招銀国际 CMB INTERNATIONAL
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Venus Medtech (Hangzhou) Inc. (2500 HK)

First mover in the rapid-growing transcatheter valve market

BUY (Initiation)

Target Price	**HK$54.9**
Up/Downside	**+23%**
Current Price	**HK$44.60**

Venus Medtech is the leading transcatheter heart valve medical device maker and dominated China transcatheter Aortic Valve Replacement (TAVR) market with 79.3% market share in terms of implantation volume in 2018. China TAVR market is in its infancy with the first TAVR from Venus Medtech commercialized in 2017. We are bullish on China TAVR market given the large pool of untapped patients and more physicians and hospitals eligible for performing TAVR procedures. We like Venus Medtech, the TAVR pioneer and initiate BUY with DCF-based TP of HK$54.9.

- **Tapping into the fast-growing transcatheter valve replacement market**. According to Frost & Sullivan (F&S), the penetration rate of TAVR procedures was only 3.5%/ 0.1% in global/ China market in 2018. F&S forecasts China TAVR market to grow from US$28.7mn in 2018 to US$956.6mn in 2025E with 65.0% CAGR, driven by 1) the improving penetration of TAVR, 2) the increasing number of hospitals and physicians eligible for TAVR procedures and 3) indication expansion to low-risk patients. Venus Medtech's VenusA-Valve was the first approved TAVR by NMPA in 2017.
- **Diversifying product portfolio with ancillary products to provide comprehensive valve replacement solution.** Venus Medtech has a comprehensive product pipeline covering all four heart valves, namely TAVR, TPVR, TMVR and TTVR. Beyond that, it has key ancillary products, including vavuloplasty balloons (V8/TAV8) and CEP device (TriGUARD3) to provide one-stop transcatheter heart valve replacement solution, which allows the Company to implement a flexible pricing strategy and provides diversified revenue sources.
- **Moderate near-term impact from COVID-19 outbreak**. In our view, the outbreak of COVID-19 will have moderate negative impact to the business in 1H20E. Due to the extension of CNY holidays, there have been delays in production and suspension of marketing activities. Meanwhile, TAVR surgeries will also be suspended during Feb due to the disease outbreak. However, we expect sales recovery from 2Q20E because of rigid demand in TAVR treatment for patients.
- **The profitable year estimated to be 2020E.** We expect total revenue to grow 97%/ 79%/ 130% YoY in FY19E/20E/21E and estimate VenusA-Valve sales unit to be 1,550/ 2,700/ 6,000 in FY19E/20E/21E. Venus Medtech recorded net losses of RMB157mn/ RMB300mn in FY17A/18A. We expect it may continue to incur net loss of RMB341mn in FY19E and may generate net profit of RMB46mn/ RMB316mn in FY20E/21E.
- **Initiate BUY with TP of HK$54.9**. Venus Medtech's future cash flow relies on sales ramp up of VenusA-Valve and further commercialization of pipeline products. We believe DCF would be a reasonable valuation method to value the Company. We derive TP of HK$54.9 based on a 11-year DCF model (WACC:10.6%, terminal growth rate: 4%).

Earnings Summary

(YE 31 Dec)	FY17A	FY18A	FY19E	FY20E	FY21E
Revenue (RMB mn)	18	115	227	407	934
YoY growth (%)	N/A	535	97	79	130
Net profit (RMB mn)	(157)	(300)	(341)	46	316
EPS (RMB)	N/A	N/A	(0.84)	0.11	0.78
YoY growth (%)	N/A	N/A	N/A	N/A	591
P/E (x)	N/A	N/A	N/A	341	49
P/B (x)	N/A	N/A	N/A	6	5
ROE (%)	(193)	(64)	(13)	2	11
Net gearing (%)	Net cash	Net cash	Net cash	Net cash	Net cash

Source: Company data, CMBIS estimates

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Mkt. Cap. (HK$ mn)	18,039
Avg. 3mths t/o (HK$ mn)	N/A
52W High/Low (HK$)	47.35/35.20
Total Issued Shares (mn)	183

Source: Bloomberg

Shareholding Structure

Management	25.93%
Employee	3.48%
Pre-IPO investors	48.27%
H-share free float	22.33%

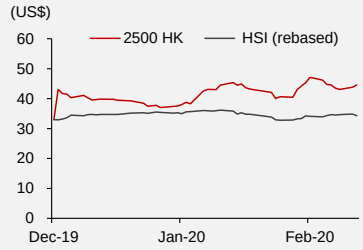
Source : HKEx, Bloomberg

Share performance

	Absolute	Relative
1-mth	-1.6%	2.3%
3-mth	N/A	N/A
6-mth	N/A	N/A

Source: Bloomberg

12-mth price performance



Source: Bloomberg

Auditor: Ernst & Young

Contents

Investment Thesis

Venus Medtech was founded in 2009 in Hangzhou, China with R&D centers in the US and China. Its VenusA-Valve is the first TAVR approved by NMPA and commercialized in China with 79.3% market share in terms of implantation volume in 2018. It developed a comprehensive product portfolio of six self-developed transcatheter heart valve replacement products and three key ancillary products.

Tapping into the fast-growing transcatheter aortic valve replacement market

Transcatheter valve replacement is an emerging treatment to the valvular heart disease, which causes smaller trauma and has a shorter postoperative recovery period and is eligible to inoperable patients. Valvular heart diseases referred to the damage to or defect in aortic, pulmonary, mitral or tricuspid valves.

According to F&S, in 2018, the number of aortic stenosis and regurgitation patients reached 45.3mn worldwide and 8.0mn in China. TAVR is suitable for severe aortic stenosis patients who are not eligible for SAVR and TAVR is also performed on low to intermediate surgical risk patients. Global TAVR eligible patients reached 3.62mn and the number of global TAVR procedures reached 127,800 in 2018. The number of TAVR eligible patients in China was 742,100 and the number of China TAVR procedures was approximately 1,000 in 2018. The penetration rate of TAVR procedures was only 3.5%/ 0.1% in global/ China market in 2018. F&S forecasts the global TAVR market to grow from US$4.1bn in 2018 to US$10.4bn in 2025E with 14.3% CAGR and China TAVR market to grow from US$28.7mn in 2018 to US$956.6mn in 2025E with 65.0% CAGR, driven by 1) the improving penetration of TAVR, 2) the increasing number of hospitals and physicians able to perform TAVR procedures, and 3) indication expansion to low-risk patients.

Broad product portfolio covering all four transcatheter heat valves

Venus Medtech has developed a product portfolio of six self-developed transcatheter heart valve replacement (TAVR) products. It now has a comprehensive product pipeline covering all four heart valves, namely TAVR, TPVR, TMVR and TTVR, including one marketed TAVR product, two upgrading TAVR products (VenusA-Plus in registration stage and VenusA-Pilot in pre-clinical stage), one approaching approved TPVR product (VenusP-Valve), one TMVR and one TTVR in design stage.

There are 10 TAVR products globally and three TAVR products marketed in China. VenusA-Valve is the first approved TAVR in China. VenusA-Valve recorded sales of RMB17.3mn/ RMB113.7mn/ RMB85.7mn in FY17A/18A/5M19, respectively, due to 1) the untapped TAVR market in China, and 2) the first mover advantage. We expect VenusA-Valve's unit sales to be 1,550/ 2,700/ 6,000 in FY19E/20E/21E, driven by 1) the improving penetration with more hospitals and physicians eligible for TAVR procedures, and 2) launch of upgrading products (VenusA-Plus and VenusA-Pilot) with retrieving and steerable functions into DCS. VenusA-Valve is also non-inferior to the international peers and has been strengthened for highly calcified aortic value leaflet, which is more suitable to Chinese patients.

For TPVR, there is currently no commercialized product in China. Venus Medtech has completed the clinical trial in China for VenusP-Valve. VenusP-Valve was granted Special Approval Procedures of Innovative Medical Devices by the NMPA in Apr 2019 and may be approved in 2021E. For overseas market, Venus Medtech filed for the CE Marking in Apr 2019 and may be approved in 2H20E. VenusP-Valve is also in the process of animal trials in the US.

Diversifying product portfolio into ancillary products

Beyond the core heart valve products, Venus Medtech also has key ancillary products for valve replacement solutions including vavuloplasty balloons (V8/TAV8) and CEP device (TriGUARD3) to provide one-stop transcatheter heart valve disease solution, which improves clinical efficacy, allows the Company to implement a flexible pricing strategy and diversify revenue sources.

CEP devices are relatively new products to market and designed to decrease the incidence of stroke during PCI procedures. Currently only one CEP device, Sentinel from Boston Scientific, received FDA approval in 2017. As per F&S, global CEP device market size was US$53mn in 2018 and will grow to US$461.0mn in 2025E with a 36.2% CAGR. Venus Medtech's CEP device, TriGUARD3, has completed clinical trials. It is in the process of applying for CE marking and expected to apply for an import product license with NMPA afterwards. We expect that it may get CE mark in 3Q20E and receive approvals from US FDA and NMPA in 2021E.

Balloon aortic valvuloplasty catheters, V8 and TAV8, have received FDA 510(k) clearance and CE marking. TAV8 has applied for an import product license with NMPA and currently in clinical trial in China and we estimate TAV8 to be approved by NMPA in 2021E. As per F&S, global market size for aortic valvuloplasty balloons reached US$233.5mn in 2018 and may increase at 14.7% CAGR in 2018-25E. The competition in aortic valvuloplasty industry is mild with five products marketed globally.

Moderate near-term impact from COVID-19 outbreak

In our view, the outbreak of COVID-19 will have moderate negative impact to the business in 1H20E. Due to the extension of CNY holidays, there have been delays in production and suspension of marketing activities. Meanwhile, TAVR surgeries will also be suspended during Feb due to the disease outbreak. However, we expect sales will recovery from 2Q20E because of rigid demand in TAVR treatment for patients.

Revenue to show 101% CAGR in FY18A-21E

We expect total revenue to grow 97%/ 79%/ 130% YoY to be RMB227mn/ RMB407mn/ RMB934mn in FY19E/20E/21E, mainly driven by the fast-growing VenusA-Valve and new product launches. We expect VenusA-Valve will contribute the most revenue to the Company. We estimate VenusA-Valve will account for 99%/ 89%/ 79% of FY19E/20E/21E total revenue and expect VenusA-Valve to record sales units of 1,550/ 2,700/ 6,000 FY19E/20E/21E.

