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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, 2021**

The Board of Venus Medtech (Hangzhou) Inc. is pleased to announce the unaudited consolidated interim results of the Company and its subsidiaries for the six months ended June 30, 2021, together with comparative figures for the same period of 2020.

FINANCIAL HIGHLIGHTS

	Six months ended June 30, 2021 (Unaudited) RMB'000	Six months ended June 30, 2020 (Unaudited) RMB'000	Period-to-period change
Revenue	239,269	102,049	134%
Gross Profit	188,088	85,087	121%
Loss before tax	(117,211)	(43,529)	169%
Loss for the period	(117,215)	(43,538)	169%
Loss attributable to owners of the parent	(113,063)	(43,524)	160%
Loss per Share attributable to ordinary equity holders of the parent			
Basic and diluted	RMB(0.26)	RMB(0.11)	136%

INTERIM RESULTS

The Board is pleased to announcement the unaudited condensed consolidated results of the Group for the six months ended June 30, 2021, as follows:

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

For the six months ended June 30, 2021

		2021	2020
	<i>Notes</i>	(Unaudited)	(Unaudited)
		RMB'000	RMB'000
REVENUE	4	239,269	102,049
Cost of sales		<u>(51,181)</u>	<u>(16,962)</u>
Gross profit		188,088	85,087
Other income and gains		34,877	50,067
Selling and distribution expenses		(99,050)	(47,215)
Research and development costs		(104,328)	(67,607)
Administrative expenses		(44,792)	(39,155)
Other expenses		(81,304)	(20,418)
Finance costs		(984)	(3,074)
Impairment losses on financial assets, net		(3,195)	(949)
Share of losses of associates		<u>(6,523)</u>	<u>(265)</u>
LOSS BEFORE TAX	5	(117,211)	(43,529)
Income tax expense	6	<u>(4)</u>	<u>(9)</u>
LOSS FOR THE PERIOD		<u>(117,215)</u>	<u>(43,538)</u>

		2021	2020
		(Unaudited)	(Unaudited)
	<i>Note</i>	RMB'000	RMB'000
OTHER COMPREHENSIVE (LOSS)/INCOME			
Other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign operations		<u>(8,452)</u>	<u>7,602</u>
Other comprehensive (loss)/income that will not be reclassified to profit or loss in subsequent periods:			
Equity investments at fair value through other comprehensive income:			
Changes in fair value		<u>(116)</u>	<u>440</u>
OTHER COMPREHENSIVE (LOSS)/INCOME FOR THE PERIOD, NET OF TAX		<u>(8,568)</u>	<u>8,042</u>
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD		<u>(125,783)</u>	<u>(35,496)</u>
Loss attributable to:			
Owners of the parent		(113,063)	(43,524)
Non-controlling interests		<u>(4,152)</u>	<u>(14)</u>
		<u>(117,215)</u>	<u>(43,538)</u>
Total comprehensive loss attributable to:			
Owners of the parent		(121,631)	(35,482)
Non-controlling interests		<u>(4,152)</u>	<u>(14)</u>
		<u>(125,783)</u>	<u>(35,496)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted	8	<u>RMB(0.26)</u>	<u>RMB(0.11)</u>

INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

June 30, 2021

	<i>Notes</i>	June 30, 2021 (Unaudited) RMB'000	December 31, 2020 (Audited) RMB'000
NON-CURRENT ASSETS			
Property, plant and equipment		105,597	100,005
Goodwill		482,497	487,317
Other intangible assets		227,971	233,004
Investment in associates		82,408	37,995
Deferred tax assets		297	1,156
Equity investments designated at fair value through other comprehensive income		12,920	6,525
Financial assets at fair value through profit or loss		144,583	64,473
Prepayments, other receivables and other assets		33,578	27,319
Total non-current assets		1,089,851	957,794
CURRENT ASSETS			
Inventories		66,249	59,904
Trade receivables	9	341,881	231,031
Prepayments, other receivables and other assets		63,860	34,984
Due from related parties		–	22,500
Financial assets at fair value through profit or loss		–	44,128
Pledged deposits		252,757	259,716
Cash and cash equivalents		3,579,774	2,708,170
Total current assets		4,304,521	3,360,433
CURRENT LIABILITIES			
Trade payables	10	7,714	5,295
Lease liabilities		13,763	11,092
Other payables and accruals		361,624	358,487
Government grants		14,993	14,046
Contract liabilities		2,756	2,442
Refund liabilities		21,230	14,155
Total current liabilities		422,080	405,517

	June 30, 2021 (Unaudited) RMB'000	December 31, 2020 (Audited) RMB'000
NET CURRENT ASSETS	<u>3,882,441</u>	<u>2,954,916</u>
TOTAL ASSETS LESS CURRENT LIABILITIES	<u>4,972,292</u>	<u>3,912,710</u>
NON-CURRENT LIABILITIES		
Lease liabilities	18,053	21,671
Deferred tax liabilities	31,655	32,942
Government grants	<u>–</u>	<u>1,062</u>
Total non-current liabilities	<u>49,708</u>	<u>55,675</u>
Net assets	<u><u>4,922,584</u></u>	<u><u>3,857,035</u></u>
EQUITY		
Equity attributable to owners of the parent		
Share capital	441,012	422,969
Reserves	<u>4,444,113</u>	<u>3,392,455</u>
	4,885,125	3,815,424
Non-controlling interests	<u>37,459</u>	<u>41,611</u>
Total equity	<u><u>4,922,584</u></u>	<u><u>3,857,035</u></u>

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

1. CORPORATE INFORMATION

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

During the six months ended June 30, 2021, the Company and its subsidiaries (the “**Group**”) were principally engaged in 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 December 10, 2019.

2. BASIS OF PREPARATION

The interim condensed consolidated financial information for the six months ended June 30, 2021 has been prepared in accordance with International Accounting Standard (“**IAS**”) 34 *Interim Financial Reporting* issued by the International Accounting Standards Board. 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 December 31, 2020.

3. CHANGES IN ACCOUNTING POLICIES

The accounting policies adopted in the preparation of the interim condensed consolidated financial information are consistent with those applied in the preparation of the Group’s annual consolidated financial statements for the year ended December 31, 2020, except for the adoption of the following revised International Financial Reporting Standards (“**IFRSs**”) for the first time for the current period’s financial information.

Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 74 and IFRS 16	<i>Interest Rate Benchmark Reform – Phase 2</i>
Amendments to IFRS 16	<i>Covid-19-Related Rent Concessions beyond 30 June 2021 (early adopted)</i>

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

- (a) Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 address issues not dealt with in the previous amendments which affect financial reporting when an existing interest rate benchmark is replaced with an alternative risk-free rate (“**RFR**”). The phase 2 amendments provide a practical expedient to allow the effective interest rate to be updated without adjusting the carrying amount of financial assets and liabilities when accounting for changes in the basis for determining the contractual cash flows of financial assets and liabilities, if the change is a direct consequence of the interest rate benchmark reform and the new basis for determining the contractual cash flows is economically equivalent to the previous basis immediately preceding the change. In addition, the amendments permit changes required by the interest rate benchmark reform to be made to hedge designations and hedge documentation without the hedging relationship being discontinued. Any gains or losses that could arise on transition are dealt with through the normal requirements of IFRS 9 to measure and recognise hedge ineffectiveness. The amendments also provide a temporary relief to entities from having to meet the separately identifiable requirement when an RFR is designated as a risk component. The relief allows an entity, upon designation of the hedge, to assume that the separately identifiable requirement is met, provided the entity reasonably expects the RFR risk component to become separately identifiable within the next 24 months. Furthermore, the amendments require an entity to disclose additional information to enable users of financial statements to understand the effect of interest rate benchmark reform on an entity’s financial instruments and risk management strategy.

