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杭州啓明醫療器械股份有限公司

Venus Medtech (Hangzhou) Inc.

 $(A\ joint\ stock\ company\ incorporated\ in\ the\ People's\ Republic\ of\ China\ with\ limited\ liability)$

(Stock Code: 2500)

ANNOUNCEMENT OF ANNUAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2020

The board (the "**Board**") of directors (the "**Director**(s)") of Venus Medtech (Hangzhou) Inc. (the "**Company**") is pleased to announce the audited consolidated results of the Company and its subsidiaries (together, the "**Group**") for the year ended December 31, 2020 (the "**Reporting Period**"), together with audited comparative figures for the same period of 2019.

FINANCIAL HIGHLIGHTS

	Year ended	Year ended	
	December 31,	December 31,	Year-to-year
	2020	2019	change
	RMB'000	RMB'000	
Revenue	276,047	233,272	18.3%
Gross Profit	227,280	194,665	16.8%
Loss before tax	(185,843)	(381,543)	(51.3%)
Loss for the year	(182,868)	(380,765)	(52.0%)
Loss attributable to			
owners of the parent	(181,989)	(380,723)	(52.2%)
Loss per Share attributable to			
ordinary equity holders			
of the parent			
Basic and diluted	RMB(0.45)	RMB (1.22)	(63.1%)

ANNUAL RESULTS

The Board is pleased to announce the audited consolidated annual results of the Group for the year ended December 31, 2020 as follows:

AUDITED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	Notes	Year ended December 31, 2020 <i>RMB'000</i>	Year ended December 31, 2019 <i>RMB</i> '000
REVENUE Cost of sales	4	276,047 (48,767)	233,272 (38,607)
Gross profit		227,280	194,665
Other income and gains Selling and distribution expenses Research and development costs Administrative expenses Other expenses Impairment losses on financial assets, net Finance costs	4 6	118,160 (134,572) (167,251) (104,064) (121,844) 50 (4,172)	$15,384 \\ (124,567) \\ (200,531) \\ (197,608) \\ (44,794) \\ (2,172) \\ (21,920)$
Share of profits of associates LOSS BEFORE TAX	5	<u> </u>	(381,543)
Income tax credit	7	2,975	778
LOSS FOR THE YEAR		(182,868)	(380,765)
OTHER COMPREHENSIVE (LOSS)/INCOME Other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent periods: Exchange differences on translation of the foreign operations		(52,524)	7,197
Other comprehensive (loss)/income that will not be reclassified to profit or loss in subsequent periods: Equity investments designated at fair value through other comprehensive income: Changes in fair value		(30,346)	256
OTHER COMPREHENSIVE (LOSS)/INCOME FOR THE YEAR, NET OF TAX		(82,870)	7,453
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		(265,738)	(373,312)

	Note	Year ended December 31, 2020 <i>RMB'000</i>	Year ended December 31, 2019 <i>RMB'000</i>
Loss attributable to:			
Owners of the parent		(181,989)	(380,723)
Non-controlling interests		(879)	(42)
		(182,868)	(380,765)
Total comprehensive loss attributable to:			
Owners of the parent		(264,859)	(373,270)
Non-controlling interests		(879)	(42)
		265,738	(373,312)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted	9	RMB (0.45)	RMB (1.22)
Dasie and unucu	7	KIND (0.43)	KWID (1.22)

AUDITED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Notes	As at December 31, 2020 <i>RMB'000</i>	As at December 31, 2019 <i>RMB</i> '000
NON-CURRENT ASSETS			
Property, plant and equipment		100,005	60,381
Goodwill		487,317	479,626
Other intangible assets		233,004	185,145
Investments in associates		37,995	_
Deferred tax assets		1,156	2,800
Equity investments designated at fair value through other			
comprehensive income		6,525	29,740
Financial assets at fair value through profit or loss		64,473	_
Prepayments, other receivables and other assets		27,319	6,665
Total non-current assets		957,794	764,357
CURRENT ASSETS			
Inventories		59,904	24,789
Trade receivables	10	231,031	162,200
Prepayments, other receivables and other assets		34,984	303,462
Due from related parties		22,500	_
Financial assets at fair value through profit or loss		44,128	_
Pledged deposits		259,716	746
Cash and cash equivalents		2,708,170	2,413,254
Total current assets		3,360,433	2,904,451
CURRENT LIABILITIES			
Trade payables	11	5,295	1,452
Lease liabilities		11,092	8,992
Other payables and accruals		358,487	396,590
Due to a related party		-	685
Interest-bearing bank borrowings		-	120,000
Government grants, current		14,046	24,046
Contract liabilities		2,442	2,392
Refund liabilities		14,155	12,362
Tax payable			1,939
Total current liabilities		405,517	568,458
NET CURRENT ASSETS		2,954,916	2,335,993
TOTAL ASSETS LESS CURRENT LIABILITIES		3,912,710	3,100,350

		As at December 31,	As at December 31,
	Note	2020 RMB'000	2019 <i>RMB</i> '000
NON-CURRENT LIABILITIES			
Lease liabilities		21,671	17,312
Deferred tax liabilities		32,942	37,292
Government grants, non-current		1,062	
Total non-current liabilities		55,675	54,604
Net assets		3,857,035	3,045,746
EQUITY			
Equity attributable to owners of the parent			
Share capital	12	422,969	404,469
Reserves		3,392,455	2,632,509
		3,815,424	3,036,978
Non-controlling interests		41,611	8,768
Total equity		3,857,035	3,045,746

NOTES TO FINANCIAL STATEMENTS

1. CORPORATE INFORMATION

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

During the year, the Group was principally engaged in the research and development, and the manufacturing and sale of bioprosthetic heart valves.

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

2.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRSs"), which include all standards and interpretations approved by the International Accounting Standards Board and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention, except for equity investments designated at fair value through other comprehensive income and financial assets at fair value through profit or loss which have been measured at fair value. They are presented in Renminbi ("RMB") and all values are rounded to the nearest thousand (RMB'000) except when otherwise indicated.

2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The Group has adopted the *Conceptual Framework for Financial Reporting 2018* and the following revised IFRSs for the first time for the current year's financial statements.