Turn profitable from 2020E

Venus Medtech recorded net losses of RMB157mn/ RMB300mn in FY17A/18A. We expect it may continue to incur net loss of RMB341mn in FY19E and may generate net profit of RMB46mn/ RMB316mn in FY20E/21E.

Initiate BUY with TP of HK$54.9

Venus Medtech commercialized the first product VenusA-Valve in 2017 and its future cash flows will rely on sales ramp up of VenusA-Valve and further commercialization of pipeline products. We believe DCF would be a reasonable valuation method. We derive TP of HK$54.9 based on a 11-year DCF model (WACC:10.6%, terminal growth rate: 4%).

Investment risks

(1) Sales mainly rely on one product, VenusA-Valve;
(2) Growth depends on the success of pipeline product candidates;
(3) Relatively limited experience in marketing and sales of products;
(4) Fierce competition and downward pricing pressure;
(5) Limited reimbursement restricts volume growth.

Company Overview

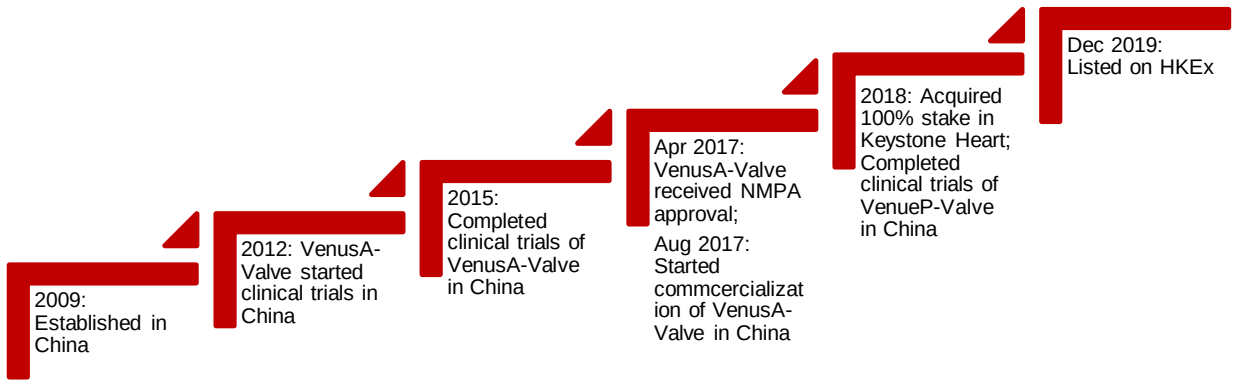
Pioneer in China's transcatheter heart valve market

Established in 2009, Venus Medtech (Hangzhou) Inc. (Venus Medtech) mainly focuses on the design, development and commercialization of transcatheter heart valve products. Its self-developed product, VenusA-Valve, is the first TAVR product approved by National Medical Products Administration (NMPA) and commercialized in China. The Company has become a dominant leading player in China's transcatheter heart valve with a 79.3% market share by implantation volume in 2018, according to F&S.

Venus Medtech has developed a product portfolio of six self-developed of transcatheter heart valve replacement (TAVR) products and three key ancillary products. It now has a comprehensive product pipeline covering all four heart valves, namely TAVR, TPVR, TMVR and TTVR, including one marketed TAVR product (VenusA-Valve), one TAVR product in the registration stage (VenusA-Plus), one pre-clinical stage TAVR product (VenusA-Pilot), one approaching approved TPVR product (VenusP-Valve), one TMVR product and one TTVR product in design stage. Beyond the core heart valve products, the Company also has key ancillary products for valve replacement solutions including vavuloplasty ballons (V8/TAV8) and CEP device (TriGUARD3) to further enrich product portfolio for transcatheter heart valve replacement procedures.

The Company also owns robust intellectual property (IP) portfolio with 193 issued patents and 196 patent applications as of Nov 2019, building a high entry barrier for potential competitors in transcatheter heart valve industry.

Figure 1: Key milestones of Venus Medtech



Source: Company data, CMBIS

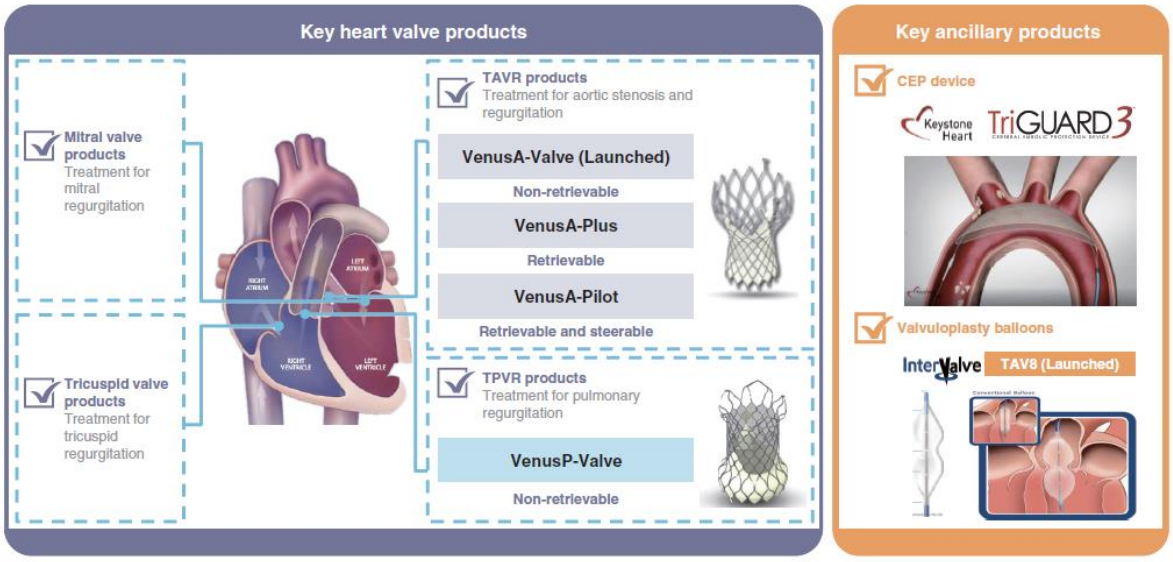
Strong R&D platform in transcatheter heart vavle products

Venus Medtech commercialized its first TAVR product in China, VenusA-Valve, in Aug 2017. To date, Venus Medtech has developed a comprehensive product portfolio to address the unmet medical needs of TAVR procedures. Its product portfolio (including pipeline products) covers transcatheter procedures of all four heart valves (i.e. aortic (主动脉), pulmonary (肺动脉), mitral (二尖瓣) and tricuspid valves (三尖瓣)).

Beyond the core heart valve products, the Company also has key ancillary products for valve replacement solutions including vavuloplasty ballons (V8/TAV8) and CEP device (TriGUARD3) to further enrich product portfolio for transcatheter heart valve replacement procedures.

With comprehensive products covering the major transcatheter heart valve replacement procedures, Venus Medtech will be able to provide one-stop solutions to patients with structural heart valve diseases. For instance, the Company will be able to offer VenusA-Valve, TAV8 and TriGUARD3 as one package. This will help to build customer loyalty to the Company's products.

Figure 2: Venus Medtech's products and product candidates (As of Nov 2019)

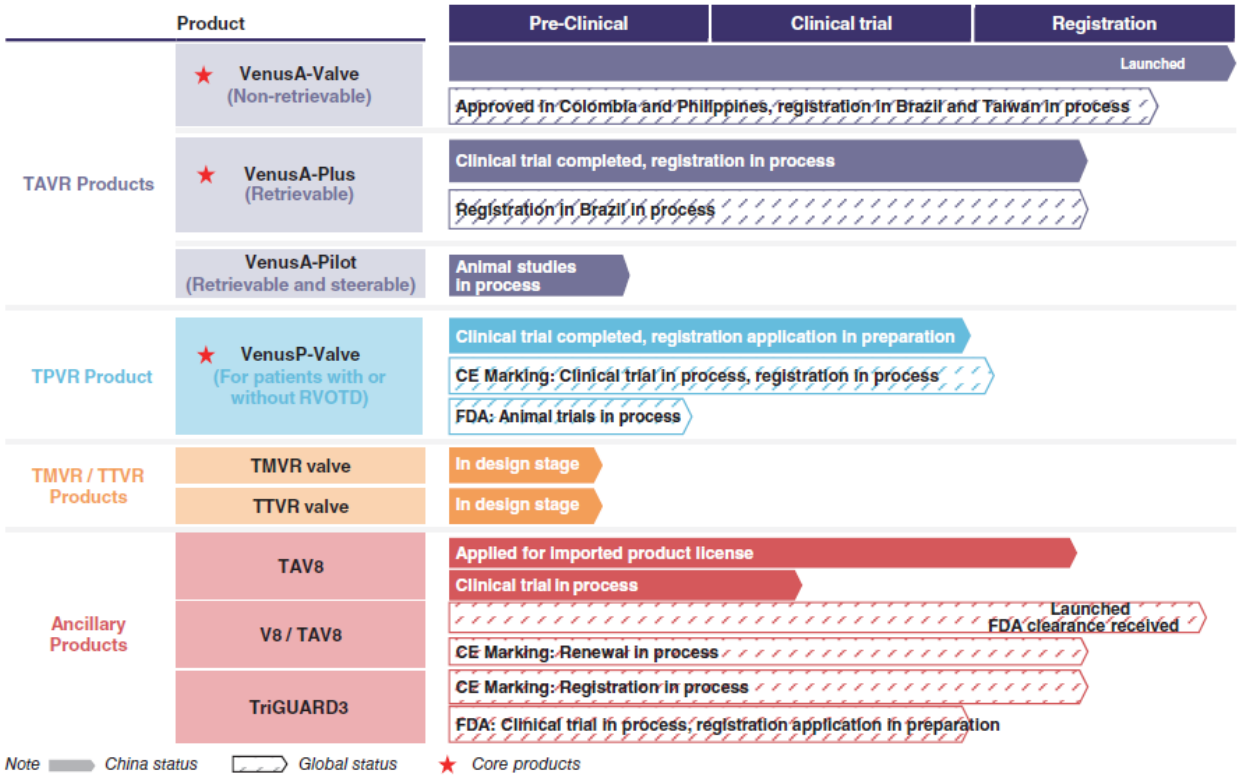


Source: Company data, CMBIS

VenusP-Valve has completed the clinical trial in China in Jan 2018. In Apr 2019, VenusP-Valve was approved by NMPA to be eligible for the Special Approval Procedures of Innovative Medical Devices and may obtain approval from NMPA in 2021E. Venus Medtech also filed registration application to EMA in Apr 2019 and is expected to be approved by EMA in 2H20E. In addition, VenusP-Valve is going through animal trials in the US. We expect VenusP-Valve, a self-developed TPVR product candidate, to be the first TPVR product approved by NMPA, the first self-expanding TPVR product globally and the first TPVR product for patients with RVOTD after receiving TAP treatment globally.