The amendments did not have any impact on the financial position and performance of the Group.

- (b) Amendment to IFRS 16 issued in March 2021 extends the availability of the practical expedient for lessees to elect not to apply lease modification accounting for rent concessions arising as a direct consequence of the covid-19 pandemic by 12 months. Accordingly, the practical expedient applies to rent concessions for which any reduction in lease payments affects only payments originally due on or before 30 June 2022, provided the other conditions for applying the practical expedient are met. The amendment is effective retrospectively for annual periods beginning on or after 1 April 2021 with any cumulative effect of initially applying the amendment recognised as an adjustment to the opening balance of retained profits at the beginning of the current accounting period. Earlier application is permitted.

The Group has early adopted the amendment on 1 January 2021 and the amendment did not have any impact on the financial position and performance of the Group.

4. REVENUE

An analysis of revenue is as follows:

	For the six months ended June 30,	
	2021	2020
	(Unaudited)	(Unaudited)
	RMB'000	RMB'000
<i>Revenue from contracts with customers</i>		
Sale of medical devices	<u>239,269</u>	<u>102,049</u>

Disaggregated revenue information for revenue from contracts with customers

	For the six months ended June 30,	
	2021	2020
	(Unaudited)	(Unaudited)
	RMB'000	RMB'000
Geographical markets		
Mainland China	233,688	101,617
Other countries/regions	<u>5,581</u>	<u>432</u>
Total revenue from contracts with customers	<u>239,269</u>	<u>102,049</u>
Timing of revenue recognition		
Goods transferred at a point in time	<u>239,269</u>	<u>102,049</u>

5. LOSS BEFORE TAX

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

	For the six months ended June 30,	
	2021	2020
	(Unaudited)	(Unaudited)
	RMB'000	RMB'000
Cost of inventories sold	48,794	16,211
Impairment of trade receivables	3,154	869
Impairment of other receivables	41	80
Write-down of inventories to net realisable value	731	1,655
Loss on disposal of items of property, plant and equipment, net	8	556
Foreign exchange differences, net	<u>17,662</u>	<u>(20,861)</u>

6. INCOME TAX EXPENSE

PRC

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “CIT Law”), the subsidiaries which operate in Mainland China are subject to CIT at a rate of 25% on the taxable income. Preferential tax treatment is available to the Company, since it was recognised as High and New Technology Enterprises as at December 4, 2019 and was entitled to a preferential tax rate of 15% (2020: 15%).

USA

Pursuant to the relevant tax laws of the USA, federal corporation income tax was levied at the rate of 21% (2020: 21%) on the taxable income arising in the USA.

Israel

Pursuant to the relevant tax laws of Israel, the corporate income tax was levied at 23% (2020: 23%) on the taxable income arising in Israel.

United Kingdom (“UK”)

Pursuant to the relevant tax laws of the UK, the principal federal tax was levied at the rate of up to 19% (2020: up to 19%) on the taxable income arising in the UK.

Netherlands (“NL”)

Pursuant to the relevant tax laws of the NL, the corporate income tax was levied at the rate of up to 25% (2020: up to 25%) on the taxable income arising in the NL during the period.

The income tax expense of the Group during the period is analysed as follows:

	For the six months ended June 30,	
	2021	2020
	(Unaudited)	(Unaudited)
	RMB'000	RMB'000
Current tax – PRC		
Charge for the period	1,125	–
Current tax – USA		
Charge for the period	14	929
Current tax – Israel		
Charge for the period	–	239
Current tax – UK		
Charge for the period	7	42
Current tax – NL		
Charge for the period	87	–
Deferred tax	(1,229)	(1,201)
	4	9

7. DIVIDEND

The Board does not recommend the payment of any dividend in respect for the six months ended June 30, 2021 (six months ended June 30, 2020: 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 438,220,338 (six months ended June 30, 2020: 403,416,478) in issue during the period.

The Group had no potentially dilutive ordinary shares in issue during the six months ended June 30, 2021 (six months ended June 30, 2020: Nil).

The calculation of basic loss per share is based on:

	For the six months ended June 30, 2021 (Unaudited) RMB'000	2020 (Unaudited) RMB'000
Loss		
Loss attributable to ordinary equity holders of the parent	<u>113,063</u>	<u>43,524</u>
	Number of shares	
	For the six months ended June 30, 2021 (Unaudited)	2020 (Unaudited)
Shares		
Weighted average number of shares in issue during the period	<u>438,220,338</u>	<u>403,416,478</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:

	June 30, 2021 (Unaudited) RMB'000	December 31, 2020 (Audited) RMB'000
Within 6 months	237,617	180,606
7 to 12 months	71,191	39,658
Over 12 months	<u>33,073</u>	<u>10,767</u>
	<u>341,881</u>	<u>231,031</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:

	June 30, 2021 (Unaudited) RMB'000	December 31, 2020 (Audited) RMB'000
Within 3 months	7,425	4,034
3 to 6 months	147	375
6 to 12 months	32	815
Over 12 months	<u>110</u>	<u>71</u>
	<u>7,714</u>	<u>5,295</u>

MANAGEMENT DISCUSSION AND ANALYSIS

I. BUSINESS OVERVIEW

Overview

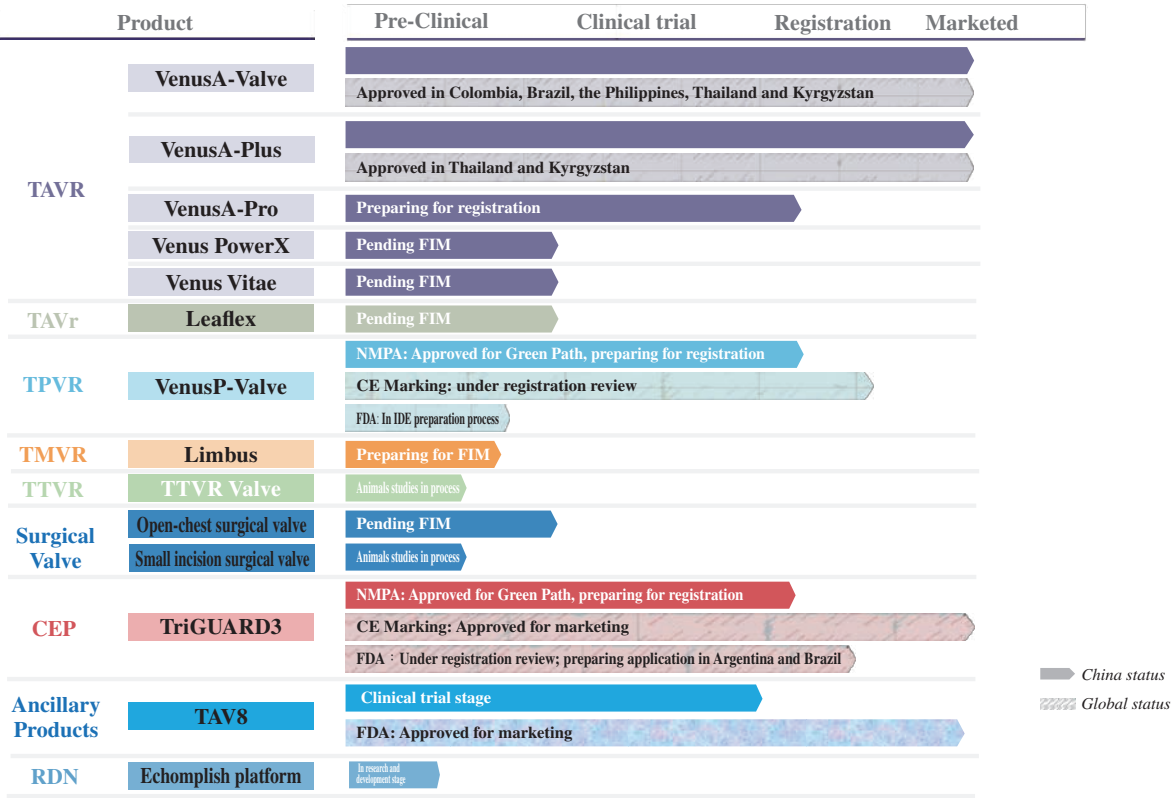
We are a global high-end innovative medical device manufacturer committed to developing and commercializing high-quality medical devices that benefit patients. Founded in 2009, the Company has built a global R&D system and established a platform integrating R&D, clinical development, manufacturing and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