Amendments to IFRS 3 Amendments to IFRS 9, IAS 39 and IFRS 7 Amendment to IFRS 16 Amendments to IAS 1 and IAS 8 Definition of a Business Interest Rate Benchmark Reform Covid-19-Related Rent Concessions Definition of Material

2.3 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

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

Amendments to IFRS 3	Reference to the Conceptual Framework ²
Amendments to IFRS 9, IAS 39,	
IFRS 7, IFRS 4 and IFRS 16	Interest Rate Benchmark Reform – Phase 2 ¹
	Sale or Contribution of Assets between an Investor and its Associate or Joint
Amendments to IFRS 10 and IAS 28	Venture ⁴
IFRS 17	Insurance Contracts ³
Amendments to IFRS 17	Insurance Contracts ^{3, 5}
Amendments to IAS 1	Classification of Liabilities as Current or Non-current ³
Amendments to IAS 1	Disclosure of Accounting Policies ³
Amendments to IAS 8	Definition of Accounting Estimates ³
Amendments to IAS 16	Property, Plant and Equipment: Proceeds before Intended Use ²
Amendments to IAS 37	Onerous Contracts – Cost of Fulfilling a Contract ²
Annual Improvements to IFRS	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and
Standards 2018-2020	IAS 41 ²

¹ Effective for annual periods beginning on or after 1 January 2021

- ² Effective for annual periods beginning on or after 1 January 2022
- ³ Effective for annual periods beginning on or after 1 January 2023
- ⁴ No mandatory effective date yet determined but available for adoption
- ⁵ As a consequence of the amendments to IFRS 17 issued in June 2020, IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before 1 January 2023

3. OPERATING SEGMENT INFORMATION

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

Geographical information

(a) Revenue from external customers

	2020 <i>RMB'000</i>	2019 <i>RMB</i> '000
Mainland China Others	272,010 4,037	231,704 1,568
	276,047	233,272

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

	2020 RMB'000	2019 <i>RMB</i> '000
Mainland China	170,734	62,231
USA	59,086	20,572
Israel	166,157	168,216
	395,977	251,019

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

Information about major customers

Revenue from each major customer which accounted for 10% or more of the Group's revenue during the year is set out below:

	2020	2019
	RMB'000	RMB'000
Customer A	30,705	N/A*
Customer B	30,269	36,509
Customer C	N/A*	39,092
Customer D	N/A*	25,296

* Less than 10% of the Group's revenue.

4. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue is as follows:

		2020 <i>RMB'000</i>	2019 <i>RMB</i> '000
	nue from contracts with customers le of medical devices	276,047	233,272
Reven	nue from contracts with customers		
(a)	Disaggregated revenue information		
		2020 RMB'000	2019 <i>RMB</i> '000
	Geographical markets		
	Mainland China	272,010	231,704
	Others	4,037	1,568
	Total revenue from contracts with customers	276,047	233,272
	Timing of revenue recognition		
	Goods transferred at a point in time	276,047	233,272

(b) **Performance obligations**

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

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

	2020	2019
	RMB'000	RMB'000
Amounts expected to be recognised as revenue:		
Within one year	2,442	2,392

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

(c) Refund liabilities

	2020 RMB'000	2019 <i>RMB</i> '000
Refund liabilities arising from sales rebates	14,155	12,362

		2020	2019
	Note	RMB'000	RMB'000
Other income			
Government grants	<i>(a)</i>	29,749	9,189
Bank interest income		34,667	6,163
Others	-	233	32
	_	64,649	15,384
<u>Gains</u> Fair value gains, net:			
Financial assets at fair value through profit or loss			
 mandatorily classified as such 		1,310	-
Fair value gain on a derivative financial instrument		44,128	-
Waiver from a non-controlling shareholder upon liquidation of subsidiary	a 	8,073	
	_	53,511	
Other income and gains	-	118,160	15,384

Note:

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

5. LOSS BEFORE TAX

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

	2020	2019
	RMB'000	RMB'000
Cost of inventories sold*	46,236	35,884
Research and development costs**	167,251	200,531
Depreciation of property, plant and equipment	10,633	7,946
Depreciation of right-of-use assets	10,285	7,977
Amortisation of other intangible assets***	16,794	12,983
Impairment of trade receivables, net	(76)	2,165
Impairment of other receivables	26	7
Impairment of inventories	2,512	592
Auditor's remuneration	3,871	2,068
Government grants	(29,749)	(9,189)
Bank interest income	(34,667)	(6,163)
Donation	58,377	32,525
Listing expenses	-	24,587
Loss on disposal of items of property, plant and equipment, net	560	35
Lease payments not included in the measurement of lease liabilities	942	939
Waiver from a non-controlling shareholder upon liquidation of a subsidiary [^]	(8,073)	_
Fair value gain on a derivative financial instrument	(44,128)	_
Fair value gains, net:		
Financial assets at fair value through profit or loss		
- mandatorily classified as such,	(1,310)	-
Foreign exchange differences, net	60,145	11,087
Employee benefit expenses (excluding directors', supervisors' and chief		
executive's remuneration):		
Wages and salaries	133,342	135,787
Pension scheme contributions	1,165	1,838
Staff welfare expenses	15,290	13,826
Equity-settled share award expense		91,764
	149,797	243,215

- * The cost of inventories sold includes RMB23,734,000 (2019: RMB19,493,000) relating to employee benefit expenses, depreciation and amortisation, which is also included in the respective total amounts disclosed above for each type of expenses.
- ** The research and development costs include RMB62,679,000 (2019: RMB63,743,000) relating to employee benefit expenses, depreciation and amortisation, which are also included in the respective total amounts disclosed above for each type of expenses. It also included share award expense for a specialist of RMB9,000,000 (2019: RMB2,346,000) during the year.
- *** The amortisation of other intangible assets is included in "Cost of sales", "Selling and distribution expenses", "Administrative expenses" and "Research and development costs" on the face of the consolidated statement of profit or loss and other comprehensive income.
- Maiver from a non-controlling shareholder upon liquidation of a subsidiary is included in "Other income and gains" in the consolidated statement of profit or loss and other comprehensive income.

6. FINANCE COSTS

An analysis of finance costs is as follows:

	2020 RMB'000	2019 <i>RMB`000</i>
Interest on bank loans	505	7,758
Interest portion of lease liabilities	1,654	1,256
Finance charge for a guarantee	2,013	12,906
	4,172	21,920

7. INCOME TAX

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 a High and New Technology Enterprise on 4 December 2019, and was entitled to a preferential tax rate of 15% during the year (2019: 15%).

USA

Pursuant to the relevant tax laws of the USA, federal corporation income tax was levied at the rate of 21% (2019: 21%) on the taxable income arising in the USA during the year.

Israel

Pursuant to the relevant tax laws of Israel, the corporate income tax was levied at 23% (2019: 23%) on the taxable income arising in Israel during the year.

United Kingdom ("UK")

Pursuant to the relevant tax laws of the UK, the principal federal tax was levied at the rate of up to 19% (2019: up to 19%) on the taxable income arising in the UK during the year.

Netherlands ("NL")

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

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

	2020 <i>RMB'000</i>	2019 <i>RMB'000</i>
Current – USA		
(Credit)/charge for the year	(461)	1,704
Current – Israel		
Charge for the year	235	269
Current – UK		
Charge for the year	110	97
Current – NL		
Charge for the year	55	_
Deferred tax	(2,914)	(2,848)
	(2,975)	(778)

8. DIVIDEND

10.

No dividend has been paid or declared by the Company during the year (2019: Nil).

9. 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 attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 409,265,072 (2019: 311,037,000) in issue during the year.

The Group had no potentially dilutive ordinary shares in issue during the years ended 31 December 2020 and 2019.