Venus Medtech's subsidiary, Keystone, has completed the clinical trial procedures and follow-up with the enrolled patients for TriGUARD3 and and expects to file for FDA registration in 1H20E. Keystone submitted the application of CE Marking for TriGUARD3 in Feb 2018. The Company plans to apply for an import product license for TriGUARD3 with the NMPA after receipt of the CE Marking. We expect TriGUARD3 be approved by EMA in 3Q20E and to receive approvals from US FDA and NMPA in 2021E.

Figure 3: Venus Medtech's products and product candidates (As of Nov 2019)



"Retrievable" function allows physicians to retrieve the valve during a TAVR procedure;
"Steerable" function allows physicians to steer the position of 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 VenusP-Valve

Source: Company data, CMBIS

As of Nov 2019, Venus Medtech has a R&D team of employees and 39 R&D staff was based in Hangzhou, China, 5 staff based in US and 6 staff based in Israel. The R&D team is led by Mr. Lim, former CTO of Transcatheter Technologies GmbH and a veteran with more than 15 years' experience in the industry. The R&D staff in the US is led by Mr. Zeng, who has over 15 years of experience in the US medical device industry with extensive expertise in product development and served as the director for LifeTech Scientific Corporation (1302 HK). The R&D team of Keystone is led by Mr. Amit Ashkenazi, who has extensive experience in R&D of medical devices.

The R&D team in China is divided into four sub-teams, including valve team, delivery system team, biomaterial team and the laboratory. The valve team is primarily responsible for the design and development of artificial valves, including PAV and PPV, and their constituent parts. The delivery system team is responsible for designing and developing delivery systems for the Company's transcatheter heart valve systems, including DCS, guide wire, sheath, dilator and other complementary products. The biomaterial team is in charge of studying and designing biomaterials for valve systems and the laboratory is mainly responsible for testing valve products to help ensure their safety and efficacy.

As of Nov 2019, Venus Medtech had a total of 389 patents and patent applications, including 93 issued patents, 60 patent applications in China and 100 issued patents and 136 patent applications overseas. Among the 389 patents and patent applications, 175 were self-developed, 142 were acquired from third parties through purchasing and 72 were acquired through business acquisition.

Significant first-mover advantages

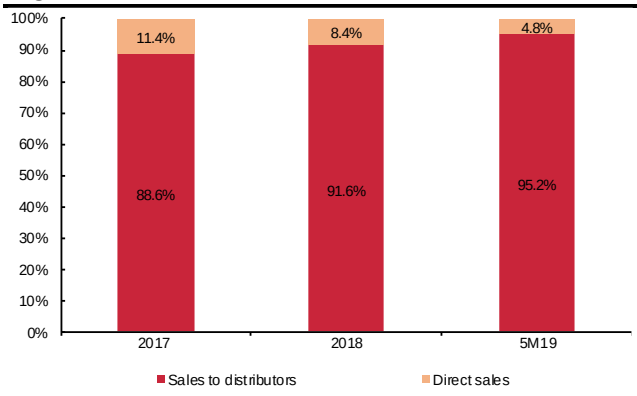
As transcatheter heart valve procedures are not well recognised by doctors, it involves many efforts in market education. Venus Medtech's sales team deeply engages with physicians and hospitals, by providing professional advice as well as assistance throughout the heart valve replacement procedures from candidate screening, operation assistance to follow-up visit post operations. The Company's sales team also assists with the implementation of TAVR training program for the purpose of product promotions. We think there is still a long way to go for TAVR market education. As the first mover in China, Venue Medtech enjoys good brand awareness and builds up strong customer royalty through extensive trainings offered to doctors.

As of 31 May 2019, 132 hospitals in China had conducted TAVR procedures using VenusA-Valve, and the Company divided them into three tiers. Tier 1 hospitals refer to the top four hospitals in TAVR field in China, including Beijing Fuwai Hospital (北京阜外心血管病医院), West China Hospital of Sichuan University (华西医院), the Second Affiliated Hospital of Zhejiang University School of Medicine (浙江大学附属第二医院), and Shanghai Zhongshan Fudan University (上海中山医院). According to F&S, each Tier 1 hospital completed over 200 TAVR procedures (including clinical trials) in 2018 and each can serve as a training center for physicians to learn and practice TAVR procedures. Tier 2 hospitals mainly refer to hospitals with the ability to conduct the implantation procedure or have completed the procedure independently. Tier 3 hospitals are hospitals with recently established procedure centers without the ability to independently complete procedures.

There are still substantial unmet demands for TAVR procedure. According to F&S, in 2018, the four Tier I hospitals that conducted TAVR procedures using VenusA-Valve, performed a total of approximately 800 TAVR procedures, while over 4,000 patients in these four hospitals were eligible for TAVR procedure. According to F&S, over 150 hospitals in China performed TAVR procedures in 2018. We believe Venus Medtech will penetrate into more hospitals by leveraging its direct access to KOLs (Key Opinion Leaders) in cardiac interventional therapy, providing systematic training to physicians, and increasing TAVR awareness among hospitals, physicians and patients.

Venus Medtech sells products both directly to hospitals and through distributors. As a common practice, the Company sells a significantly portion of the products to distributors who resell the products to hospitals. Due to the high technology and knowledge requirement, TAVR distributors are only responsible for distributing and cannot provide value-added services, while physician educations are provided directly by Venus Medtech. As of Nov 2019, Venus Medtech had 48 distributors and an inhouse direct sales team in China. In 2018, sales to distributors accounted for 92% of the total revenue.

Figure 4: Breakdown of sales to distributors and direct sales



Source: Company data, CMBIS

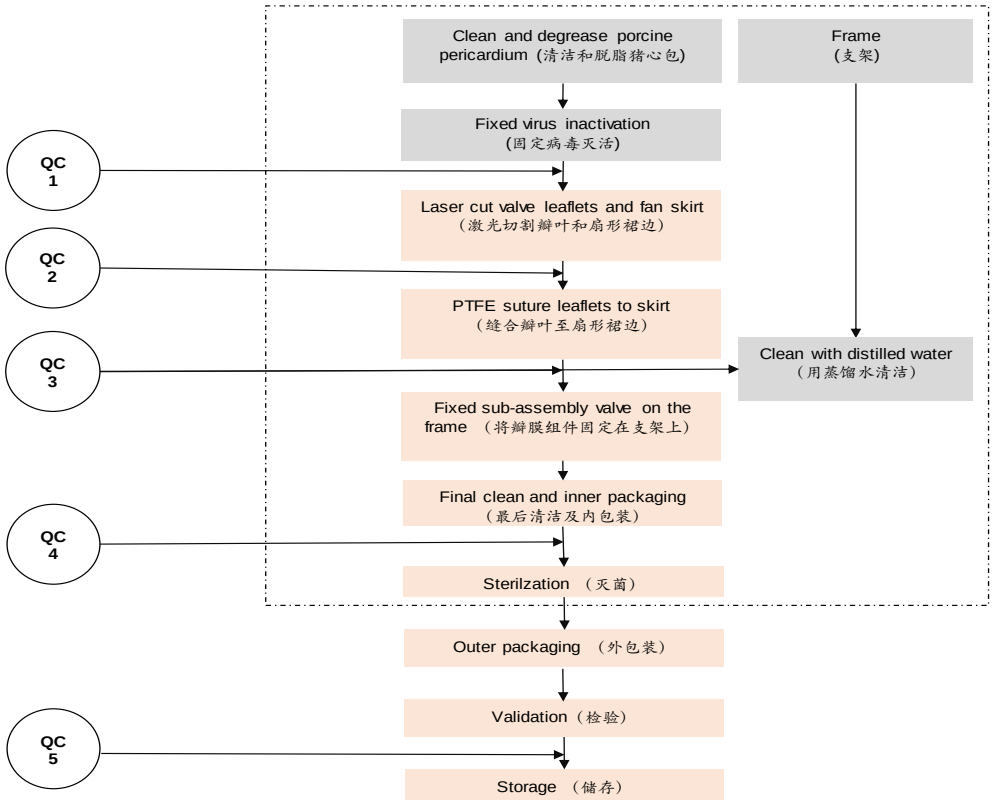
High barrier in manufacturing

Venus Medtech already has sufficient manufacturing facilities meeting GMP requirements in the US, EU and China. Venus Medtech has built state-of-the-art manufacturing facilities in Hangzhou, China with an aggregate GFA of approximately 3,500 sqm. The Company also leased manufacturing facilities in Israel with an aggregate GFA of around 816 sqm. Manufacturing process of heart valve products is complex and technologically challenging.

Producing VenusA-Valve involves 10 steps in delicately-controlled environment and production of a single valve typically requires on average 16-18 hours per person. Venus Medtech has accumulated extensive expertise and know-how in manufacturing heart valve products and obtained several patents for tissue engineering technology.

Experienced manufacturing staff is essential for the production of heart valve products. The manufacturing process of the PAV and PPV is highly labor intensive, since the valve leaflets are sutured to the stent frame manually. Typically, Venus Medtech requires new employees to undergo extensive training before they commence work. The training continues with respect to specific steps in the production process after employees commence work on the production lines.