We strive to become a world leading service provider of integrated solutions for structural heart disease, and focus on the innovation, R&D, manufacturing and commercialization of high-end innovative interventional medical devices, covers the entire pipeline for aortic valve, pulmonary valve, mitral valve and tricuspid valve as well as hypertrophic cardiomyopathy, hypertensive renal artery denervation ablation and surgical accessory products. We will focus on the fields of new materials, bionics, image fusion technology and digital sensing in terms of our future medical technology portfolio, and leverage constant innovations to cover the entire therapeutic process of patients, so as to meet the large needs of doctors and patients.

Our Products and Product Pipeline

Our products consist of ten internally developed devices, including two marketed TAVR products (VenusA-Valve and VenusA-Plus), one TAVR product in registration stage (VenusA-Pro), two TAVR products in pre-clinical stage (Venus Vitae and Venus PowerX), one TPVR product in registration stage (VenusP-Valve), one TMVR product in pre-clinical stage (Limbus), one TTVR product in design stage and two surgical valves in pre-clinical stage. In addition to internally developed products, we also offer key ancillary products compatible with transcatheter heart valve replacement procedures, including the marketed valvuloplasty balloon products (V8 and TAV8) and the marketed cerebral embolic protection (CEP) device (TriGUARD3). We also offer one aortic valve repair device in pre-clinical stage (Leaflex) and one renal artery denervation (RDN) product in pre-clinical stage.

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



VenusA-Valve – Our Core Product

As a leader in TAVR technologies in China, we focus on the R&D, manufacturing and commercialization of transcatheter aortic heart valves and their respective delivery systems. We currently have two products on the market, VenusA-Valve and VenusA-Plus. VenusA-Valve is our first-generation TAVR device, which is used to treat severe aortic stenosis (“AS”) using a transcatheter approach. VenusA-Valve received marketing approval from the NMPA in April 2017, which marked the first NMPA approved TAVR product in China. Moreover, VenusA-Valve was successfully registered in Southeast Asia including Philippines and Thailand, and Latin America including Colombia and Brazil. It was registered in Kyrgyzstan in Central Asia in June 2021.

VenusA-Valve, as the TAVR product with the largest market share in China, has accumulated abundant clinical follow-up data to verify its safety and effectiveness. It has been implanted into over 6,000 patients in clinical operations so far, and is the only TAVR product with long-term safety verification for more than five years in China. The six-year follow-up results of VenusA-Valve clinical study released at CIT Conference in May 2021 showed that the all-cause mortality of patients with VenusA-Valve was 36.4%, and the cardiac mortality rate was only 11.4%.

VenusA-Valve has been used to treat patients with severe AS. Since August 2019, TAVR has been approved by the FDA to be used in server AS patients at low-risk for surgery. The White Paper of China Structural Heart Disease Industry 2020 listed medium to high-risk surgeries as the absolute indication of TAVR, and the low-risk surgeries as the relative indication of TAVR. It is expected that a growing number of patients with AS will receive TAVR treatment in the future, which enjoys broad market prospects.

VenusA-Plus – Our Core Product

VenusA-Plus is an upgraded product based on VenusA-Valve. VenusA-Plus was approved by NMPA for marketing in November 2020, which is the first retrievable TAVR product 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 cycle of surgeons. VenusA-Plus was successfully registered in Thailand in December 2020 and in Kyrgyzstan in June 2021.

At the 7th China Valve (Hangzhou) Conference in July 2021, the one-year clinical follow-up data of VenusA-Plus was released, which showed that compared with the previous 30-day clinical data, there was only one more all-cause death case, and no cardiac death case, demonstrating its good prognosis safety. Follow-up results also showed that patients with either tricuspid valve or bicuspid valve diseases did not experience aortic regurgitation or experienced trace regurgitation one year after the surgery, which accentuated the long-term effect.

As of June 30, 2021, the total number of implants of VenusA-Valve and VenusA-Plus in hospitals reached approximately 1,900, and the number of terminal hospitals using VenusA-Valve and VenusA-Plus was approximately 300, of which the number of hospitals using VenusA-Plus was nearly 100, and the percentage of procedures with VenusA-Plus accounted for more than 20%.

For the six months ended June 30, 2021, sales revenue from VenusA-Valve and VenusA-Plus was RMB234.7 million, representing an increase of 131.0% from RMB101.6 million for the six months ended June 30, 2020.

VenusP-Valve – Our Core Product

VenusP-Valve is a TPVR system, which is used to treat patients with RVOTD after undergoing TAP treatment. We have completed the clinical trials of VenusP-Valve in the EU and China. In April 2019, VenusP-Valve was approved by the NMPA to be eligible for the Special Approval Procedures of Innovative Medical Devices promulgated by the NMPA. We submitted the application for the CE Marking in April 2019, completed on-site inspection by the EU in May 2021 and will submit marketing application in China soon. Once launched, VenusP-Valve is expected to be the first self-expanding TPVR product in the EU, and the first large-sized TPVR product for patients with RVOTD after receiving TAP treatment globally. On March 22, 2021, VenusP-Valve has obtained the special use from the Medicines & Healthcare Products Regulatory Agency in the United Kingdom (the “UK”) and can be used in designated medical institutions, which means that VenusP-Valve has entered the UK market before obtaining the CE Marking.

Compared with marketed overseas TPVR products, VenusP-Valve has a wider range of specifications, which is not only suitable for patients implanted with artificial vascular channel, but also for patients with RVOTD undergoing transannular patching without the use of stents and expansion balloons. It can meet the needs of more than 85% of patients.