The calculation of basic loss per share is based on:

	2020 RMB'000	2019 <i>RMB</i> '000
Loss	(101.000)	(200, 722)
Loss attributable to ordinary equity holders of the parent	(181,989)	(380,723)
	Number of sl	nares
	2020	2019
Shares		
Weighted average number of shares in issue during the year	409,265,072	311,037,000
TRADE RECEIVABLES		
	2020	2019
	RMB'000	RMB'000
Trade receivables	234,698	166,002
Impairment	(3,667)	(3,802)
	231,031	162,200

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

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

	2020 RMB'000	2019 <i>RMB</i> '000
Within 6 months 7 to 12 months Over 12 months	180,606 39,658 10,767	122,109 36,216 3,875
	231,031	162,200

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

	2020 <i>RMB'000</i>	2019 <i>RMB</i> '000
At beginning of year	3,802	1,637
Impairment losses, net (note 5)	(76)	2,165
Amount written off as uncollectible	(59)	
At end of year	3,667	3,802

An impairment analysis is performed at each reporting date using a provision matrix to measure expected credit losses. The provision rates are based on ageing for groupings of various customer segments with similar loss patterns. The calculation reflects the probability-weighted outcome, the time value of money and reasonable and supportable information that is available at the reporting date about past events, current conditions and forecasts of future economic conditions. The expected credit loss rate was reviewed, and adjusted if appropriate, as at the end of the reporting period. The provision matrix is initially based on the historical observed default rates from listed companies in the same sector. The Group calibrates the matrix to adjust the historical credit loss experience with forward-looking information.

Set out below is the information about the credit risk exposure on the Group's trade receivables using a provision matrix:

	Less than 1 year	1 to 2 years	Total
	RMB'000	RMB'000	RMB'000
As at 31 December 2020			
Expected credit loss rate (%)	0.99%	11.91%	1.56%
Gross carrying amount	222,475	12,223	234,698
Expected credit losses	2,211	1,456	3,667
As at 31 December 2019			
Expected credit loss rate (%)	1.85%	17.42%	2.29%
Gross carrying amount	161,310	4,692	166,002
Expected credit losses	2,985	817	3,802

11. TRADE PAYABLES

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

	2020 RMB'000	2019 <i>RMB</i> '000
Within 3 months	4,034	1,419
3 to 6 months	375	30
6 to 12 months	815	1
Over 12 months	71	2
	5,295	1,452

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

12. SHARE CAPITAL

Shares

	2020 <i>RMB</i> '000	2019 RMB'000
Issued and fully paid: 422,968,943 (2019: 404,468,943) ordinary shares of RMB1.00 each	422,969	404,469

A summary of movements in the Company's share capital is as follows:

	Nu	mbers of ordinary	
		shares	Share capital
	Notes		RMB'000
At 1 January 2019		300,000,000	300,000
Issue of ordinary shares	<i>(a)</i>	14,150,943	14,151
Issue of shares from initial public offering	<i>(b)</i>	90,318,000	90,318
At 31 December 2019 and 1 January 2020		404,468,943	404,469
Issue of shares upon placement of shares	(c)	18,500,000	18,500
As at 31 December 2020		422,968,943	422,969

Notes:

- (a) In May 2019, the Company issued 14,150,943 shares in total with a par value of RMB1.00 each to Jiangsu Zhaoyin Modern Production Shareholding Investment Fund Phase I (Limited Partnership), Shenzhen Zhaoyin Gongying Shareholding Investment Partnership (Limited Partnership), Taizhou Huitianjin Investment Partnership (Limited Partnership), Start New Limited and Huzhou Muxin Health Production Investment Partnership (Limited Partnership). Proceeds of RMB308,643,000 were received during the year, with approximately RMB14,151,000 and RMB294,492,000 credited to the Company's share capital and share premium, respectively.
- (b) In connection with the Company's initial public offering (including the full exercise of the over-allotment option), 90,318,000 shares of RMB1.00 each were issued at a price of HK\$33.00 per share for a total cash consideration, before expenses, of approximately HK\$2,980,494,000 (equivalent to RMB2,678,521,000). Dealings in these shares on the Stock Exchange commenced in December 2019.
- (c) On 10 September 2020, the Company placed, through the placing agent, 18,500,000 shares at a price of HK\$64.19 per placing share for a total cash consideration, before expenses, of approximately HK\$1,187,515,000 (equivalent to RMB1,046,949,000). The share issue expense was approximately HK\$14,341,000 (equivalent to RMB12,644,000).

MANAGEMENT DISCUSSION AND ANALYSIS

I. BUSINESS OVERVIEW

Overview

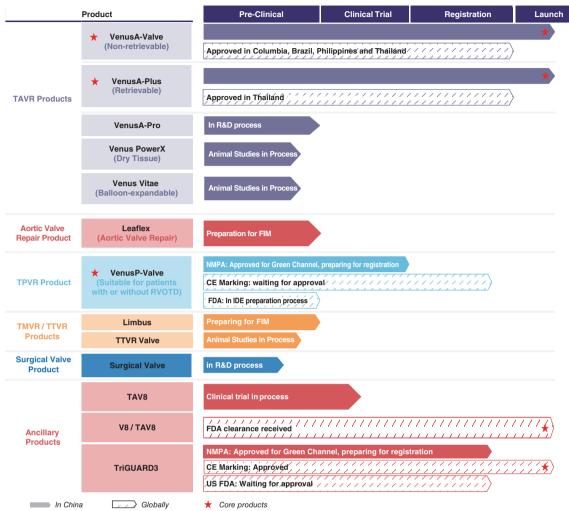
We operate in a large untapped and fast-growing transcatheter heart valve market in China and globally. Our products and product candidates are designed for transcatheter implantation to replace dysfunctional heart valves (i.e. TAVR, TPVR, TMVR and TTVR) mainly associated with aortic stenosis and pulmonic, mitral and tricuspid regurgitation.

Due to COVID-19 pandemic, the TAVR surgeries were negatively impacted in the first half of 2020. However, we see significant revival from the second half of 2020 and based on current condition, we expect the negative impact from COVID-19 pandemic will be limited for 2021. Also, COVID-19 pandemic imposed difficulties of material purchasing from overseas, which may slow down our R&D or manufacturing process. The Company has taken various measures to decrease the negative impacts from COVID-19 pandemic, including strengthening market education via online tools and purchasing materials earlier to ensure safe stocking. Considering the Company possesses plentiful resources to carry out business operation in the future, we will continue our current development and commercialization strategy.

Our Products and Product Pipeline

Our heart valve portfolio comprises of nine self-developed products and product candidates, including two marketed TAVR products (VenusA-Valve and VenusA-Plus), one TAVR product in pre-registration stage (VenusA-Pro), two TAVR products in design stage (Venus PowerX and Venus Vitae), one TPVR product in registration stage (VenusP-Valve), one TMVR product in design stage (Limbus), one TTVR product in design stage and one surgical valve in design stage. In addition to heart valve systems, we offer key ancillary products compatible with transcatheter heart valve replacement procedures, including marketed valvuloplasty balloon products (V8 and TAV8) and one marketed CEP device (TriGUARD3). We also offer one aortic valve repair device in pre-clinical stage (Leaflex).