Figure 5: Manufacturing process of artificial valves



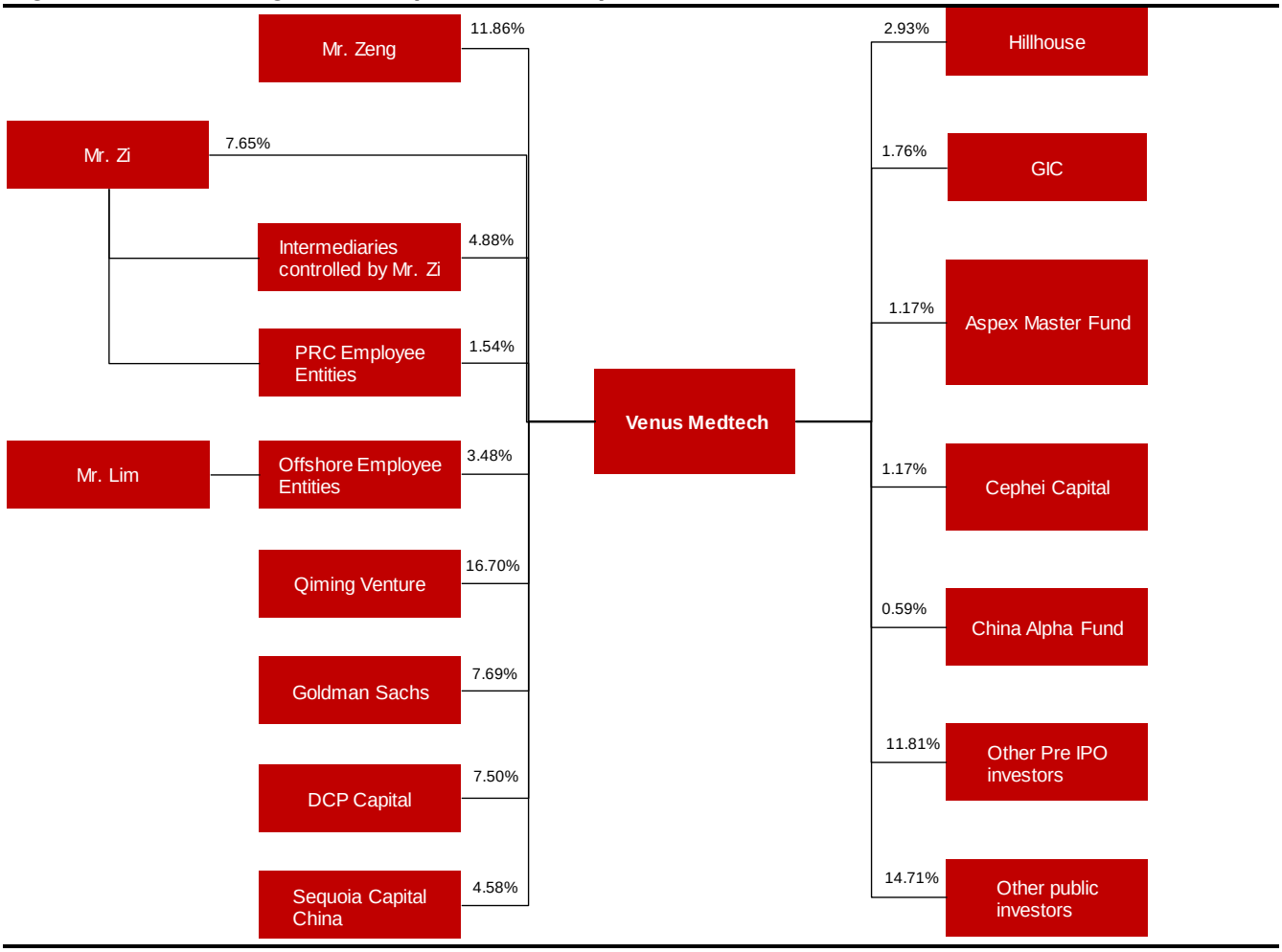
Source: Company data, CMBIS

Shareholding structure

Post IPO, Mr. Min Frank Zeng, Founder and Chairman of the Company, held 11.86% stake and Mr. Zhenjun Zi, General Manager of the Company, controlled a combined 14.06% stake.

Pre-IPO investors included Qiming Venture Partners, Goldman Sachs, DCP Capitals, Sequoia Capital China, etc. Venus raised HK$2.78bn net proceeds from its IPO in Dec 2019. H-share offering attracted cornerstone investors, such as Hillhouse, GIC, Aspex Management, Cephei Capital and China Alpha.

Figure 6: Shareholding structure (As of Feb 2020)



Source: Company data, CMBIS

Riding the fast-growing transcatheter heart valve market

Wide prevalence of valvular heart diseases

Narrowly defined, structural heart disease refers to the pathophysiological changes of the heart caused by anatomical abnormalities in the heart structure, including valvular disease (心脏瓣膜疾病), congenital heart disease （先天性心脏病）, cardiomyopathy and ventricular abnormalities （心肌症及心室异常）. Valvular heart disease is caused by the damage to or a defect in one of the four heart valves: aortic (主动脉瓣), pulmonary (肺动脉瓣), mitral (二尖瓣) and tricuspid valves (三尖瓣). Normal valves facilitate proper blood flows, and if they become too narrow and hardened (stenosis, 狭窄) or are unable to close completely (regurgitation, 返流), normal blood flows will be disrupted. In 2018, about 209.3mn patients suffered from valvular heart disease globally, which caused about 2.6mn deaths during that year.

Aortic valve disease

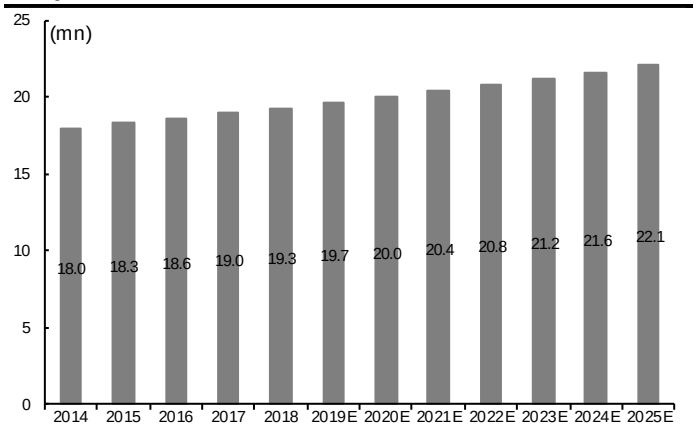
Aortic valve disease mainly consists of aortic stenosis and aortic regurgitation, both strongly related to aging population. In 2018, the global patient population affected by vast aortic valve disease reached 45.3mn, which is expected to climb to 51.9mn in 2025E, mainly driven by the increasing prevalence of rheumatic fever (风湿性热), congenital aortic valve structural abnormality (先天性主动脉瓣结构异常) or senile aortic valve calcification (老年性主动脉瓣钙化).

Aortic stenosis:

Aortic stenosis is the narrowing of the aortic valve that obstructs blood flow from the left ventricle to the ascending aorta during systole. Causes of aortic stenosis include a congenital bicuspid valve, idiopathic degenerative sclerosis with calcification and rheumatic fever. The mortality rate for patients that have progressed to the symptomatic stage of aortic stenosis is higher than 50% in two years unless aortic-valve replacement is performed properly.

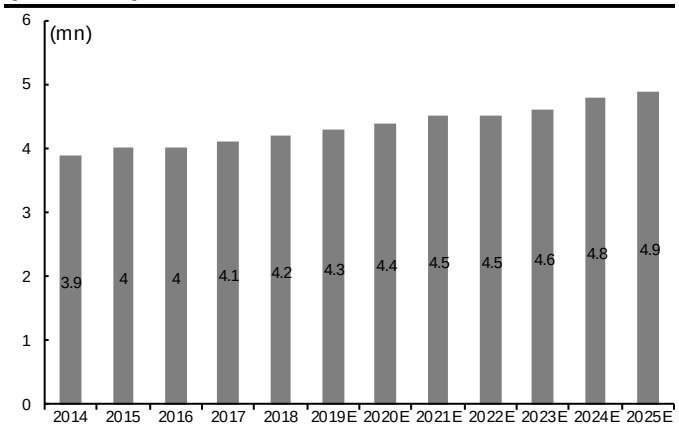
F&S estimates that globally, the number of aortic stenosis increased from 18mn in 2014 to 19.3mn in 2018 and is expected to increase to 22.1mn in 2025E.

Figure 7: Global prevalence of aortic stenosis (2014-25E)



Source: F&S, CMBIS; Note: Aortic stenosis includes congenital aortic stenosis, rheumatic aortic stenosis and degenerative aortic stenosis

Figure 8: Prevalence of aortic stenosis in China (2014-25E)



Source: F&S, CMBIS; Note: Aortic stenosis includes congenital aortic stenosis, rheumatic aortic stenosis and degenerative aortic stenosis

In China, the number of aortic stenosis patients may increase from 4.2mn in 2018 to 4.9mn in 2025E, according to F&S. The growth will mainly be driven by the increasing prevalence of rheumatic valvular heart disease.

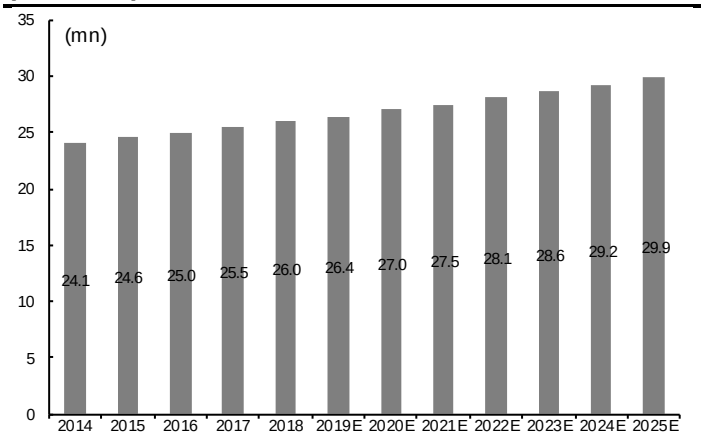
Balloon valvotomy is used primarily in children and very young adults with congenital aortic stenosis. SAVR is a common choice for patients less than 65 years old with low surgical risk. TAVR is usually performed on patients ineligible for surgeries as well as patients over 65 years old with intermediate to high surgical risk, and in Aug 2019, FDA expanded TAVR application to patients who are at low surgical risk.

Aortic regurgitation:

Aortic regurgitation is the incomplete closure of the aortic valve causing backflow of blood from the aorta into the left ventricle during diastole. Pathological causes of aortic regurgitation degeneration (瓣膜退化), aortic root dissection (主动脉根部扩大), rheumatic fever, endocarditis (心内膜炎), myxomatous degeneration (粘液状变性), aortic root dissection (主动脉根部剥离) and connective tissue or rheumatologic disorders.