VenusP-Valve has been used in clinical operations for eight years since 2013, with clinical trials on 55 patients completed in China and clinical trials on 83 patients completed in Europe. No complications such as annulus rupture, coronary artery compression, valve embolism and valve dislocation were found immediately after procedures. The average follow-up period of all subjects was three years, and the longest follow-up period reached seven years. In general, VenusP-Valve maintained good valve function and shows sound safety, effectiveness and steerability. In addition, there are nearly 200 cases of clinical use for humanitarian reasons in 50 medical centers across 20 countries or regions, covering Asia, Europe, North America and South America.

WE MAY NOT BE ABLE TO ULTIMATELY MARKET VENUSP-VALVE SUCCESSFULLY.

Venus PowerX Valve

Venus PowerX Valve product in pre-clinical stage is the third generation self-expanding dry tissue TAVR device for treating AS. The animal experiment of Venus PowerX Valve has been completed, and it is expected to progress into the clinical trial stage in China in the first half of 2022.

Venus PowerX Valve is currently the only 100% retrievable valve in the world with the world's first active anti-paravalvular leak technology. Such technology is based on its proprietary expandable polymer, which will not cause problems such as increased delivery size triggered by physical skirt or skirt damage from retrieving valve, and effectively resist paravalvular leak. In addition, the unique preloaded dry tissue technology and anti-calcification technology increase the durability of the valve. With smaller size and one third less in height than the second generation products, it is equipped with the precise positioning and steerable performance. We will conduct clinical trials of Venus PowerX Valve in international markets such as Europe and the U.S., and promote the approval of Venus PowerX Valve for marketing in the global market.

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

Venus Vitae Valve

The Venus Vitae Valve product in the pre-clinical stage is the third generation of dry valve balloon expansion TAVR device, which is used to treat severe AS. At present, we have completed the animal experiment of Venus Vitae Valve, and expect to commence clinical trials in the second half of 2021.

Venus Vitae Valve adopts wire-controlled balloon expansion technology, which makes the release more stable and safer. The design of Supra-Annular Prosthesis provides larger opening area compared with the middle of the annulus flap and is therefore advantaged in treating patients with bicuspid aortic valve diseases. It uses dry tissue technology and anti-calcification technology to increase valve durability. With adjustable bending delivery system, it is more steerable. We will conduct clinical trials of Venus Vitae Valve in international markets such as Europe and the U.S., and promote the approval of Venus Vitae Valve for marketing in the global market.

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

Limbus

Limbus is a product in clinical preparation stage for TMVR procedures for patients with mitral regurgitation (“MR”), which comprises two generations products. LimBus1 is a TMVR product implanted transapical with an intra-annular bi-leaflet design bovine pericardial tissue, and is close to the original mitral valve structure of human body in design. LimBus2 is applied in the special new valve anchoring technology of Opus Medical Therapiest introduced in May 2020, and implanted trans-septal to improve safety and effectiveness.

MR is the most prevalent heart valve disease in the world. At present, TMVR therapies have developed slower than interventional repair technology worldwide, but TMVR may offer some theoretical advantages over transcatheter repair. The development of a complete TMVR device to target all anatomic variations, TMVR could offer a more predictable decrease in MR severity, in a procedure that could potentially be less invasive compared with surgery.

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

Venus Tricuspid Valve

We are designing Venus Tricuspid Valve, a product for TTVR treatment for patients with tricuspid regurgitation (“TR”).

TR is a common heart valve disease. Transcatheter intervention of tricuspid valve provides a new treatment option for patients at prohibitive or high surgical risk. Compared with transcatheter tricuspid valve repair, TTVR is applicable to a wider range of patients and can effectively reduce regurgitation. At present, the Company has several TTVR devices in the pre-clinical or early clinical trial stage.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET VENUS TRICUSPID VALVE SUCCESSFULLY.

Surgical Valve

The surgical valve products we designed are surgical valve replacement products for patients with AS and regurgitation. The surgical valve adopts dry tissue technology and uses bovine pericardium tissue. It leverages anti-calcification technology to improve valve durability without cold chain transportation. At present, there are two surgical valves in pipeline. One is the open-chest surgical valve. Compared with existing marketed products, it improves hydrodynamic performance, increases effective opening area, reduces pressure difference across valves, and adopts valve-in-valve design, which provides more possibilities for future treatment of patients. It is expected to commence clinical trials in the second half of 2021. The other is the small incision surgical valve which is implanted through the median or intercostal small incision, thus contributing to quick recovery, and causing less trauma and less injury to patients. At present, it is undergoing animal study.

In September 2020, the Company and Jilin Changchun Haoyue Halal Meat Industry Co., Ltd. established a subsidiary, Venus Haoyue Medtech Limited which opened up the upstream bovine pericardium supply chain and to develop surgical valves and related products to further upgrade heart valve disease treatment.

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

CEP device – TriGUARD3

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

TriGUARD3 obtained the CE Marking from the EU on March 4, 2020, and completed the first clinical application in the PRC on January 15, 2021. It completed the first commercial application in Asia-Pacific region in Hong Kong, the PRC on March 14, 2021 and its registered clinical trials were initiated in the General Hospital of Northern Theater Command on April 28, 2021 and completed the first patient enrollment. The 510(K) clearance application in the U.S. is currently under review.

For the six months ended June 30, 2021, the sales revenue of TriGUARD3 was RMB4.2 million (for the six months ended June 30, 2020: Nil).

Aortic Valve Repair – Leaflex

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

Leaflex can be used not only for young patients who may be too young for TAVR, but also for future value-in-valve procedures of aortic valve after TAVR implantation, so as to provide lifetime management of AS at a lower cost than replacement. In September 2020, we completed the cooperative transaction with Pi-Cardia, and introduced Leaflex products into the Chinese market, and proposed to commence clinical trials in the second half of 2021. Pi-cardia has commenced clinical trials in Europe.

WE MAY NOT BE ABLE TO ULTIMATELY MARKET LEAFLEX SUCCESSFULLY.

Renal artery denervation (“RDN”) product

RDN addresses uncontrolled hypertension by reducing the drive of the sympathetic nervous system, which is central to blood pressure. It is a minimally invasive procedure that regulates the output of sympathetic nerves outside the renal artery walls. On June 30, 2021, the Company established Renaly Ltd. (“**Renaly**”), a joint venture with Israeli high-tech company Healium Medical Ltd, to introduce a new generation RDN innovative system of Healium Medical Ltd. (“**Healium**”), and to research and develop, manufacture and commercialize it globally.

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 principal investigator (PI) of the product.

In the field of RDN, Professor Martin and his team have served as the PI in clinical trials for several innovative systems including Medtronic’s Symplicity Spyral Renal Denervation System and ReCor Medical’s Paradise Ultrasonic Denervation System, both of which were awarded Breakthrough Device Designation by the FDA in 2020.

R&D innovation

The Company primarily adopts an independent R&D model and has established a global R&D innovation platform. Our three R&D centers are located in Hangzhou, the PRC, Caesarea, Israel and California, the U.S., and are consisted of talents with rich professional experience and innovative capability. The Company continues to be granted awards and be included in national key projects for its R&D efforts. For example, in April 2021, the key materials of a minimally invasive self-expanding and interventional pulmonary valve system won the first prize of Technical Invention Award in 2020 Scientific Research Outstanding Achievement Award of Higher Institutions (Science and Technology). In June 2021, the national key R&D project “Development and Application of Transcatheter Interventional Self-expandable Pulmonary Valve Replacement System” was officially launched.

