u> |

Cost of Sales

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 six months ended June 30, 2023 was RMB54.4 million, representing an increase of 18.8% compared to RMB45.8 million for the six months ended June 30, 2022. The increase was in line with the change in sales revenue for the same period of 2023.

Gross Profit and Gross Profit Margin

As a result of the aforementioned factors, the gross profit of the Group increased by 22.5% from RMB164.2 million for the six months ended June 30, 2022 to RMB201.2 million for the six months ended June 30, 2023. Gross profit margin is calculated as gross profit divided by revenue. For the six months ended June 30, 2022 and 2023, the Group's gross profit margin was 78.2% and 78.7%, respectively.

Other Income and Gains

The Group's other income and gains for the six months ended June 30, 2023 was RMB33.1 million, representing a decrease of 47.0% compared to RMB62.4 million for the six months ended June 30, 2022, primarily attributable to a decrease in foreign exchange gains.

Selling and Distribution Expenses

The Group's selling and distribution expenses for the six months ended June 30, 2023 was RMB157.9 million, representing an increase of 28.0% compared to RMB123.4 million for the six months ended June 30, 2022. The increase was mainly due to increase in promotional activities in the overseas market.

R&D Costs

The Group's R&D costs for the six months ended June 30, 2023 was RMB294.7 million, representing an increase of 33.8% compared to RMB220.3 million for the six months ended June 30, 2022, primarily attributable to increase in R&D investment with the progress of R&D projects.

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

| | Six months ended June 30, 2023 (Unaudited) RMB'000 | Six months ended June 30, 2022 (Unaudited) RMB'000 |
|--------------------------------|---|--|
| Staff cost | 84,094 | 71,468 |
| Raw material cost | 54,488 | 33,804 |
| R&D service expenses | 48,909 | 18,503 |
| Intellectual property expenses | 9,214 | 10,457 |
| Clinical trial expenses | 27,793 | 18,855 |
| Depreciation and amortization | 35,265 | 42,916 |
| Others | 34,952 | 24,313 |
| | 294,715 | 220,316 |

Administrative Expenses

The Group's administrative expenses for the six months ended June 30, 2023 was RMB77.9 million, representing an increase of 42.4% compared to RMB54.7 million for the six months ended June 30, 2022. The increase was primarily attributable to an increase in professional fees, utilities and office expenses to accommodate our business growth.

Other Expenses

The Group's other expenses for the six months ended June 30, 2023 was RMB26.3 million, representing a decrease of 30.8% compared to RMB38.0 million for the six months ended June 30, 2022. The decrease was primarily due to a decrease in donations during the Reporting Period.

Impairment of Goodwill and Intangible Assets

The Group did not record impairment on goodwill and intangible assets for the six months ended June 30, 2023.

Finance Costs

The Group's finance costs for the six months ended June 30, 2023 was RMB31.2 million, representing an increase of RMB12.8 million compared to RMB18.4 million for the six months ended June 30, 2022. The increase was primarily attributable to the impact of fluctuations in floating rates.

Impairment Losses on Financial Assets, Net

The Group's impairment losses on financial assets, net, for the six months ended June 30, 2023 was RMB9.7 million, representing an increase of RMB6.1 million compared to RMB3.6 million for the six months ended June 30, 2022, primarily attributable to an increase in trade receivables resulting from our enhanced marketing efforts, and increase in ageing of certain trade receivables, leading to an increase in impairment allowance provided on trade receivables.

Share of Losses of Associates and Joint Ventures Accounted for under the Equity Method

The Group's share of losses of associates and joint ventures accounted for under the equity method for the six months ended June 30, 2023 was RMB7.0 million, representing a decrease of 52% from RMB14.6 million for the six months ended June 30, 2022, primarily attributable to changes in losses recorded by our investees during the Reporting Period.

Income Tax

The Group's income tax credit for the six months ended June 30, 2023 was RMB4.1 million, as compared to income tax expense of RMB6.7 million for the six months ended June 30, 2022. The tax credit for the Reporting Period was primarily attributable to deferred tax recognized in profit or loss relating to fair value adjustment on acquisition of a subsidiary.

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, 2023 were RMB1,453.2 million, representing a decrease of 22.7% compared to RMB1,879.4 million as at December 31, 2022. The decrease was primarily attributable to an increase in R&D and operating expenses incurred.

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

As at June 30, 2023, the Group's total interest-bearing bank borrowings were RMB778.7 million (December 31, 2022: RMB796.0 million). All of the Group's bank borrowings carry interest at floating rates. For a breakdown of the borrowings of the Group, please refer to the 2023 interim report of the Company to be published in due course.

The gearing ratio (calculated by dividing the sum of borrowings and lease liabilities by total equity) of the Group as at June 30, 2023 was 26.3% (December 31, 2022: 24.8%).

Net Current Assets

The Group's net current assets, as at June 30, 2023, were RMB1,473.0 million, representing a decrease of 25.5% compared to net current assets of RMB1,976.9 million as at December 31, 2022.

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

During the Reporting Period, we did not have any material acquisitions or disposals of subsidiaries, associates and joint ventures of the Company.

Capital Expenditure

For the six months ended June 30, 2023, the Group's total capital expenditure amounted to approximately RMB96.0 million, which was used for (i) payment for additional investment in a joint venture; (ii) purchase of financial assets at fair value through profit or loss; (iii) purchase of items of property, plant and equipment; and (iv) purchase of other intangible assets.

Indebtedness and Charge on Assets

Certain of the Group's loans amounted to RMB648.9 million (December 31, 2022: RMB695.9 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.