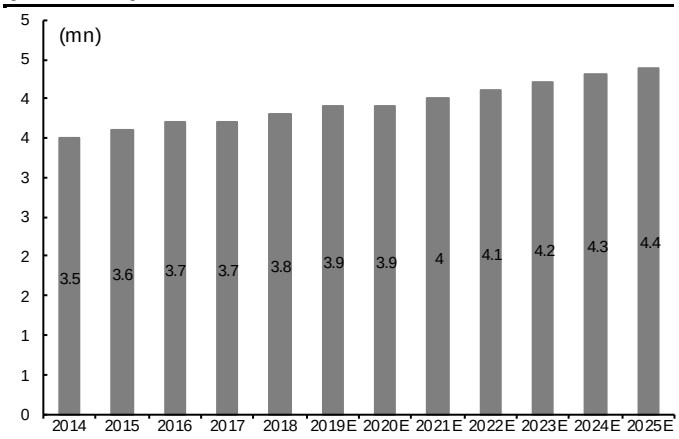
F&S estimates that globally, the aortic regurgitation patient population increased from 24.1mn in 2014 to 26.0mn in 2018 and will reach 29.9mn in 2025E.

Figure 9: Global prevalence of aortic regurgitation (2014-25E)



Source: F&S, CMBIS

Figure 10: Prevalence of aortic regurgitation in China (2014-25E)



Source: F&S, CMBIS

According to F&S, in China, the number of aortic regurgitation patients has climbed from 3.5mn in 2014 to 3.8mn in 2018, and may increase to 4.4mn in 2025E. Aortic regurgitation can be treated with surgical aortic valve replacement, or less commonly, with valve repair. For SAVR, an aortic bioprosthetic valve requires anticoagulation for 3-6 months postoperatively, and a mechanical valve requires lifetime anticoagulation using warfarin.

According to F&S, there is an increasing population of aortic stenosis (主动脉瓣狭窄) and aortic regurgitation (主动脉瓣反流). Globally, the number of aortic stenosis and aortic regurgitation patients reached 45.3mn in 2018 and is expected to increase to 51.9mn in 2025E. In China, the aortic valve disease affected population increased from 7.4mn in 2014 to 8.0mn in 2018 and is projected to further increase to 9.2mn in 2025E.

The application of TAVR to aortic stenosis and regurgitation patients has been increasing. With the growing number of TAVR procedures and the development of TAVR technologies, we expect the industry to grow fast worldwide and in China.

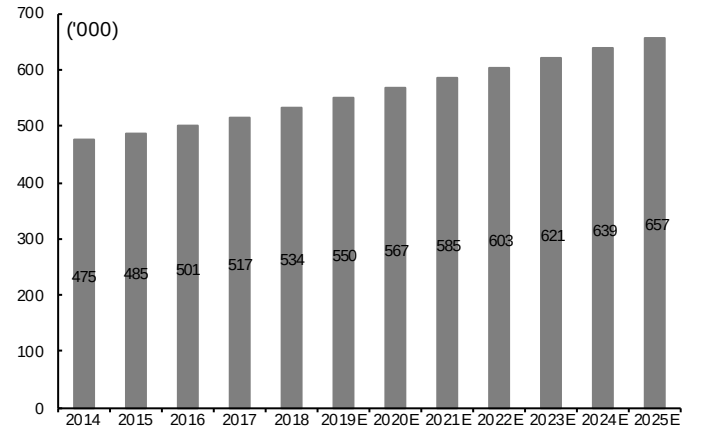
Pulmonary valve disease

Pulmonary valve disease mainly consists of pulmonary regurgitation (PR) and pulmonary stenosis. PR is pulmonic valve's inability to close completely that causes blood to flow from the pulmonary artery into the right ventricle during diastole. The most common and significantly cause of PR are iatrogenic related (医源性相关), including degeneration of right ventribular outflow tract (RVOT, 右心室流出道) from previous surgeries to treat patients of tetralogy of fallot (ToF,法洛氏四联症) and other congenital heart diseases.

During their teenage, ToF patients need to receive a third procedure to repair the function of their pulmonary valve. In China, such pulmonary valve function repairs are usually performed through open-chest surgeries which may result in major trauma and slow recovery. In the US, TPVR is usually performed with relatively lower risk and minimal trauma. Such patients may need additional valve-in-valve procedures every 10 to 15 years after the initial TPVR procedure.

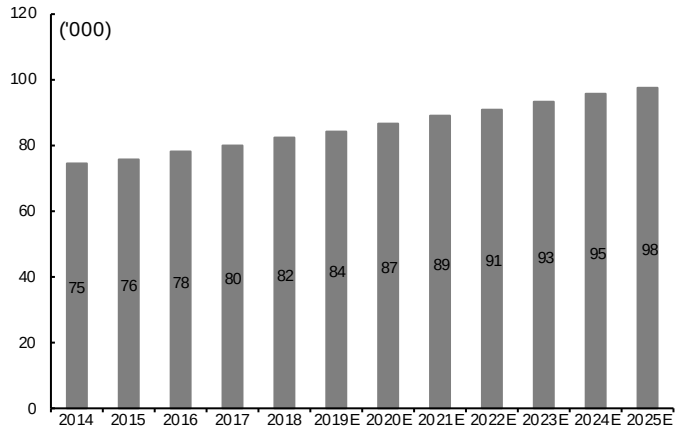
According to F&S, globally, the number of ToF patients increased from 475,400 in 2014 to 533,500 in 2018 and may increase to 657,300 in 2025E. In China, F&S estimates that the number of ToF patients increased from 74,600 in 2014 to 82,100 in 2018 and will increase to 97,700 in 2025E.

Figure 11: Global prevalence of ToF (2014-25E)



Source: F&S, CMBIS

Figure 12: Prevalence of ToF in China (2014-25E)



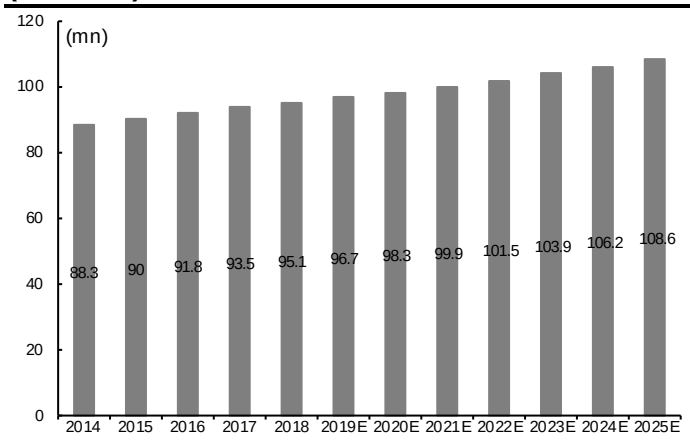
Source: F&S, CMBIS

Mitral valve disease

Mitral valve disease mainly consists of mitral regurgitation (MR, 二尖瓣反流), mitral stenosis (二尖瓣狭窄) and mitral valve prolapse (二尖瓣脱垂). MR is the mitral valve's inability to close completely that causes blood to flow from the left ventricle into the left atrium during ventricular systole. MR's prevalence rate increases with age, and is approximately 10% among the population over 75 years old in western countries.

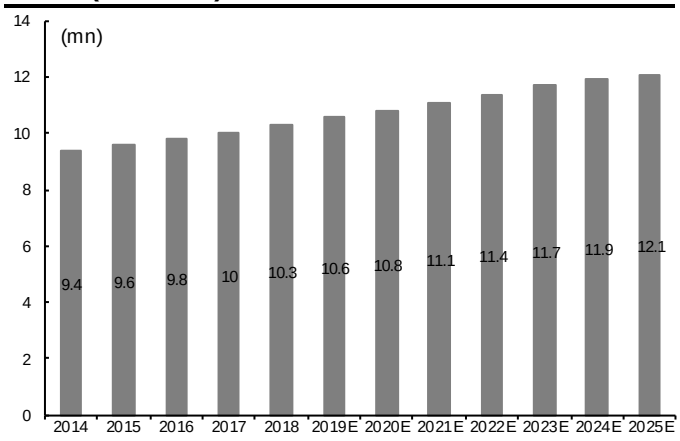
Globally, the number of MR patients increased from 88.3mn in 2014 to 95.1mn in 2018 and is expected to reach 108.6mn in 2025E, according to F&S. In China, F&S estimates that the number of MR patients increased from 9.4mn in 2014 to 10.3mn in 2018 and will increase to 12.1mn in 2025E.

Figure 13: Global prevalence of Mitral Regurgitation (2014-25E)



Source: F&S, CMBIS

Figure 14: Prevalence of Mitral Regurgitation in China (2014-25E)



Source: F&S, CMBIS

Venus Medtech is developing Venus Mitral Valve to treat patients with MR which accounts for approximately 65% of all mitral valve disease prevalence.

As for severe MR, mitral valve replacement or repair under extracorporeal circulation through open-chest surgery is the standard treatment. As an alternative to open-chest surgery, MitraClip is the only transcatheter mitral valve repair product that currently has received FDA approval, and there is no marketed TMVR product worldwide.

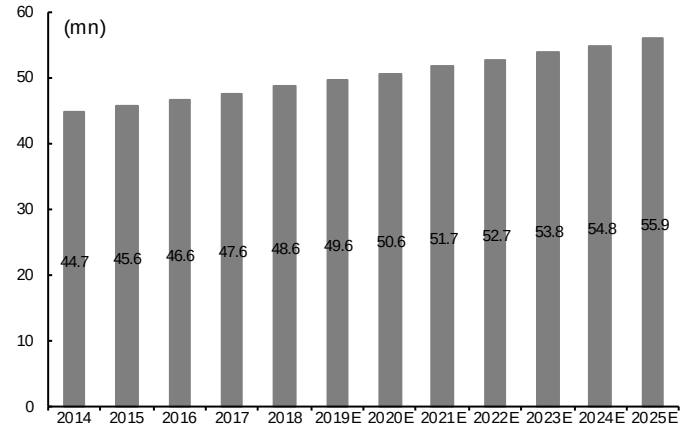
Due to high risks associated with invasive surgeries, not many MR patients have received surgical treatment. For instance, in China, less than 1% of MR patients received surgical treatment in 2018. F&S forecasts the global market size of TMVR to reach US$17.4bn within the first 10 years after the first TMVR product launches and eventually grow to 3-4 times of the TAVR market size.

Tricuspid valve disease

Tricuspid valve disease mainly consists of tricuspid regurgitation (TR, 三尖瓣反流) and tricuspid stenosis (三尖瓣狭窄). TR is the tricuspid valve's inability to close completely that causes blood to flow from the right ventricle to the right atrium during systole. The most common cause is dilation of the right ventricle.