The Company not only possesses strong in-house R&D capabilities, but also constantly enriches and improves its product pipeline through cooperation with innovative device companies and academic institutions, striving to keep abreast with structural heart disease technologies. The Global Advisory Board (comprising Professor Ziyad M Hijazi, Professor Martin B. Leon, Professor Horst Sievert and Professor Ron Waksman) consists of world-renowned experts in cardiovascular and structural heart disease interventional therapy, who offers regular insightful opinions and suggestions on the Company's R&D activities and global commercialization of products, so as to promote the Company's technological innovation and global layout of products. On April 16, 2021, the Company held an Investor Open Day, and invited top experts in cardiovascular field at home and abroad, such as Professor Martin B. Leon, Professor Scott Lim and Professor Ziyad Hijazi, to interpret in-depth the Company's product development, pipeline progress and international commercial layout.

For the six months ended June 30, 2020 and 2021, our R&D expenses were RMB67.6 million and RMB104.3 million, respectively.

Intellectual Properties

The Company attaches great importance to intellectual property protection. Leveraging its strong R&D capability, as of June 30, 2021, the Company had a total of 503 patents and patents under applications, including 204 authorized invention patents. We had 218 patents under application and authorized in the PRC, including 135 issued patents; and 266 patents under application and authorized overseas, including 150 authorized patents. We had 19 PCT applications. Our global IP portfolio mainly covers China, the U.S., Europe, Japan, Canada, Russia, India, Brazil and other countries.

External business development

The Company continues to improve its in-house R&D capability through establishment of a strong internal R&D team, and meanwhile it also proactively seeks to establish partnership with the world's leading innovative device companies and academic institutions to gain access to the world's leading technologies and high-value products, expand the Company's product layout and enrich product pipelines.

On January 28, 2021, the Company reached cooperation with Endoluminal Sciences Pty Ltd. ("**Endoluminal Sciences**"), the global leader in transcatheter solutions for structural heart disease, and introduced its active anti-paravalvular leak technology into China and applied to the Company's new generation of valve products.

On May 6, 2021, the Company invested in the innovative medical device company Valgen Holding Corporation. With such investment, the Company will strengthen its mitral valve repair and tricuspid valve repair product pipeline, and further improve its strategic layout in the field of structural heart disease treatment.

On June 30, 2021, the Company established a joint venture, Renaly, with Israeli high-tech company, Healium, which focuses on the R&D of ultrasonic treatment and imaging capabilities, to introduce the new generation of innovative devices for RDN from Healium, and conduct R&D, production and commercialization of RDN products worldwide. Renaly, the joint venture, will be controlled by the Company. Professor Martin B. Leon and his team served as the global PI of the project.

Manufacturing

We have an approximately 3,500 sq.m. facility in Hangzhou and an approximately 816 sq.m. facility in Israel for manufacturing our heart valve products and product candidates. Our manufacturing facilities comply with the GMP requirements in the U.S., the EU and the PRC and follow rigorous manufacturing and quality control standards to ensure high product quality and safety standards. The Company maintains strong synergy between R&D and production, and focuses on the management process of whole product life cycle. In the process of launching R&D for new products, it will pay due consideration to the convenience of production and optimizes product design to improve production efficiency and product quality. The Company continuously strengthens the production capacity and production management level, establishes and improves advanced quality management system and refines production system. We conduct all the key valve manufacturing procedures in-house. Over the years, we have accumulated expertise and know-how in manufacturing heart valve products, which sets a solid foundation for our long-term growth. The valve production capacity of the Company was 8,000 sets per annum.

Quality system

The Company has established a quality management system that meets the requirements of GMP of NMPA of the PRC, cGMP of FDA of the U.S., MDR of EU, BGMP of ANVISA of Brazil, ISO13485 and other regulations and standards, and carries out quality control in the whole life cycle of products from R&D to post-marketing sales. The Company develops and maintains a quality management system with high standards and strict requirements to ensure the quality of its products. In 2019 and 2021, the Company was admitted to the first and third experience exchange meeting regarding national medical device production quality management standards. This year, the Company introduced and shared experiences with national medical device enterprises as an outstanding representative in Beijing. As the COVID-19 remains challenging globally, the Company accepted the remote and on-site quality system audit conducted by the EU Notified Body this year, and successfully passed the quality system audit under the new EU MDR regulations. The Company was selected as the training base of medical devices in Hangzhou to provide the inspectors of medical device quality management system with a training platform integrating theoretical knowledge and practical operation.

Commercialization

We continuously strengthened the construction of marketing systems, gradually established an independent marketing system matching our existing products and products to be marketed, and persist in the strategic commercialization direction of professional, brand and digital development. As of June 30, 2021, we have established a team comprising nearly 180 staff, which covered 300 tertiary hospitals. The independent marketing model adopted by the Company is determined by the development stage of the industry and the market environment. VenusA-Valve was approved to be marketed in China in April 2017. As the first listed company in China who is confronted with the challenge that TAVR is at the initial development stage and the barrier of industry development lies in the small number of hospitals and doctors who can perform TAVR surgery, thus a large number of academic promotion and professional trainings are crucial to the Company. As distributors lack complete product understanding and promotion authority, the Company established professional in-house marketing team and focused on academic promotion and doctor education with our rich professional knowledge and clinical resources, in a bid to constantly expand the TAVR market.

As the pioneer to launch the first TAVR product in China, our products provide guidance for leading experts and doctors in the PRC on clinical experience related to TAVR and TPVR procedures. We have set up a set of systematic TAVR training courses in the PRC to promote our TAVR products, improve TAVR awareness, and promote the penetration in the PRC's TAVR market. In terms of digitalization, we established exclusive strategic cooperation with FEOPS to introduce CE-marked FEops HEART guide technology in China, which combines unique digital twins and AI-enabled anatomical analysis technologies, and set up pre-procedure planning through pre-procedure image analysis, which plays a significant role in the training, development and promotion of TAVR procedures.

To facilitate the marketing of innovative products and expansion into international market, we are also forming a global commercialization team.

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. Sales of VenusA-Valve have comprised the major portion of our revenue since its commercialization in August 2017 and are expected to account for a substantial portion of our sales in the near future. VenusA-Plus was also approved for marketing by the NMPA in December 2020.

The Group's revenue for the six months ended June 30, 2021 was RMB239.3 million, representing an increase of 134.6% compared to RMB102.0 million for the six months ended June 30, 2020. The increase was primarily attributable to an increase in sales revenue from VenusA-Valve, a TAVR product; rapid growth of VenusA-Plus, a second generation TAVR product; and enhanced penetration of TriGUARD3 into the overseas market. For the six months ended June 30, 2021, revenue from sales of VenusA-Valve and VenusA-Plus accounted for 98.1% of our total revenue, as compared to 99.6% for the six months ended June 30, 2020.