Saved as disclosed above, (i) the Company had no bank loans, convertible loans and borrowings nor did the Company issue any bonds; and (ii) there was no other pledge of the Group's assets as at June 30, 2023.

Contingent Liabilities

As at June 30, 2023, except for the contingent consideration payable for acquisition of a subsidiary, we did not have any contingent liabilities.

Employees and Remuneration Policies

As of June 30, 2023, we had 1,006 employees in total.

Among the 1,006 employees, 862 of our employees are stationed in China, and 144 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 have upheld the long-term strategies of “global localization and localized profit generation”, 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 focus on seeking profitability to drive our quality development, and facilitate our innovative products to achieve breakthroughs in clinical trials, registration review 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 pivotal 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

We will continue to tap into our first-mover advantages, strengthen the construction and integration of our own marketing system, provide comprehensive intraoperative solutions for clinical hospitals with our rich professional knowledge, clinical resources and perfect product portfolio, reduce the difficulty of surgery with constantly optimized products, serve physicians and a wider range of patients, and improve the commercial profit of TAVR business through scale effect and optimization of business processes. 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 the second half of 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

Interim Dividend

The Board does not recommend the payment of interim dividend for the six months ended June 30, 2023 to the shareholders (six months ended June 30, 2022: 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, 2023, the Company has used (i) RMB742.38 million for payment of expenses incurred by the core products of the Company; (ii) RMB714.05 million for payment of expenses incurred by other product candidates of the Company; (iii) RMB383.40 million to finance internal research and development and/or potential acquisition for the purpose of complementing our product portfolio; and (iv) RMB255.80 million* for replenishment of working capital and other general corporate purposes.

Saved as disclosed above, the Company intends to use the net proceeds that had not been utilized as of June 30, 2023 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 2023 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, 2023, 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, 2023, 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 2023 interim report of the Company to be published in due course.

*Note**

The amount of unutilized proceeds for payment of considerations and other transaction expenses related to acquisition of Keystone Heart Ltd. (“**Keystone**”) represents the amount of certain contingent milestone payment of consideration related to the acquisition of Keystone. As part of the share purchase agreement of Keystone, contingent consideration is payable depending on the occurrence of certain milestone events for TriGUARD3, which includes, among others, authorization and clearance by the FDA to market and sell TriGUARD3 in the U.S. Given the marketing application of TriGUARD3, which was contemplated under the share purchase agreement of Keystone and filed with the FDA, has been suspended in September 2021, the Board is of the opinion that such contingent consideration was no longer payable according to the share purchase agreement.

The Company is considering the reallocation of the amount of unutilized proceeds for this purpose of RMB255.8 million to other purposes, and will make announcement on any change in use of proceeds of such use as appropriate 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, 2023, the Company has used (i) RMB401.68 million for Expanded Development and Research; (ii) RMB49.60 million for Investments; and (iii) RMB221.82 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, 2023. 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 2023 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, 2023.

Subsequent Events

The Company is not aware of any material subsequent events from June 30, 2023 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, 2023.

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, 2023.

Compliance with the Corporate Governance Code

Deviation from Code Provision D.1.2 of the Corporate Governance Code

Under Code Provision D.1.2 of the Corporate Governance Code (the “**CG Code**”), management should provide all members of the board with monthly updates giving a balanced and understandable assessment of the issuer’s performance, position and prospects in sufficient detail to enable the board as a whole and each director to discharge their duties under Rule 3.08 and Chapter 13 of the Listing Rules.

During the relevant financial reporting period of the Financial Reports and the Results Announcements, since the finance department of the Company did not fully understand the requirement under Code Provision D.1.2 of Appendix 14 to the Listing Rules, such financial statements (despite being compiled and consolidated on a monthly basis at the material time) were not provided for review by the Board every month. Without being able to review such information on a monthly basis, the Board did not receive “a balanced and understandable assessment of the issuer’s performance, position and prospects” to the extent necessary for compliance with the requirements in Code Provision D.1.2 of Appendix 14 to the Listing Rules.

The Directors recognized the importance of monthly updates to enable the Board as a whole and each Director to discharge their duties under Rule 3.08 and Chapter 13 of the Listing Rules. As remedial measures, the Company has:

- (i) conducted training on the relevant obligations under the Listing Rules for its directors, senior management, supervisors and personnel of the Group;
- (ii) established a whistle blowing policy as disclosed in the section headed “(ii) Insufficient understanding of the Listing Rules” of the announcement dated August 4, 2023; and
- (iii) since June 2023, in light of the recommendations given under the Internal Control Review, provided to all members of the Board the financial statements on a monthly basis to reflect the financial position and business performance of the Group, in order to enable the Directors to receive sufficiently detailed information to give a balanced and understandable assessment of the performance of the Group, and discharge their respective duties under Rule 3.08 and Chapter 13 of the Listing Rules in accordance with Code Provision D.1.2 of Appendix 14 to the Listing Rules.

Saved as disclosed above and in the announcement dated August 4, 2023 in relation to the deviation from Code Provision D.1.2 of 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.

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, 2023. The Audit Committee considers that the interim financial results for the six months ended June 30, 2023 are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

Publication of Interim Results Announcement and Interim Report

This announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (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 |
| “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 |
| “Directors” | the director(s) of the Company |
| “EU” | the European Union |
| “FDA” | U.S. Food and Drug Administration |
| “FIM” | First In Man |

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| “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 |
| “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, 2023 to June 30, 2023 |

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| “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 a transannular 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 |
| “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 |

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| “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, one of our TAVR product |
| “VenusP-Valve” | VenusP-Valve System, one of our TPVR product |

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

Hangzhou, August 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.