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



"Retrievable" function allows physicians to retrieve the valve during a TAVR procedure "Patients without RVOTD" refers to patients without RVOTD but have symptoms similar to those of RVOTD that can be treated with TPVR procedures using our VenusP-Valve

VenusA-Valve – Our Core Product

As a leader in TAVR technologies in China, we focus on the development, manufacturing and sale of transcatheter aortic heart valves and their respective delivery systems. We currently have two products on the market, VenusA-Valve is our first-generation TAVR device, which is used to treat severe aortic stenosis using a catheter-based approach. VenusA-Valve received marketing approval from the NMPA in April 2017, and was subsequently commercialized in August 2017, which marked the first NMPA-approved TAVR product and the first TAVR product commercialized in China. Moreover, we registered VenusA-Valve in Colombia in April 2018 and we commercialized VenusA-Valve in Philippines in the third quarter of 2019. We submitted the GMP application of the manufacturing system of VenusA-Valve in Brazil in August 2018 and on-site audit was postponed due to COVID-19. We also submitted the product registration of VenusA-Valve in Brazil in August 2018 and proved in Thailand in December 2020.

For the year ended December 31, 2020, our revenue generated from the sales of VenusA-Valve amounted to RMB272.0 million, representing an increase of 17.2% compared to RMB232.1 million for the year ended December 31, 2019.

VenusA-Valve has been used to treat patients with severe aortic stenosis. According to Frost & Sullivan, there is an increasing population of aortic stenosis patients worldwide and in China, and the TAVR procedure in China has been applied to patients ineligible for surgeries and patients with intermediate to high surgical risk. Similarly in the Philippines and other markets where we have launched or are preparing to launch our TAVR products, the application of TAVR procedure is expected to be approved for severe aortic stenosis patients with low to intermediate surgical risk.

As of December 31, 2020, in China, there were five TAVR products approved for marketing by the NMPA in China, including VenusA-Valve and VenusA-Plus of our Company, J-Valve of Jiecheng, VitaFlow-Valve of MicroPort and Sapien 3 of Edwards Lifesciences. There were several TAVR pipeline products in China at clinical trial stage.

VenusA-Plus – Our Core Product

VenusA-Plus is an upgraded product based on VenusA-Valve. Compared to VenusA-Valve, VenusA-Plus contains a DCS with retrieving function. VenusA-Plus received marketing approval from the NMPA in November 2020, and has been commercialized in early 2021. VenusA-Plus is the first retrievable TAVR product that obtained approval in China. We also submitted the product registration of VenusA-Plus in Thailand and received approval in December 2020.

Driven by the increasing number of patients with severe aortic stenosis and regurgitation, the number of TAVR procedures and the size of TAV market is expected to continue to grow. As of December 31, 2020, VenusA-Plus was the only one TAVR product with retrievable function approved for marketing by NMPA in China. For details, see "VenusA-Valve – Our Core Product" above.

VenusP-Valve – Our Core Product

VenusP-Valve is a transcatheter pulmonary valve system, which is designed for percutaneous implantation via cardia catheterization into the RVOT to treat RVOTD including pulmonary valve backflow as a result of treatment for patients with congenital heart disease. We have completed the clinical trial in China for VenusP-Valve. 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 and it is in technical review process. Once launched, VenusP-Valve is expected to become the first self-expanding TPVR product in the EU, the first large-sized TPVR product for patients with RVOTD after receiving TAP treatment globally.

VenusP-Valve is designed to treat patients with pulmonary regurgitation, which is mainly caused by degeneration of RVOT from a previous repair to treat ToF patients and other congenital heart diseases. With the increasing number of ToF and other RVOTD patients, demand for TPVR products such as VenusP-Valve is expected to increase. Considering the high prevalence of newborns with congenital heart defects every year in China and global market, TPVR treatment may become reimbursable under governmental medical insurance in the future, which will increase its accessibility and affordability. Meanwhile, the improved safety and efficacy of TPVR procedure over SPVR procedure will increase the acceptance among patients and physicians. Therefore, we expect the market adoption of our VenusP-Valve will increase.

As of December 31, 2020, there were three TPVR products approved by the FDA or received CE Marking, including Sapien 3 and Sapien XT from Edwards Lifesciences and Melody from Medtronic.

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

VenusA-Pro Valve

We are in the process of designing our product, VenusA-Pro Valve, TAVR device, which is used to treat severe aortic stenosis using a catheter-based approach and self-expanding valve. Our pre-clinical studies for VenusA-Pro Valve is in process. This program will feature improved control on valve deployment and retrievability. For the sales of VenusA-Pro Valve in China, similar to the registration of VenusA-Plus Valve, we will submit to the NMPA for its approval.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET VENUSA-PRO VALVE SUCCESSFULLY.

Venus PowerX Valve

We are in the process of designing our product, Venus PowerX Valve, TAVR device, which is used to treat severe aortic stenosis using a catheter-based approach and self-expanding valve. Our design-stage animal studies for Venus PowerX Valve are currently on-going, and we are in the process of refining our design based on the animal studies. This program will feature coronary access, retrievability, steerability and dry tissue technology. For the sales of Venus PowerX Valve in China, similar to the registration of VenusA-Valve, we will submit our clinical trial results to the NMPA for its approval.

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

Venus Vitae Valve

We are in the process of designing our product, Venus Vitae Valve, TAVR device, which is used to treat severe aortic stenosis using a catheter-based approach and balloon expandable valve. Our design-stage animal studies for Venus Vitae Valve are currently on-going, and we are in the process of refining our design based on the animal studies. The product will feature low profile, coronary access, steerability and innovative dehydrated tissue technology. For the sales of Venus Vitae Valve in China, similar to the registration of VenusA-Valve, we will submit our clinical trial results to the NMPA for its approval.

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

Venus Mitral Valve – Limbus

We are in the process of designing our product, Limbus, for TMVR treatment of mitral regurgitation patients. Our design-stage animal studies for Limbus are currently on-going, and we are in the process of refining our design based on the animal studies. For the sales of Limbus in China, similar to the registration of VenusA-Valve, we will submit our clinical trial results to the NMPA for its approval. We have strengthened Limbus program with the signing of a license agreement with Opus Medical Therapies, LLC., allowing us access to leading edge technology in this field.

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

Venus Tricuspid Valve

We are in the process of designing our product, Venus Tricuspid Valve, for TTVR treatment of tricuspid regurgitation patients. Our design-stage animal studies for Venus Tricuspid Valve are currently ongoing, and we are in the process of refining our design based on the animal studies. For the sales of Venus Tricuspid Valve in China, similar to the registration of VenusA-Valve, we will submit our clinical trial results to the NMPA for its approval.

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

Surgical Valve

We are in the process of designing our product, Surgical Valve, a surgical valve replacement product for treatment of aortic valve stenosis and regurgitation patients. We are currently preparing for our first design stage animal studies. This program will feature a dry tissue valve with improved hemodynamic performance features to accomodate future VIV TAVR procedures. For the sales of Surgical Valve, we will submit our clinical trial results to the NMPA for its approval.

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

V8 and TAV8

A balloon aortic valvuloplasty catheter system is designed to be used in stand-alone balloon aortic valvuloplasty procedures and the dilatation of aortic valve leaflets prior to and after TAVR procedure. InterValve has developed two generations of bicuspid aortic valve catheter system, V8 and TAV8, both of which have received FDA 510 (k) clearance. In November 2016, InterValve assigned V8 and TAV8 related patents and transferred related regulatory approvals to us. We are in the process of clinical trials of TAV8 and expect to apply for an import product license with the NMPA for TAV8 after the clinical trials are completed.