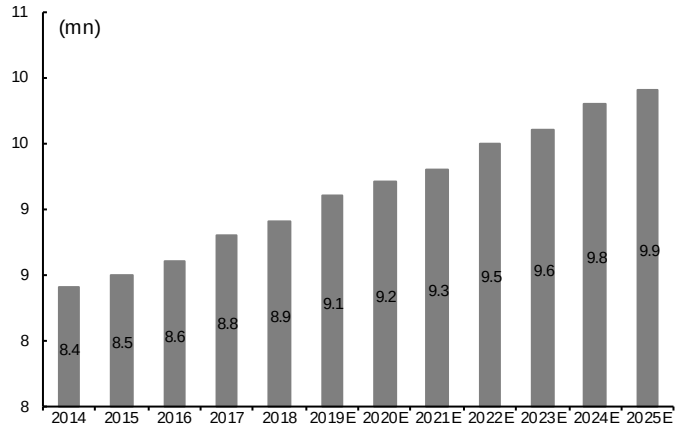
Globally, the number of TR patients increased from 44.7mn in 2014 to 48.6mn in 2018 and is expected to reach 55.9mn in 2025E, according to F&S. In China, F&S estimates that the number of TR patients increased from 8.4mn in 2014 to 8.9mn in 2018 and will increase to 9.9mn in 2025E.

Figure 15: Global prevalence of Tricuspid Regurgitation (2014-25E)



Source: F&S, CMBIS

Figure 16: Prevalence of Tricuspid Regurgitation in China (2014-25E)



Source: F&S, CMBIS

Mild TR does not require medical action, but patients with severe TR need to receive operations, including annuloplasty (瓣环成形术), valve repair or valve replacement by open-chest surgeries. Valve repair or replacement is recommended when the TR is due to primary valve abnormalities or when annuloplasty is not technically feasible. Currently, there is no TTVR pipeline product at the clinical trial stage worldwide.

Venus Medtech is designing the Venus Tricuspid Valve to treat patients with TR, which accounts for around 60% of all prevalence of tricuspid valve disease.

China TAVR market to grow at 65.0% CAGR in 2018-25E

TAVR to penetrate into intermediate to low-risk patients

Currently, valvular heart disease procedures are generally divided into three categories: traditional open-chest surgery, minimally invasive valve surgery and transcatheter valve therapy (TVT). Among the three types of procedures, TVT are similarly effective but safer than the other two alternatives.

There are three common AS procedures, balloon valvotomy (瓣膜球囊扩张术), surgical aortic valve replacement (SAVR, 外科手术置换主动脉瓣膜) and transcatheter aortic valve replacement (TAVR, 经导管主动脉瓣膜置换术). Traditional surgical aortic valve replacements require doctors to make a big incision on patients' chests and open their hearts to put the prosthetic valve inside manually, which poses risks of wrong positioning of valve and loss of blood.

Cardiac surgeons commonly use risk models of Society of Thoracic Surgeons (STS) score or EUROSCORE II (EUROII) to identify eligible patients for TAVR. Patients eligible for TAVR consisted of 1) SAVR ineligible patients, 2) patients at high risk measured by STS score greater than 8%, 3) patients at intermediate risk measured by STS score between 4% to 8%, and 4) patients at low surgical risk measured by a STS score lower than 4%.

Prior to TAVR, SAVR and balloon aortic valvuloplasty were considered the best choices and performed in patients with severe aortic stenosis, but restenosis usually occurs because the improvement in valve opening is temporary in nature. As a promising alternative to SAVR, TAVR is similarly effective but less invasive with a shorter recovery period. Hence, TAVR's application is expanding from high risk to intermediate and low risk patients in general. In 2017, the American College of Cardiology/American Heart Association released the 2017 edition of the guidelines for the management of patients with valvular heart diseases, which officially included SAVR intermediate-risk patients into the indications for TAVR. In Aug 2019, the US FDA approved the application of certain TAVR products, namely Sapien 3 and Sapien 3 Ultra from Edwards Lifesciences and Evolut R and Evolut PRO from Medtronic in TAVR procedures that treat low surgical risk patients.

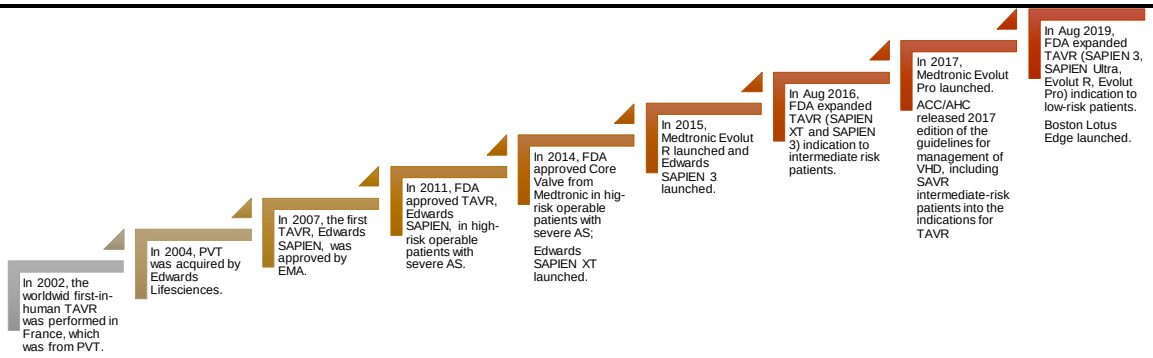
Figure 17: The comparison of TAVR and SAVR procedure

Country	Surgery	Type of hospital	# of eligible hospital (in 2018)	Price per procedure	Reimbursement	Patient eligibility	Require resources	Required technical expertise
China	SAVR	Class III Grade A hospitals	>1,000	<RMB100,000	Yes	Except patients with surgical contraindications	Extracorporeal circulation equipment, thoracoscopy, anesthesia equipment, echocardiography equipment, etc.	Cardiac surgeon, anesthesiologist, echocardiography doctor, nurse
	TAVR	Class III Grade A hospitals	>150	>RMB280,000 (including valve system)	No	Except patients with anatomical limitations or endocardial infection	Digital subtraction angiography system, anesthesia equipment, echocardiography equipment and extracorporeal circulation, computerized tomography, etc.	Interventional physician, cardiac surgeon, radiologist, anesthesiologist, echocardiography doctor, nurse
US	SAVR	General hospitals/ Cardiology and Heart Medical Center	>1,000	~US$14,500	Yes	Except patients with surgical contraindications	Extracorporeal circulation equipment, thoracoscopy, anesthesia equipment, echocardiography equipment, etc.	Cardiac surgeon, anesthesiologist, echocardiography doctor, nurse
	TAVR	General hospitals/ Cardiology and Heart Medical Center	600	~US$36,700 (including valve system)	Yes	Except patients with anatomical limitations or endocardial infection	Digital subtraction angiography system, anesthesia equipment, echocardiography equipment and extracorporeal circulation, computerized tomography, etc.	Interventional physician, cardiac surgeon, radiologist, anesthesiologist, echocardiography doctor, nurse

Source: F&S, CMBIS

The worldwide first TAVR, Edwards SAPIEN, was approved by EMA in 2007 and later the product was approved by US FDA on high-risk surgical patients in 2011. The two-year PARTNER 2 trial reported in 2016 showed non-inferiority of TAVR versus SAVR on rate of death or disabling stroke and furthermore, in the transfemoral-access cohort, TAVR resulted in a significantly lower rate of death or disabling stroke than surgery. This led FDA to extend approval of TAVR to intermediate risk patients in Aug 2016. In 2017, the American College of Cardiology/American Heart Association released the 2017 edition of the guidelines for the management of patients with valvular heart diseases, which officially included SAVR intermediate-risk patients into the indications for TAVR.

Figure 18: The evolution of TAVR development



Source: FDA, literature review, CMBIS

In May 2019, two trials were published in the New England Journal of Medicine (NEJM) showing superior outcomes with TAVR than SAVR in low-risk patients. In the PARTNER 3 trial of SPAIEN 3 (a balloon expanding TAVR product from Edward Lifesciences) showed the primary composite endpoint (death, stoke, re-hospitalization at 1 year) occurred in 8.5% of patients undergoing TAVR vs. 15% undergoing SAVR. Separately, in a prespecified interim analysis of the Evolut Low Risk Trial, the rate of combined deaths and disabling strokes at 24 months was 5.3% for TAVR with Medtronic's line of self-expanding bioprostheses and 6.7% with SAVR. The results of two trials inevitably lead to a major change in clinical practice. In Aug 2019, FDA has approved an expanded TAVR indication to patients with severe aortic valve stenosis at low surgical risk, which followed a thorough review of data demonstrating these devices are safe and effective for larger population, given the impressive outcomes of abovementioned trials.

Figure 19: Clinical data of TAVR vs SAVR in low surgical risk patients (Partner 3 Trial)

Trial name	Partner 3	
Trial registration No.	NCT02675114	
Treatment	TAVR (SAPIEN 3)	SAVR
N	496	454
Age (yr)	73.3±5.8	73.6±6.1
STS score	1.9±0.7	1.9±0.6
Primary end point:		
Death, Strok or Rehospitalization at 12 months	8.5%	15.1%
- Death at 12 months	*1.0%*	*2.5%*
- Stroke at 12 months	*1.2%*	*3.1%*
- Rehospitalization at 12 months	*7.3%*	*11.0%*
Secondary end points:		
New-onset atrial fibrillation at 30 days	5.0%	39.5%
Length of index hospitalization (median of days)	3.0	7.0

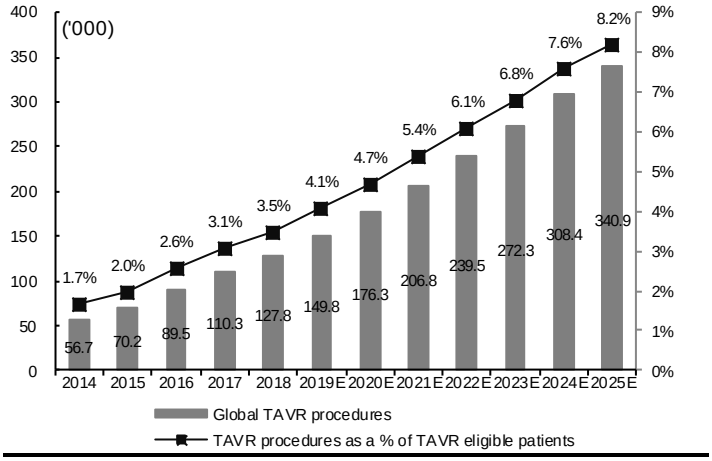
Source: NEJM, CMBIS

Globally, the number of TAVR eligible patients increased from 3.4mn in 2014 to 3.6mn in 2018 and may increase to 4.1mn in 2025E, according to F&S. SAVR low-risk patients account for a majority of the TAVR eligible patient population, and in Aug 2019 FDA has approved an expanded TAVR indication to patients at low surgical risk.