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

Revenue	Six months ended June 30, 2021 (Unaudited)		Six months ended June 30, 2020 (Unaudited)	
	RMB'000	Proportion	RMB'000	Proportion
VenusA-Valve/VenusA-Plus	234,699	98.1%	101,617	99.6%
TriGUARD3	4,160	1.7%	–	0%
Others	410	0.2%	432	0.4%
Total	<u>239,269</u>	<u>100%</u>	<u>102,049</u>	<u>100%</u>

Cost of Sales

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

The Group's cost of sales for the six months ended June 30, 2021 was RMB51.2 million, representing an increase of 201.2% compared to RMB17.0 million for the six months ended June 30, 2020. The increase was primarily attributable to the increase in staff cost and cost of raw materials as a result of increased sales volume of VenusA-Valve, VenusA-Plus and TriGUARD3.

Gross Profit and Gross Profit Margin

As a result of the aforementioned factors, the gross profit of the Group increased by 121.0% from RMB85.1 million for the six months ended June 30, 2020 to RMB188.1 million for the six months ended June 30, 2021. Gross profit margin is calculated as gross profit divided by revenue. The gross profit margin of the Group decreased from 83.4% for the six months ended June 30, 2020 to 78.6% for the six months ended June 30, 2021, mainly due to the significantly lower gross profit of TriGUARD3 as compared to TAVR products, leading to a decrease in overall gross profit margin.

Other Income and Gains

The Group's other income and gains for the six months ended June 30, 2021 was RMB34.9 million, representing a decrease of 30.3% compared to RMB50.1 million for the six months ended June 30, 2020.

Selling and Distribution Expenses

The Group's selling and distribution expenses for the six months ended June 30, 2021 was RMB99.1 million, representing an increase of 110.0% compared to RMB47.2 million for the six months ended June 30, 2020. The increase was in line with the increase of sales revenue during the corresponding period of 2021, which was primarily attributable to the corresponding increase in sales bonuses with the increase in sales revenue and growth of staff cost resulting from the increased number of sales personnel and increase in investment in market exploration.

R&D Costs

The Group's R&D costs for the six months ended June 30, 2021 was RMB104.3 million, representing an increase of 54.3% compared to RMB67.6 million for the six months ended June 30, 2020. The increase was primarily attributable to our on-going efforts to enrich and optimize product pipeline and the increase in staff cost due to expansion of the R&D team.

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

	Six months ended June 30, 2021 (Unaudited) RMB'000	Six months ended June 30, 2020 (Unaudited) RMB'000
R&D Costs for Core Products		
Staff cost	6,826	3,782
Raw material cost	7,048	2,210
Third-party contracting cost	3,708	39
Intellectual property expenses	671	897
Clinical trial expenses	3,822	1,824
Others	5,980	5,149
R&D Costs for Other Product Candidates		
Staff cost	23,860	14,437
Raw material cost	6,714	4,621
Third-party contracting cost	529	1,046
Intellectual property expenses	8,180	3,828
Clinical trial expenses	14,608	17,438
Others	22,382	12,336

Administrative Expenses

The Group's administrative expenses for the six months ended June 30, 2021 was RMB44.8 million, representing an increase of 14.3% compared to RMB39.2 million for the six months ended June 30, 2020. The increase was primarily attributable to the increase in staff cost and administrative expenses resulting from scale expansion of the Company.

Other Expenses

The Group's other expenses for the six months ended June 30, 2021 was RMB81.3 million, representing an increase of 298.5% compared to RMB20.4 million for the six months ended June 30, 2020. The increase was primarily attributable to increase in donations during the Reporting Period.

Finance Costs

The Group's finance costs for the six months ended June 30, 2021 was RMB1.0 million, representing a decrease of 67.7% compared to RMB3.1 million for the six months ended June 30, 2020. The decrease was primarily attributable to no more interest on loans accrued during the Reporting Period as the Group repaid bank loans in the previous year.

Impairment Losses on Financial Assets, Net

The Group's impairment losses on financial assets, net, for the six months ended June 30, 2021 was RMB3.2 million, representing an increase of 255.6% compared to RMB0.9 million for the six months ended June 30, 2020. The increase was primarily attributable to the increase in trade receivables resulting from increase in sales revenue and increase in provision for impairment allowance of certain trade receivables as a result of the increase in aging of trade receivables.

Share of Losses of Associates

The Group's share of losses of associates for the six months ended June 30, 2021 was RMB6.5 million, representing an increase of 2,066.7% from RMB0.3 million for six months ended June 30, 2020. The increase was primarily attributable to losses incurred in the Reporting Period by two associates newly added in the second half of 2020.

Income Tax

The Group's income tax expense for the six months ended June 30, 2021 was RMB4,000, as compared to income tax expense of RMB9,000 for the six months ended June 30, 2020.

Capital Management

The primary goal of the Group's capital management is to maintain the Group's stability and growth, safeguard its normal operations and maximize shareholders' value. The Group reviews and manages its capital structure on a regular basis, and makes timely adjustments to it in light of changes in economic conditions. 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, 2021 were RMB3,579.8 million, representing an increase of 32.2% compared to RMB2,708.2 million as at December 31, 2020. The increase was primarily attributable to placement of new H Shares by the Company in January 2021.

We rely on capital contributions by our shareholders and bank loans as the major sources of liquidity. We also generate cash from our sales revenue of existing commercialized products, including VenusA-Valve, VenusA-Plus and TriGUARD3. As our business develops and expands, we expect to generate more net cash from our operating activities, through increasing sales revenue of existing commercialized products and by launching new products, as a result of the broader market acceptance of our existing products and our continued efforts in marketing and expansion, improving cost control and operating efficiency and accelerating the turnover of trade receivables by tightening our credit policy.

Borrowings and Gearing Ratio

The Group did not have borrowings as at June 30, 2021 (December 31, 2020: Nil).

The gearing ratio (calculated by dividing the sum of borrowings and lease liabilities by total equity) of the Group as at June 30, 2021 was 0.6%, as compared to 0.9% as at December 31, 2020.

Net Current Assets

The Group's net current assets, as at June 30, 2021 were RMB3,882.4 million, representing an increase of 31.4% compared to net current assets of RMB2,954.9 million as at December 31, 2020. The increase was primarily attributable to placement of new H Shares by the Company in January 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, Material Acquisitions and Disposals

As at June 30, 2021, we did not hold any significant investments. For the Reporting Period, we did not have material acquisitions or disposals of subsidiaries, associates and joint ventures.

Capital Expenditure

For the six months ended June 30, 2021, the Group's total capital expenditure amounted to approximately RMB165.3 million, which was used for (i) increase in investment in an associate; (ii) purchases of financial assets at fair value through profit or loss; (iii) purchase of items of property, plant and equipment; (iv) purchase of equity investment at fair value through other comprehensive income; and (v) purchase of other intangible assets.

Charge on Assets

As at June 30, 2021, there was no charge on assets of the Group.

Contingent Liabilities

As at June 30, 2021, we did not have any contingent liabilities.

Employees and Remuneration Policies

As of June 30, 2021, we had 675 employees in total.

Among the 675 employees, 622 of our employees are stationed in China, and 53 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

We will continue to adhere to the strategies of innovation, internationalization and intelligentization, uphold the development model of “organic growth and external expansion”, and improve product strength and brand influence, innovation capability, commercialization and intelligentization with a focus on unmet medical needs.