WE MAY NOT BE ABLE TO ULTIMATELY MARKET V8 AND TAV8 SUCCESSFULLY IN THE EU AND CHINA.

CEP Device – TriGUARD3

TriGUARD3 is a CEP device designed to provide coverage of all three major aortic vessels (brachiocephalic artery, left carotid artery, and left subclavian artery) to minimize the risk of cerebral damage during TAVR and other structural heart procedures. It is the only CEP device designed to cover all three major aortic vessels globally according to Frost & Sullivan. In June 2020, TriGUARD3 was approved by the NMPA to be eligible for the Special Approval Procedures of Innovative Medical Devices promulgated by the NMPA. TriGUARD3 received CE Marking for use in cardiac procedures on in March 2020 and we have submitted for the FDA registration in September 2020. In addition, TriGUARD3 has completed its first clinical application in the PRC in January 2021, which is also its first clinical application in Asia.

Aortic Valve Repair – Leaflex

Leaflex is a stand-alone catheter-based treatment of aortic stenosis. It modifies leaflet calcium to restore mobility to the affected valve, thereby improving flow and reducing transvalvular gradient. The procedure is simple to perform, non-implant based and requires only a short hospital stay. We will be importing the Leaflex product to the Chinese market and plan to conduct FIM in the second quarter of 2021.

WE MAY NOT BE ABLE TO ULTIMATELY MARKET LEAFLEX SUCCESSFULLY.

Our Platform

As we build our pipeline, we have established a transcatheter heart valve platform with robust R&D, manufacturing and commercialization capabilities.

R&D

Our R&D team, based in China, Israel and the U.S., is led by our COO, Mr. Lim Hou-Sen (Lin Haosheng), former CTO of Transcatheter Technologies GmbH and a veteran with more than 16 years' experience in the industry. The R&D team of Keystone is led by Mr. Amit Ashkenazi, who has extensive experience in the R&D of medical devices. We remain at the forefront of heart valve technology by maintaining close contact with leading cardiologists globally, and develop products that specifically address the clinical needs of transcatheter heart valve replacement procedures. Our powerful R&D capabilities are reflected by our strong intellectual property portfolio.

The time required from developing to commercializing a new product varies by product candidate and can be affected by various factors which may be beyond our control, such as clinical trial results and government policies and approvals.

Manufacturing

We have an approximately 9,000 sq.m. facility in Hangzhou, China and an approximately 816 sq.m. facilities 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 China and follow rigorous manufacturing and quality control standards to ensure high product quality and safety. We conduct all the key valve manufacturing procedures in-house. Over the years, we have accumulated extensive expertise and know-how in manufacturing heart valve products, which sets a solid foundation for our long-term growth.

Commercialization

We have a dedicated in-house sales team with a focus on academic marketing driven by our extensive expertise and clinical resources. As the pioneer in launching the first TAVR product in China, our products have contributed to the underlying clinical experience of leading experts in China in setting up the guidelines for physicians conducting TAVR and TPVR procedures. We have also established a systematic TAVR training program in China to promote our TAVR products as well as TAVR awareness and drive the penetration rate of TAV market in China.

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.

The Group's revenue for the year ended December 31, 2020 was RMB276.0 million, representing an increase of 18.3% compared to RMB233.3 million for the year ended December 31, 2019. The increase was primarily attributable to enhanced market recognition of VenusA-Valve and an increase in sales volume leveraging our constant promotion and business expansion. For the year ended December 31, 2020, revenue from sales of VenusA-Valve accounted for 98.5% of our total revenue, as compared to 99.5% for the year ended December 31, 2019.

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

	Year en	ded	Year end	ded
	December 3	December 31, 2020		1, 2019
Revenue	RMB'000	Proportion	RMB'000	Proportion
VenusA-Valve	272,010	98.5%	232,073	99.5%
TriGUARD3	3,347	1.2%	0	0%
Others	690	0.3%	1,199	0.5%
Total	276,047	100%	233,272	100%

Cost of Sales

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

The Group's cost of sales for the year ended December 31, 2020 was RMB48.8 million, representing an increase of 26.4% compared to RMB38.6 million for the year ended December 31, 2019. The increase was primarily attributable to increases in staff cost and raw materials costs as a result of increased sales volume of VenusA-Valve.

Gross Profit and Gross Profit Margin

As a result of the aforementioned factors, the gross profit of the Group increased by 16.7% from RMB194.7 million for the year ended December 31, 2019 to RMB227.3 million for the year ended December 31, 2020. Gross profit margin is calculated as gross profit divided by revenue. The gross profit margin of the Group decreased from 83.5% for the year ended December 31, 2019 to 82.3% for the year ended December 31, 2020, mainly due to a slight decrease in unit price in certain regions for the purpose of sales promotion and market share expansion.

Other Income and Gains

The Group's other income and gains for the year ended December 31, 2020 was RMB118.2 million, representing an increase of 667.5% compared to RMB15.4 million for the year ended December 31, 2019, primarily attributable to an increase in government grants received during the year of 2020 as compared with the year of 2019, increase in interest income due to increase in balance of bank deposits and gains from fair value changes as a result of a forward exchange settlement.

Selling and Distribution Expenses

The Group's selling and distribution expenses for the year ended December 31, 2020 was RMB134.6 million, representing an increase of 8.0% compared to RMB124.6 million for the year ended December 31, 2019. The increase was in line with the increase in sales revenue during the year of 2020 compared with the year of 2019, primarily due to an increase in the number of sales staffs and therefore an increase in staff cost as well as increased investment in market development.

R&D Costs

The Group's R&D costs for the year ended December 31, 2020 was RMB167.3 million, representing a decrease of 16.6% compared to RMB200.5 million for the year ended December 31, 2019. The decrease was primarily attributable to an expense in relation to the Employee Incentive Scheme of approximately RMB36.7 million incurred in the previous year.

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

	Year ended December 31, 2020 <i>RMB'000</i>	Year ended December 31, 2019 <i>RMB'000</i>
R&D Costs for Core Products		
Staff cost	8,865	8,866
Raw material cost	4,659	2,734
Third-party contracting cost	500	3,500
Intellectual property expenses	2,432	2,248
Clinical trial expenses	10,183	10,080
Others	11,021	9,444
R&D Costs for Other Product Candidates		
Staff cost	32,463	38,602
Raw material cost	11,517	9,094
Third-party contracting cost	6,952	2,216
Intellectual property expenses	4,164	6,765
Clinical trial expenses	31,577	35,654
Others	33,918	25,604

Administrative Expenses

The Group's administrative expenses for the year ended December 31, 2020 was RMB104.1 million, representing a decrease of 47.3% compared to RMB197.6 million for the year ended December 31, 2019. The decrease was primarily attributable to an expense in relation to the Employee Incentive Scheme of approximately RMB69.2 million and listing expenses of approximately RMB24.6 million incurred in the previous year while no such expenses were incurred in the current year.

Other Expenses

The Group's other expenses for the year ended December 31, 2020 was RMB121.8 million, representing an increase of 171.9% compared to RMB44.8 million for the year ended December 31, 2019. The increase was primarily attributable to an increase in charitable donations and exchange losses arising from conversion of Renminbi to Hong Kong dollars.