The number of TAVR procedures conducted globally has experienced rapid growth at 22.5% CAGR in 2014-18 and reached 127,800 in 2018, and is expected to further grow at 15% CAGR in 2018-25E. Accordingly, the percentage of TAVR procedures out of the total number of TAVR and SAVR procedures is estimated to increase from 36.5% in 2018 to 58.5% in 2025E.

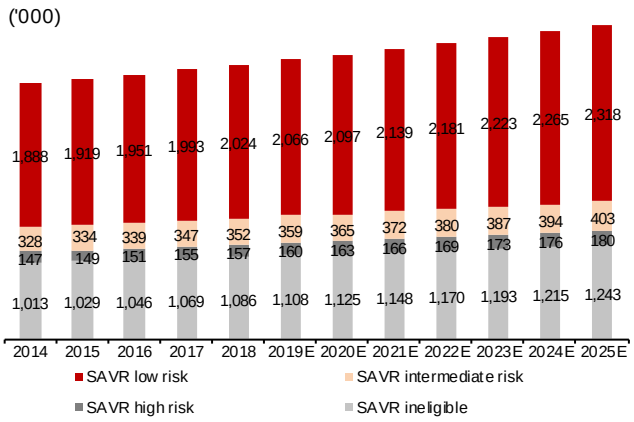
F&S forecasts the number of TAVR procedure worldwide to increase from 127,800 in 2018 to 340,900 in 2025E with penetration rate to improve to 8.2%.

Figure 20: Global TAVR procedures and penetration rate (2014-25E)



Source: F&S, CMBIS

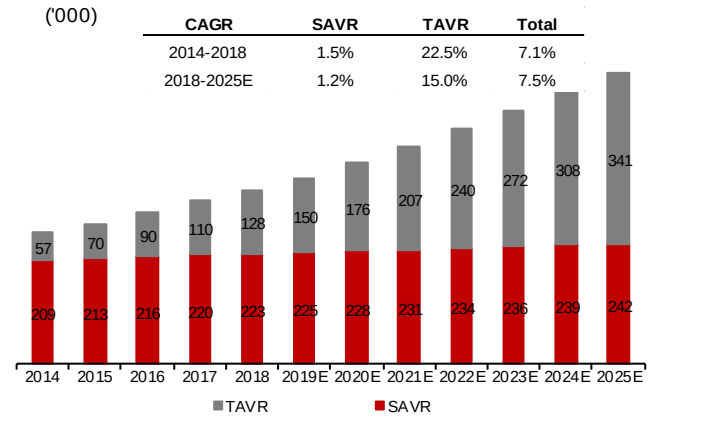
Figure 21: Global eligible patients for TAVR (2014-25E)



Source: F&S, CMBIS

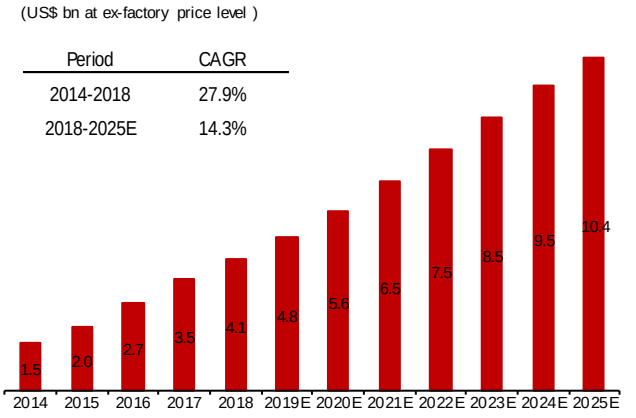
Given the rapid growth in demand for TAVR procedures, F&S forecasts the global market size of TAV to grow from US$4.1bn in 2018 to US$10.4bn in 2025E, driven by 1) indication expansion, 2) technology advance, 3) aging population, and 4) awareness of therapy.

Figure 22: Global SAVR and TAVR procedures (2014-25E)



Source: F&S, CMBIS

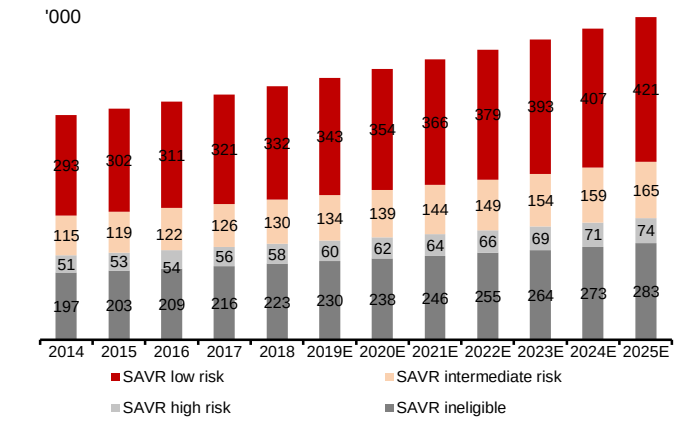
Figure 23: Global market size of TAV (2014-25E)



Source: F&S, CMBIS

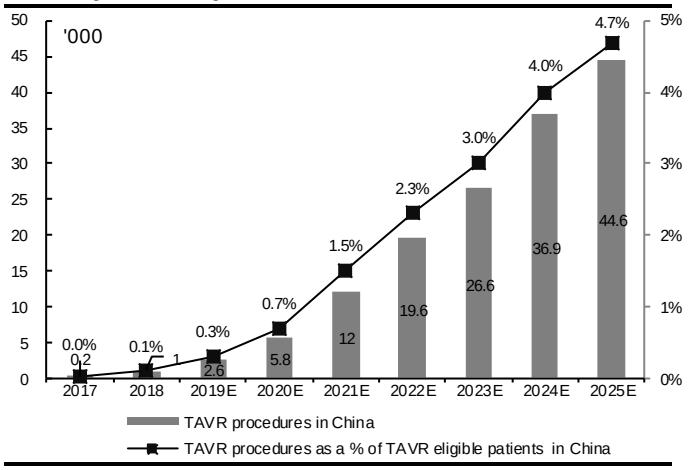
F&S forecasts the number of eligible patients for TAVR in China to increase from 742,100 in 2018 to 942,800 in 2025E. F&S also estimates that in China, only 0.1% of eligible patients were treated with TAVR in 2018 and the penetration rate in China will increase to 4.7% in 2025E. The TAV market size in China is expected to grow from US$28.7mn in 2018 to US$956.6mn in 2025E.

Figure 24: Total eligible patients for TAVR in China (2014-25E)



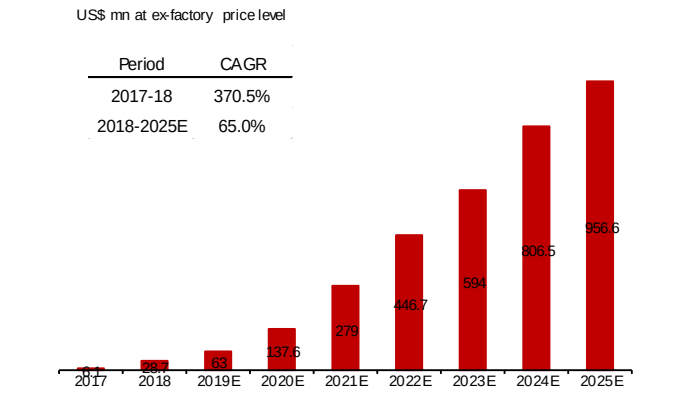
Source: F&S, CMBIS

Figure 25: TAVR procedures and penetration rate in China (2017-25E)



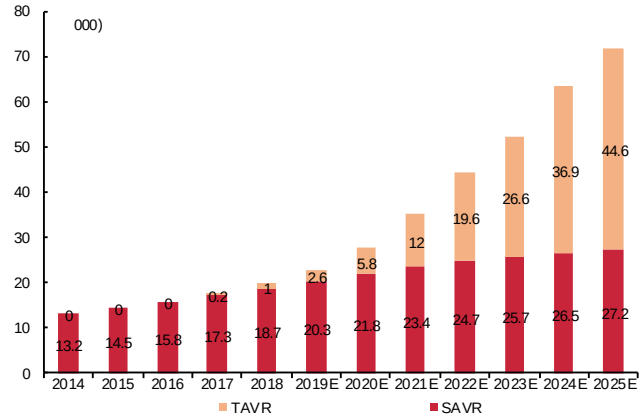
Source: F&S, CMBIS; Note: Only include procedures with commercial TAVR products

Figure 26: Market size of TAV in China (2017-25E)



Source: F&S, CMBIS; Note: Only includes procedures with commercial TAVR products

Figure 27: # of China SAVR and TAVR (2014-25E)

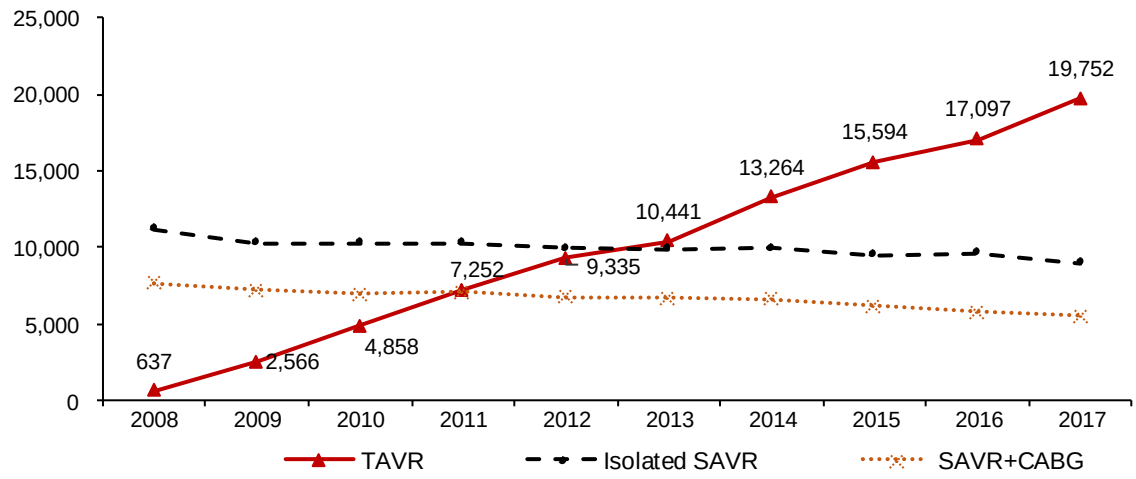


Source: F&S, literature review.