Continue to Strengthen Marketing Advantages

As the first company in the PRC with VenusA-Valve, the first-generation of TAVR products, and VenusA-Plus, the second-generation TAVR products, that have been approved for marketing, the Company possesses great first-mover advantage. VenusA-Valve has been used in more than 6,000 procedures since marketing. Capitalizing on the professional academic promotion team, the Company has covered 300 hospitals in the first half of 2021, an increase of 51 from the end of 2020. In the first half of 2021, we proactively organized training promotion and academic education to expand the Company’s academic influence. The Company independently held the TAVR typical case competition (in Yangzhou and Wuhan) and on-line broadcasting of six procedures. More than 50 renowned experts nationwide participated and shared procedure skills, experience and cases, attracting a total of 45,000 online viewers. In May, the Company participated in the Oriental Cardiology Conference and held a satellite meeting. In June, it participated in the Conference of Chinese Interventional Cardiology, co-organized special seminars, satellite meetings and interviews, which had an influence on more than 8,000 people.

The Company’s product portfolio enjoys apparent competitive advantages. VenusA-Valve and VenusA-Plus achieves mutual complement in that VenusA-Valve targets price-sensitive patients and gives priority to market accessibility, while VenusA-Plus provides higher safety with the retrievable function and meet the safety needs of patients. According to the one-year clinical follow-up data of VenusA-Plus, compared with the previous 30-day clinical data, there was only one more all-cause death case, and no cardiac death case, demonstrating its safety and good prognosis. Follow-up results also showed that patients with either tricuspid valve or bicuspid valve diseases did not experience aortic regurgitation or experienced trace regurgitation one year after the surgery, which accentuated the long-term effect. At present, sales of VenusA-Plus show a rapid growth trend.

The independent marketing model adopted by the Company is determined by the development stage of the industry and the market environment. As TAVR is at the initial development stage and the obstacles for industry development lies in the small number of hospitals and doctors who can perform TAVR surgery, a large number of academic promotion and trainings are crucial to the Company. As distributors lack complete product understanding and promotion authority, the Company adopted the independent marketing model, established professional in-house marketing team and focused on academic promotion and doctor education with our rich professional knowledge and clinical resources, in a bid to constantly expand the TAVR market. At present, our sales team consists of 180 personnel, which integrates the functions of patient education, clinical technical support, marketing and sales to provide comprehensive clinical support. The core laboratory has accumulated more than 25,000 cases of pathological screening experience, and achieves an accuracy rate of over 95%, providing doctors with professional services before, during and after surgery to benefit patients and support clinical development. The Company’s own supply chain system relies on professional distribution teams and direct delivery from warehouses, which provides the faster response and better quality delivery services to guarantee the closed-loop system of the entire process before and after procedures, thus effectively integrating upstream and downstream resources of marketing channels, and improving service levels.

In addition to continuously improving specialization and brand awareness, we also actively develop digitalization. We established exclusive strategic cooperation with FEOPS, to introduce CE-marked FEops HEART guide technology in China, which combine unique digital twins and AI-enabled anatomical analysis technologies, and established pre-procedure planning through pre-procedure image analysis. Accurate surgical strategy plays a great role in the training, development and popularization of TAVR surgery. The FEOPS system significantly reduces the frequency of use of valve-in-valve products, the occurrence of complications such as paravalvular leak, and the risk of pacemaker implantation, and ensures surgical safety.

Focus on Expansion of Innovative R&D Layout

The Company focuses on independent R&D, constantly promotes the upgrading of existing pipeline products, and further expands our leading edge in the field of structural heart disease. Meanwhile, leveraging its industry experience and resources and cooperation with external leading products and technology platforms, the Company constantly taps the development potential at home and abroad. Through independent R&D, cooperative development and license-in, the Company has established technical platforms in the fields of aortic valve, pulmonary valve, mitral valve, tricuspid valve, hypertension and hypertrophic cardiomyopathy, enriched product pipelines, and actively explored cutting-edge technical fields such as new materials and new energy, bionics, image fusion technology and digital sensing, so as to enhance innovation capability.

Relying on its own dry tissue technologies accumulated throughout the years, the Company has launched the global innovative balloon-expandable product, Vitae, the self-expanding valve product, PowerX, and surgical valve products to improve the calcification anti-calcification properties and durability of valve products. Vitae balloon-expandable valve products adopt exclusive wire-controlled technology for precise positioning and preventing valve displacement and the annulus valve design is tailored for patients in the PRC, especially patients with high calcified bicuspid valve. It is expected to commence clinical trials in the second half of 2021. PowerX is the world's first fully retrievable and repositionable self-expanding valve, which solves the problem of inaccurate positioning of self-expanding valve and has an adaptive skirt design for preventing paravalvular leak. PowerX adopts highly compressible polymer, and the conveyor can be adjustable and bending. It is expected to commence clinical stage in the first half of 2022. The surgical valve improved hydrodynamic performance and has strong anti-calcification capability. It has completed animal experiments and is expected to commence clinical trials in the second half of 2021.

The Company introduced the special valve anchoring technology from Opus Medical Therapiest in May 2020, which was applied to LimBus, a mitral valve replacement product, and the upgraded product can be implanted through femoral vein, thus improving the safety and effectiveness. On January 28, 2021, the Company reached cooperation with Endoluminal Sciences Pty Ltd, an Australian company, and introduced the active anti-paravalvular leak technology. Such technology is based on proprietary expandable polymer, which will not cause problems such as increased delivery size triggered by physical skirt or skirt damage from retrieval, and effectively resist perivalvular leakage. The third generation of dry tissue aortic valves products including PowerX and Vitae takes advantage of the annular sealing technology to effectively improve the safety of the valve. In May 2021, the Company invested in Valgen Holding Corporation to establish presence in the mitral and tricuspid valve repair field. On June 30, 2021, the Company formed a joint venture, Renaly, with Healium Medical, an innovative medical company in Israel to further expand into RDN products and extend footprints to innovative intervention therapy for hypertension, moving towards a comprehensive supplier of high-value medical devices for heart diseases.

Steadily Promote the Internationalization Strategy

The Company continues to expand the international market primarily leveraging the distribution model, gradually develops a distribution system with wide coverage and has established relations with overseas high-end medical groups, general hospitals and specialized hospitals. As of June 30, 2021, sales revenue of TAVR products in the overseas market reached RMB1.0 million. TriGUARD3, a CEP device, generated sales revenue of RMB4.2 million in Europe, and its market share is on constant rise. VenusP-Valve, the pulmonary valve products which will be approved in the second half of 2021, has established distributor channels in Germany, Belgium, the Netherlands, Canada, Britain and Ireland to proactively expand sales.

We are conducting various clinical trials and registration applications in the U.S., the EU and emerging markets. We plan to introduce VenusP-Valve, TAV8 and TriGUARD3 into the U.S. and EU markets. In March 2020, the CEP device TriGUARD3 obtained the CE Marking and was marketed and sold in the EU, which was the Company's first innovative device approved in Europe. In terms of international commercialization of TAVR products, VenusA-Valve has been approved for marketing in Colombia, the Philippines, Brazil, Thailand, Kyrgyzstan and other markets. Vitae and PowerX, the new generation of dry tissue product candidates, are expected to be launched in the global market. VenusP-Valve, a pulmonary valve product, has been reviewed in Europe and is expected to become the first marketed self-expanding TPVR product in the EU in the second half of 2021.

CORPORATE GOVERNANCE AND OTHER INFORMATION

Interim dividend

The Board does not recommend the payment of interim dividend for the six months ended June 30, 2021 to the Shareholders.