Impairment Losses on Financial Assets, Net

The Group's reversal on impairment losses on financial assets, net, for the year ended December 31, 2020 was RMB0.1 million, representing a change of 104.5% compared to RMB2.2 million of impairment loss on financial assets, net for the year ended December 31, 2019. The above change was primarily attributable to a decrease in expected credit loss rate and reversal of bad debts provision on trade receivables.

Finance Costs

The Group's finance costs for the year ended December 31, 2020 was RMB4.2 million, representing a decrease of 80.8% compared to RMB21.9 million for the year ended December 31, 2019. The decrease was primarily attributable to repayment of bank loans and a decrease in finance charge for a guarantee compared with the previous year.

Income Tax Credit

The Group's income tax credit for the year ended December 31, 2020 was RMB3.0 million, representing an increase of 275.0% compared to the income tax credit of RMB0.8 million for the year ended December 31, 2019. The increase was primarily attributable to more additional deductible allowance for R&D costs compared with the previous year.

Non-IFRS Measures

To supplement our audited consolidated statement of profit or loss and other comprehensive income which is presented in accordance with the International Financial Reporting Standards ("IFRS"), we also use adjusted net loss as a non-IFRS measure, which is not required by, or presented in accordance with, IFRS. We believe that the presentation of non-IFRS measure when shown in conjunction with the corresponding IFRS measures provides useful information to investors and management in facilitating a comparison of our operating performance from period to period by eliminating potential impacts of certain non-operational or one-off expenses that do not affect our ongoing operating performance, including share awards and listing expenses. Such non-IFRS measure allows investors to consider metrics used by our management in evaluating our performance.

The following table shows our adjusted net loss and its reconciliation to loss for the periods indicated:

	Year ended	Year ended
	December 31,	December 31,
	2020	2019
	(RMB'000)	(RMB'000)
Loss for the year	(182,868)	(380,765)
Add:		
Share awards ⁽¹⁾	9,000	120,705
Listing expenses ⁽²⁾	-	24,587
Adjusted net loss for the year ⁽³⁾	(173,868)	(235,473)

Notes:

- (1) Share awards expenses are non-operational expenses arising from granting shares to selected chief executives, employees and R&D consultants, the amount of which may not directly correlate with the underlying performance of our business operations, and is also affected by non-operating performance related factors that are not closely or directly related to our business activities.
- (2) Listing expenses are one-off expenses in relation to the listing of the Company's H Shares on the Main Board of the Stock Exchange and its initial global offering.
- (3) We consider share awards and listing expenses as non-operational or one-off expenses which do not affect our ongoing operating performance. We believe the net loss as adjusted by eliminating potential impacts of the share awards and listing expenses provides useful information to investors in facilitating a comparison of our operating performance from period to period.

The use of the non-IFRS measures has limitations as an analytical tool, and you should not consider it in isolation from, or as a substitute for or superior to analysis of, our results of operations or financial condition as reported under IFRS. In addition, the non-IFRS financial measure may be defined differently from similar terms used by other companies and therefore may not be comparable to similar measures presented by other companies.

Capital Management

The primary goal of the Group's capital management is to maintain the Group's stability and growth, safeguard its normal operations and maximize shareholders' value. The Group reviews and manages its capital structure on a regular basis, and makes timely adjustments to it in light of changes in economic conditions. To maintain or realign our capital structure, the Group may raise capital by way of bank loans or issuance of equity or convertible bonds.

Liquidity and Financial Resources

The Group's cash and cash equivalents as at December 31, 2020 were RMB2,708.2 million, representing an increase of 12.2% compared to RMB2,413.3 million for the year ended December 31, 2019. The increase was primarily attributable to placement of new H Shares by the Company in September 2020.

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

Borrowings and Gearing Ratio

The Group did not have any borrowings as at December 31, 2020, representing a decrease of 100% compared to RMB120.0 million as at December 31, 2019. The decrease was primarily attributable to repayment of principal and interest of such borrowings by the Group at the beginning of 2020.

The gearing ratio (calculated by dividing the sum of borrowings and lease liabilities by total equity) of the Group as at December 31, 2020 was 0.9%, representing a decrease of 81.3% compared to 4.8% as at December 31, 2019.

Net Current Assets

The Group's net current assets, as at December 31, 2020 were RMB2,954.9 million, representing a an increase of 26.5% compared to net current assets of RMB2,336.0 million as at ended December 31, 2019. The increase was primarily due to an increase in the cash of the Group as an result of the placement of new H shares by the Company in September 2020.

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 future foreign currency risk. Management of the Group monitors foreign exchange exposure and will enter into forward exchange settlement agreements with financial institutions to lock exchange rate risks should the need arise.

Pledge of Shares

On January 30, 2019, Mr. Zhenjun Zi, one of our controlling shareholders at the time of our Prospectus, provided the Share Pledge of 9,000,000 Shares to Hangzhou Gaoxin Technology Innovation Services Ltd. (杭州高新科技創業服務有限公司), an Independent Third Party, as a counter guarantee for the loan of RMB100 million (i.e. the principal amount) to our Company, at an interest rate of the loan prime rate issued by the National Interbank Funding Centre plus 0.04% per annum, for a term of twelve months, effective from January 30, 2019 to January 29, 2020. For details, please refer to the section headed "Relationship with Our Controlling Shareholders" in the Prospectus. On February 21, 2020, the Share Pledge was released.

We do not have any controlling shareholder during the Reporting Period.

Significant Investments, Material Acquisitions and Disposals

For the year ended December 31, 2020, 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 year ended December 31, 2020, the Group's total capital expenditure amounted to approximately RMB218.2 million, which was used in (i) purchase of property, plant and equipment; (ii) payments related to acquisition of 510 Kardiac and investment in associates; and (iii) purchase of other intangible assets.

Charge on Assets

As at December 31, 2020, there was no charge on assets of the Group.

Contingent Liabilities

As at December 31, 2020, we did not have any contingent liabilities.

Subsequent Events

On January 22, 2021, the Company entered into a placing agreement with Goldman Sachs (Asia) L.L.C. and UBS AG Hong Kong Branch (as the placing agents), pursuant to which the Company conditionally agreed to place 18,042,500 new H shares at the placing price of HK\$80.08 per placing share to no less than six professional, institutional and/or individual investors which are not connected persons of the Company (the "January 2021 Placing"). The completion of the January 2021 Placing took place on January 29, 2021 and an aggregate of 18,042,500 new H shares have been successfully allotted and issued by the Company at the placing price of HK80.08 per placing share on the same day. The aggregate gross proceeds from the January 2021 Placing amounted to approximately HK\$1,445 million and the aggregate net proceeds from the January 2021 Placing. For details of the January 2021 Placing, please refer to the Company's announcements dated January 22, 2021 and January 29, 2021, respectively.

Save as disclosed above, the Company is not aware of any material subsequent events from December 31, 2020 to the date of this announcement.

Employees and Remuneration Policies

As of December 31, 2020, we had 514 employees in total.

Among the 514 employees, 461 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 for 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 our mission to become a global leader in the development and commercialization of transcatheter solutions for structural heart diseases. We plan to execute the following strategies to achieve our mission.

Continue to grow sales of VenusA-Valve

Sales of TAVR products in China possess substantial growth potential. We intend to solidify our leadership position in China's TAV market by increasing VenusA-Valve's sales volume. Towards that goal, we plan to substantially increase sales to hospitals with which we have existing relationships as well as expand our sales network to cover more hospitals and further promote TAVR awareness among hospitals, physicians and patients in China.

We believe there are still substantial unmet demands for TAVR products from the hospitals to which we currently sell VenusA-Valve. We also believe there is significant potential to develop new hospitals to perform TAVR procedures. We plan to increase sales efforts to deepen the penetration in hospitals to which we currently sell VenusA-Valve and expand into new hospitals in China by leveraging our direct access to KOLs in cardiac interventional therapy, providing systematic training to physicians, and increasing TAVR awareness among hospitals, physicians and patients. We plan to continue to implement and improve our systematic TAVR training program to expedite the physician education process and to promote our TAVR products.

We also plan to further promote TAVR awareness among patients with structural heart diseases in China, in particular to low surgical risk patients, in order to broaden the patient base of our TAVR products. We cooperate with several foundations to subsidize patients' medical expenses and conduct regular follow-up visits post procedures. We will continue to participate in heart valve conferences and academic events to further promote awareness of our products and TAVR generally. We believe that these marketing activities will strengthen our brand name and enable us to accumulate first-hand know-how for structural heart diseases and keep abreast of the market developments in transcatheter heart valve solutions.

Leverage our experience with VenusA-Valve to commercialize VenusP-Valve and other product candidates in China

We plan to leverage our experience in successfully commercializing VenusA-Valve in China to launch VenusP-Valve and our other product candidates in the Chinese market in the future. We have completed the clinical trial for VenusP-Valve in China in January 2018. We believe our experiences with respect to the regulatory approval will significantly facilitate the approval process of VenusP-Valve. In April 2019, VenusP-Valve was approved by the NMPA to be eligible for the Special Approval Procedures of Innovative Medical Devices. We will benefit from our established network with and direct access to KOLs, hospitals and physicians to introduce our new valve products. We believe that our existing brand and reputation for VenusA-Valve will facilitate our commercialization of VenusP-Valve upon approval. We also plan to replicate our existing training model for TAVR procedures to VenusP-Valve and our other product candidates to educate hospitals and physicians and promote our new products.

Expand our presence in North America, the EU and emerging markets to become a global leader

We plan to broaden our sales and expand our presence globally, especially in North America and the EU, as we believe we will benefit from higher medical expense levels in these developed regions. Medical expense levels in China remain low compared to the U.S. and the EU.

We are in the process of various clinical trials and registration applications in the U.S., the EU and emerging markets. We plan to leverage on the existing brand names of TriGUARD3 to enter the U.S. and the EU markets and subsequently establish our own brand name. With our acquisition of Keystone in December 2018, we plan to have Keystone as our platform for the U.S. and the EU markets which could help us with the clinical trials, registration and promotion of our products in these markets. TriGUARD3 received CE Marking for use in cardiac procedures on March 4, 2020. We have submitted for the FDA registration in September 2020. We believe we can leverage the global experience in product development and clinical trial of Keystone to advance the clinical trials of our other product candidates in the U.S. and the EU in order to obtain approvals and launch our products worldwide. We also plan to promote VenusP-Valve in the EU and North America. We have submitted application for CE Marking for VenusP-Valve in April 2019, which is currently under technical review. With respect to emerging markets, we registered VenusA-Valve in Colombia in April 2018 and commercialized VenusA-Valve in Philippines in the third quarter of 2019. We submitted for GMP application for the production system of VenusA-Valve in Brazil in August 2018 but suffered a delay in on-site review due to COVID-19 pandemic. We also submitted for registration for VenusA-Valve in Brazil in August 2019 and received the approval in April 2020.

To execute our global expansion strategy, we will continue to participate in international heart valve conferences and academic events to further promote our products and brand.

Continue to advance and strengthen our pipeline products within the structural heart disease space

We plan to advance our existing pipeline products to further expand our coverage within the structural heart disease space, both horizontally covering all four heart valves and vertically from valves, CEP, valvuloplasty balloons to other ancillary devices. We will invest in technological innovation to strengthen our R&D capabilities to develop new products and enhance our competitiveness as we believe innovation is a key factor to achieve our mission to become a global leader of transcatheter solutions for structural heart diseases.

We may selectively form partnerships with complementary product providers to enhance our clinical strengths and market advantages and make acquisitions that have the potential to broaden our product portfolio. We believe our established network with and direct access to KOLs, hospitals and physicians gives us the best knowledge of strategic opportunities which could complement or improve our existing product offerings. As of the date of this announcement, we had not identified any specific acquisition targets.

CORPORATE GOVERNANCE AND OTHER INFORMATION

Compliance with the Corporate Governance Code

The Company has adopted and applied the principles and code provisions as set out in the Corporate Governance Code. During the year ended December 31, 2020, the Company has strictly complied with the provisions of the Corporate Governance Code.

Compliance with the Model Code

The Company has adopted a code of conduct regarding Directors' and Supervisors' securities transactions on terms no less exacting than the required standard set out in the Model Code set out in Appendix 10 to the Listing Rules. The Company has made specific enquiries to all Directors and Supervisors concerning their compliance with the Model Code. All Directors and Supervisors confirmed that they had strictly observed all standards set out in our Company's code of conduct regarding Directors' and Supervisors' securities transactions during the year ended December 31, 2020.

The Company's employees, who are likely to be in possession of inside information of the Company, have also been subject to the code of conduct regarding Directors' and Supervisors' securities transactions of the Company. No incident of non-compliance of code of conduct regarding Directors' and Supervisors' securities transactions by the employees was noted by the Company during the year ended December 31, 2020.

Purchase, Sale or Redemption of Listed Securities

Neither the Company nor any of its subsidiaries purchased, redeemed or sold any of the Company's listed securities during the year ended December 31, 2020.

H Share Full Circulation

On June 15, 2020, the Company submitted an application (the "**Application**") to the China Securities Regulatory Commission (the "**CSRC**") in respect of the conversion of certain of its domestic shares and unlisted foreign shares into H shares of the Company.

On June 19, 2020, the Company obtained from the CSRC an official acceptance letter in respect of the Application, pursuant to which, the application materials had completed and the CSRC had accepted and will process the Application.

On August 14, 2020, the Company received a formal approval of the Application from the CSRC, under which the Company is allowed to convert an aggregate of 221,752,871 unlisted domestic shares into overseas-listed shares that are eligible to be listed and traded on the Main Board of the Stock Exchange, and the listing of such shares on the Stock Exchange. The formal approval shall be valid for 12 months from August 11, 2020.

On November 16, 2020, the approval for the listing of and the permission to deal in 221,752,871 H shares, representing the maximum number of unlisted domestic shares to be converted under the conversion and listing of 221,752,871 unlisted domestic shares, was granted by the Stock Exchange.