Use of Proceeds

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 million (equivalent to RMB2,558 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). As at June 30, 2021, the Company has used RMB1,321 million for (i) our core products; (ii) our other products and product candidates; (iii) our continued expansion of product portfolio through internal research and/or potential acquisition; and (iv) working capital and other general corporate purposes. The Company intends to use the unutilized net proceeds as of June 30, 2021 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 2021 interim report of the Company to be published in due course.

The net proceeds received by the Company from the placing of an aggregate of an aggregated of 18,500,000 new H Shares taken place in September 2020 were approximately HK\$1,173 million after deducting the expenses of the placing. For the six months ended June 30, 2021, the Company has used RMB135 million for investments in upstream and downstream companies to achieve synergies in operations, expansion in our facilities, and general working capital, in order to facilitate the long-term strategic development of the Company. The Company intends to use the unutilized net proceeds as of June 30, 2021 in the same manner as set out in the announcement of the Company dated September 3, 2020. For details of the breakdown of the use of proceeds, please refer to the 2021 interim report of the Company to be published in due course.

The net proceeds received by the Company from the placing of an aggregate of 18,042,500 new H Shares taken place in January 2021 were approximately HK\$1,427 million after deducting the expenses of the placing. For the six months ended June 30, 2021, the Company has used RMB51 million for (i) accelerating the development and research of the Company's product candidates, including Venus PowerX Valve, Venus Vitae Valve, an aortic valve repair device at pre-clinical stage (Leaflex), transcatheter mitral valve replacement (TMVR), transcatheter tricuspid valve replacement (TTVR) and other products and technologies; (ii) development of and investment in other new technologies; and (iii) working capital and other general corporate purposes. For details of the breakdown of the use of proceeds, please refer to the 2021 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, 2021.

Subsequent Events

On July 20, 2021, after release of the pledge of the 9,302,786 unlisted and pledged domestic shares (the "**Relevant Unlisted Domestic Shares**") and with the authorisation and on behalf of the holders of the Relevant Unlisted Domestic Shares, the Company completed the cancellation registration procedure for the Relevant Unlisted Domestic Shares held by such shareholder in China Securities Depository and Clearing Corporation Limited, Beijing Branch and the name of the shareholder holding the Relevant Unlisted Domestic Shares has been removed from the register of members of Unlisted Domestic Shares maintained by China Clearing. The conversion of the Relevant Unlisted Domestic Shares into H Shares (the "**Converted H Shares**") was completed on July 20, 2021 and the listing of such portion of Converted H Shares on the Stock Exchange has commenced at 9:00 a.m. on July 20, 2021.

Save as disclosed above, the Company is not aware of any material subsequent events from June 30, 2021 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 Directors and the 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, 2021.

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, 2021.

Compliance with the Corporate Governance Code

The Company has adopted and applied the principles and code provisions as set out in the Corporate Governance Code contained in Appendix 14 to the Listing Rules. During the six months ended June 30, 2021, the Company has complied with the mandatory code provisions in the Corporate Governance Code.

Audit Committee

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

The Audit Committee has considered and reviewed the accounting principles and practices adopted by the Group and has discussed matters in relation to internal controls, risk management and financial reporting with the management, including the review of the unaudited condensed consolidated interim financial results of the Group for the six months ended June 30, 2021. The Audit Committee considers that the interim financial results for the six months ended June 30, 2021 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
“Audit Committee”	the audit committee of the Board
“BGMP”	Brazil Good Manufacture Practice
“Board”	the board of directors of the Company
“CE Marking”	a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area
“CEP”	cerebral embolic protection, the function of the devices designed to capture or deflect emboli traveling to the brain during TAVR procedures in order to protect the supra-aortic vessels from embolic debris
“cGMP”	Current Good Manufacture Practice
“China” or “the PRC”	the People’s Republic of China, excluding, for the purpose of this announcement, Hong Kong, Macau Special Administrative Region and Taiwan
“CIT”	Chinese Interventional Therapeutics
“Company”	Venus Medtech (Hangzhou) Inc. (杭州啓明醫療器械股份有限公司), a limited liability company incorporated in the PRC on July 3, 2009 and converted into a joint stock limited liability company incorporated in the PRC on November 29, 2018, whose H Shares are listed on the Hong Kong Stock Exchange (Stock Code: 2500)
“Corporate Governance Code”	the Corporate Governance Code set out in Appendix 14 to the Listing Rules
“COVID-19”	an infectious disease caused by a newly discovered coronavirus, the outbreak of which began in December 2019
“Directors”	the director(s) of the Company
“EU”	the European Union
“FDA”	U.S. Food and Drug Administration
“FIM”	First In Man

“GMP”	good manufacturing practices, the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification
“Group” or “we/our/us”	the Company and its subsidiaries
“H Share(s)”	the overseas listed foreign shares with a nominal value of RMB1.00 each in the share capital of the Company, which are listed on the Hong Kong Stock Exchange and subscribed for and traded in Hong Kong dollars
“HK\$”	Hong Kong dollars, the lawful currency of Hong Kong
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“IDE”	Investigation Device Exemption
“IFRS”	International Financial Reporting Standards
“InterValve”	InterValve Medical Inc., a company incorporated in Delaware, the U.S, on November 18, 2016 and is indirectly wholly-owned by the Company as of the date of announcement
“Keystone”	Keystone Heart Ltd. and its subsidiaries
“KOLs”	acronym for Key Opinion Leaders who are doctors that influence their peers’ medical practice, including but not limited to prescribing behavior
“Listing Rules”	the Rules governing the Listing of Securities on the Stock Exchange, as amended or supplemented from time to time
“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)
“Prospectus”	the prospectus published by the Company on November 28, 2019 in relation to its Hong Kong public offering
“R&D”	research and development
“Reporting Period”	the six months period from January 1, 2021 to June 30, 2021

“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
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“SPVR”	surgical pulmonary valve replacement, a treatment of RVOTD through open-chest surgery
“Supervisor(s)”	member(s) of the supervisory committee of the Company
“TAP treatment”	Transannular patching, a type of treatment for ToF that involves closing the ventricular septal defect and placing atransannular patch (a patch across the pulmonary valve connective tissue to enlarge the pulmonary annulus), which helps blood flow from the pulmonary valve
“TAV8”	TAV8 Balloon Aortic Valvuloplasty Catheter, one of our balloon transluminal aortic valvuloplasty catheter system products
“TAVR”	transcatheter aortic heart valve replacement, a catheter-based technique to implant a new aortic valve in a minimally invasive procedure that does not involve 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 pulmonary stenosis, an opening in the interventricular septum, malposition of the aorta over both ventricles, and hypertrophy of the right ventricle
“TPVR”	transcatheter pulmonary valve replacement, a catheter-based technique to implant a new pulmonary valve in a minimally invasive procedure that does not involve open-chest surgery
“TriGUARD3”	TriGUARD3 Cerebral Embolic Protection Device, our CEP product candidate
“TTVR”	transcatheter tricuspid valve replacement, a catheter-based technique to implant a new tricuspid valve in a minimally invasive procedure that does not involve open-chest surgery

“U.S.”	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 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 product candidates
“VenusA-Valve”	VenusA-Valve System, our TAVR product
“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

Hangzhou, August 31, 2021

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