On November 27, 2020, the conversion of 212,450,085 unlisted and unpledged domestic shares into the H shares was completed and the listing of such portion of converted H shares on the Stock Exchange commenced on November 30, 2020. It is expected that the conversion and listing of 9,302,786 unlisted and pledged domestic shares will be completed no later than August 11, 2021.

For details in relation to the H share full circulation programme of the Company, please refer to the Company's announcements dated June 15, 2020, June 22, 2020, August 14, 2020, November 23, 2020 and November 27, 2020.

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 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).

For the year ended December 31, 2020, the Company has used RMB957.5 million for (i) our core products; (ii) our other products and candidates; (iii) continuous 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 net proceeds that had not been utilized as of December 31, 2020 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 2020 annual report of the Company to be published in due course.

(2) Use of Proceeds from the September 2020 Placing

On September 3, 2020, the Company entered into a placing agreement with Goldman Sachs (Asia) L.L.C. and China International Capital Corporation Hong Kong Securities Limited (as the placing agents), pursuant to which the Company conditionally agreed to place 18,500,000 new H shares at the placing price of HK\$64.19 per placing share to no less than six professional, institutional and/ or individual investors which are not connected persons of the Company (the "**September 2020 Placing**"). The completion of the September 2020 Placing took place on September 10, 2020 and an aggregate of 18,500,000 new H shares have been successfully allotted and issued by the Company at the placing price of HK64.19 per placing share on the same day. The aggregate gross proceeds from the September 2020 Placing amounted to approximately HK\$1,188 million and the aggregate net proceeds from the September 2020 Placing. For details of the September 2020 Placing, please refer to the Company's announcements dated September 3, 2020 and September 10, 2020, respectively.

For the period from September 10, 2020 (i.e. the date of completion of the September 2020 Placing) to December 31, 2020, the Company has used (i) RMB61.3 million for general working capital. The Company intends to use the net proceeds that had not been utilized as of December 31, 2020 in the same manner and proportion as set out in the Company's announcement dated September 10, 2020.

(3) Use of Proceeds from the January 2021 Placing

As set out in the section headed "II. Financial Review – Subsequent Events" in this announcement, the aggregate gross proceeds from the January 2021 Placing amounted to approximately HK\$1,445 million and the aggregate net proceeds from the January 2021 Placing amounted to approximately HK\$1,427 million after deducting the expenses of the January 2021 Placing. The Company intends to use the net proceeds in the same manner and proportion as set out in the Company's announcement dated January 29, 2021.

Audit Committee

The audit committee of the Board (the "Audit Committee") has three members comprising all independent non-executive Directors, being Mr. Chi Wai Suen (chairman of the Audit Committee), Mr. Ting Yuk Anthony Wu and Mr. Wan Yee Joseph Lau, with terms of reference in compliance with the Listing Rules. The Audit Committee has considered and reviewed the accounting principles and practices adopted by the Company and the Group and discussed matters in relation to internal control, risk management and financial reporting with the management. The Audit Committee reviewed the annual financial results for the year ended December 31, 2020 and considers that the annual financial results are in compliance with the relevant accounting standards, rules and regulations and appropriate disclosures have been duly made.

Auditor

The financial information set out in this announcement does not constitute the Group's audited accounts for the year ended December 31, 2020, but represents an extract from the consolidated financial statements for the year ended December 31, 2020 which have been audited by the auditor of the Company, Ernst & Young, in accordance with Hong Kong Standards on Auditing issued by the Hong Kong Institute of Certified Public Accountants.

FINAL DIVIDEND

The Board has resolved not to recommend the payment of a final dividend for the year ended December 31, 2020 (2019: Nil).

CLOSURE OF REGISTER OF MEMBERS AND RECORD DATE

The H share register of members of the Company will be closed from Wednesday, April 21, 2021 to Friday, May 21, 2021, both days inclusive, in order to determine the eligibility of the holder of H shares to attend and vote at the AGM to be held on Friday, May 21, 2021. The holder of H shares whose names appear on the H share register of members of the Company on Friday, May 21, 2021 will be entitled to attend and vote at the AGM. In order to be eligible to attend and vote at the AGM, all transfer accompanied by the relevant share certificates and transfer forms must be lodged with the Company's H share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited, at Shops 1712–1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong before 4:30 p.m. on Tuesday, April 20, 2021.

PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

This announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.venusmedtech.com).

The annual report of the Company for the year ended December 31, 2020 containing all the information required by the Listing Rules will be despatched to the Company's shareholders and published on the websites of the Stock Exchange and the Company in due course.

DEFINITIONS

"510 Kardiac"	510 Kardiac Devices, Inc.
"AGM"	annual general meeting of the Company to be held on Friday, May 21, 2021
"Audit Committee"	the audit committee of the Board
"Board"	the board of Directors
"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
"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 Stock Exchange (Stock Code: 2500)
"COO"	Chief Operating Officer
"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
"СТО"	Chief Technology Officer
"DCS"	delivery catheter system, a catheter system of our products with a pushing handle, outer sheath and a tip to freely pass through guide catheter to deliver the valve to the designated position
"Directors"	the director(s) of the Company

"Edwards Lifesciences"	a U.S. medical equipment company specializing in artificial heart valves and hemodynamic monitoring
"Employee Incentive Scheme"	the employee incentive scheme of our Company approved and adopted by our Board on March 10, 2017, a summary of the principal terms of which is set forth in the Prospectus under the section headed "Appendix VI – Statutory and General Information – Further information about our Directors, management and substantial shareholders – 5. Employee Incentive Scheme"
"EU"	the European Union
"FDA"	U.S. Food and Drug Administration
"FDA 510(k)"	section 510(k) of the Food, Drug and Cosmetic Act, which requires device manufacturers who must register, to notify the FDA of their intent to market a medical device at least 90 days in advance
"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", "We" or "us"	the Company and its subsidiaries (or the Company and any one or more of its subsidiaries, as the context may require)
"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 Main Board of the Stock Exchange and subscribed for and traded in Hong Kong dollars
"H Share Registrar"	Computershare Hong Kong Investor Services Limited
"HK\$"	Hong Kong dollars, the lawful currency of Hong Kong
"Hong Kong"	the Hong Kong Special Administrative Region of the PRC
"IFRS"	International Financial Reporting Standards
"IDE"	Investigational Device Exemption
"InterValve"	InterValve Medical Inc., a company incorporated in Delaware, the United States on November 18, 2016 and is indirectly wholly-owned by our 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
"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 one-year period from January 1, 2020 to December 31, 2020
"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
"Share Pledge"	meaning the pledge of 9,000,000 shares provided by Mr. Zhenjun Zi, one of the Company's controlling shareholders at the time of the Prospectus to Hangzhou Gaoxin Technology Innovation Services Ltd. (杭州高新科技創業服務有限公司), on January 30, 2019
"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

"Surgical Valve"	Surgical Valve, our surgical valve replacement product candidate
"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 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
"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 products
"VenusA-Pro Valve"	VenusA-Pro Valve, one of our TAVR product candidates
"VenusA-Valve"	VenusA-Valve System, one of our TAVR products
"VenusP-Valve"	VenusP-Valve System, our TPVR product candidate
	By Order of the Boa

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

Hangzhou, March 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.