Developed countries experienced rapid penetration of TAVR

Data from Applied Quality Improvement and Research in Health Care (AQUA) showed the annual number of isolated SAVR procedures in Germany declined from 11,205 in 2008 to 9,011 in 2017 since the first TAVR commercialized in Europe in 2007. A similar trend was observed for combined SAVR plus coronary artery bypass grafting (CABG). In contrast, TAVR procedures increased 30-fold, from 637 in 2008 to 19,752 in 2017 and had surpassed the annual number of isolated SAVR since 2013. While the number of transapical TAVR has been relatively constant, the main increase in overall TAVR numbers is related to the increase in transfemoral TAVR. The mean age of TAVR patients remained stable over time at 81 years. The proportion of patients aged over 80 years underwent TAVR increased from 17% in 2008 to 95% in 2017. That said, TAVR in Germany had become the standard of care and preferred procedure for patients at over 80 years.

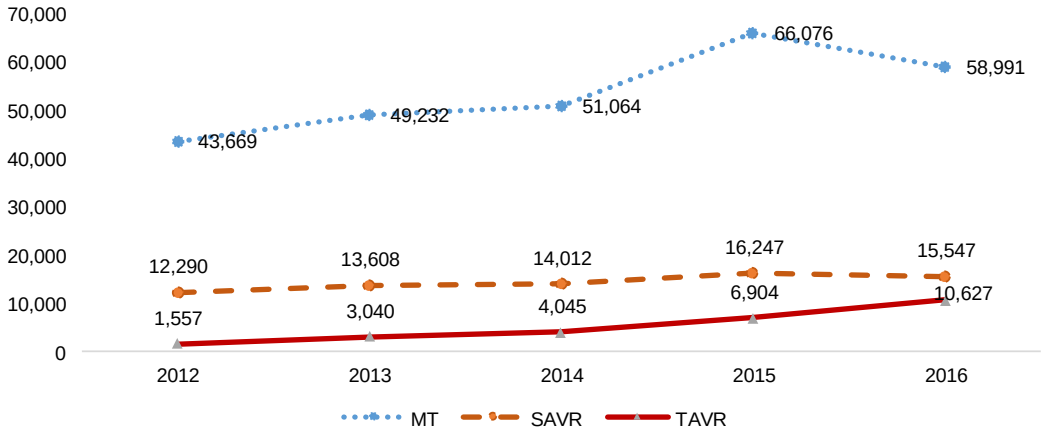
Figure 28: Annual procedure numbers for TAVR, isolated SAVR and SAVR plus CABG in Germany



Source: AQUA, CMBIS

An research article "The Evolving Management of Aortic Valve Disease: 5-Year Trends in SAVR, TAVR, and Medical Therapy" published at the American Journal of Cardiology analysed the utilization trends for SAVR, TAVR, and MT (medical therapy) in patients with aortic valve disease admitted from 2012 to 2016 in the US. Among the sample of 366,909 patients hospitalized for aortic valve disease during 2012 and 2016, 19.9%, 6.7%, and 73.4% of patients received SAVR, TAVR, and MT, respectively. SAVR decreased from 21.9% in 2012 to 18.5% in 2016, whereas TAVR increased from 2.6% to 12.5%, and MT decreased from 75.5% to 69.0%. TAVR has increased at the expense of both SAVR and MT.

Figure 29: Trends in TAVR, SAVR and MT from 2012 to 2016 (sample analysis in US)



Source: "The Evolving Management of Aortic Valve Disease: 5-Year Trends in SAVR, TAVR, and Medical Therapy", CMBIS

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Penetration to increase with more physicians being able to perform TAVR procedure

We think Chinese TAVR market is now at the infant stage due to 1) time needed for education of physicians about conducting TAVR procedures, 2) TAVR devices sold at expensive prices and 3) limited medical insurance reimbursement coverage for TAVR devices.

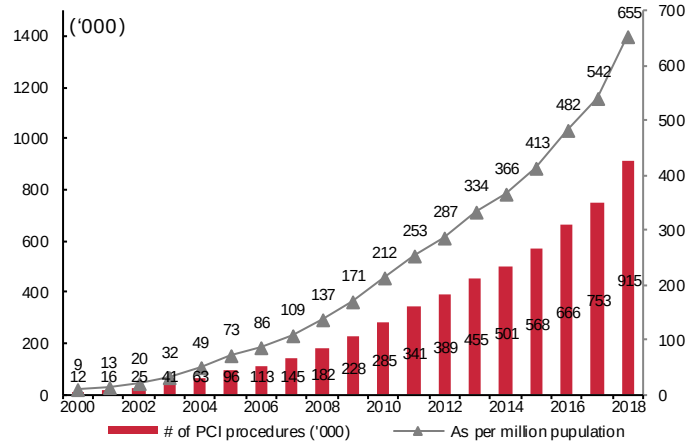
TAVR procedures has high requirements for surgical equipment, personnel configuration and technical operation. We believe lack of experienced physicians for conducting TAVR procedures is a key bottleneck for the penetration of TAVR products. For instance, Beijing Fuwai Hospital performed about 220 TAVR procedures (including clinical trials) in 2018 while more than 1,200 patients made such demand. Shanghai Zhongshan Hospital of Fudan University performed about 200 TAVR procedures (including clinical trials) in 2018 while about 1,100 patients made such demand. We believe, as more TAVR products become commercialized and market education from TAVR makers, more physicians could accumulate experiences performing TAVRs in China.

According to Consensus of Chinese Experts on Transcatheter Aortic Valve Replacement, only hospitals that have the ability to perform more than 100 SAVRs per year and more than 200 interventional operations per year can perform TAVR. Furthermore, TAVR must be performed in modified cardiac catheter rooms or hybrid operation rooms. According to "2017 Chinese Heart Surgery and Cardiopulmonary Data White Paper" (2017 中国心外科手术和体外循环数据白皮书) released by Chinese Society of Biomedical Engineering, as of 2017, 708 hospitals in China have performed cardiac surgeries and conducted a total of 65,749 cardiac valve surgeries, up 6.6% YoY. In China, over 150 hospitals performed TAVR procedures in 2018. The majority of TAVRs were performed in hybrid operation rooms, while China had over 1,788 cardiac catheter rooms in 2018. It is estimated that more TAVR procedures will be conducted in cardiac catheter rooms instead hybrid operation rooms thanks to comparable success rates and lower costs using cardiac catheter rooms. We see a large room for increase in number of hospitals eligible for TAVR procedures.

Experiences from PCI procedure penetration

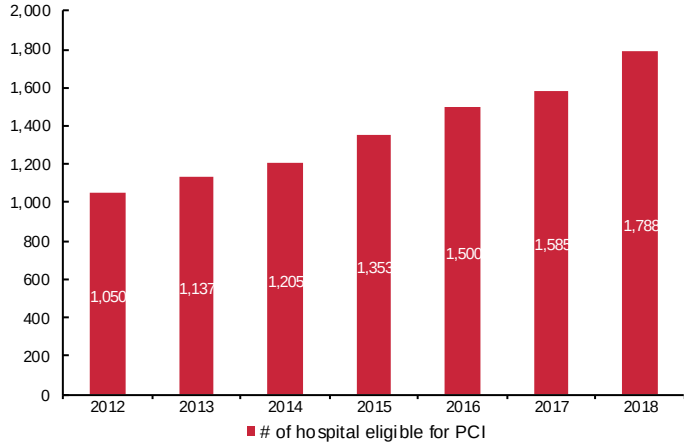
Number of PCI procedures in China has experienced high-teens growth Cagr in the past years and reached 915,256 in 2018, mainly driven by the increasing number of qualified physicians. Hospitals eligible for PCI procedures in China increased from 1,050 in 2012 to 1,788 in 2018. Among the 1,788 hospitals, 479 county-level hospitals conducted only 9% of the total PCI procedures, indicating large room for penetration increase in lower-tier hospitals. Penetration of PCI procedures in China is still far behind developed countries. According to F&S, in 2018, China had an average 655 PCI procedures per million population, which was below 2,907 for the US, 2,242 for Japan and 2,178 for Europe. It is estimated that PCI procedures in China will ramp up rapidly thanks to 1) more physicians and lower-tier hospitals eligible for PCI procedures, 2) improving affordability, 3) increasing incidence of acute myocardial infarction due to aging population.

Figure 30: # of PCI procedure in China (2000-18)



Source: NHS, CMBIS

Figure 31: # of hospitals able to perform PCI in China (2012-18)



Source: NHS, CMBIS

Favorable competition landscape in China

As of Feb 2020, more than 10 TAVR products in the global market had received FDA approval or CE Marking, and the major players are Edwards Lifesciences (EW US) and Medtronic (MDT US). These two companies dominate the global TAVR market with Edwards Lifesciences occupying around 60% market share and Medtronic taking approximately 30% market share in 2018. According to available clinical data, there were no significant differences in the incidence of all-cause mortality, myocardial infarction, stroke and major complications between the TAVR products of Edwards Lifesciences and Medtronic, except that Medtronic's Core-Valve was associated with more permanent pacemaker implantation and more incidence of perivascular leakage.

As of Feb 2020, there were three TAVR products approved for marketing in China, including VenusA-Valve of Venus Medtech, J-Valve of Jiecheng Medical and VitaFlow-Valve of MicroPort (853 HK). Meanwhile, there was one TAVR in the process of registration, namely VenusA-Plus, which was an upgraded product of VenusA-Valve. There're several TAVR products at clinical stage, including VitaFlow II-Valve of MicroPort, SAPIEN XT and SAPIEN 3 of Edwards Lifesciences, TaurusOne of Peijia Medical, etc.

Figure 32: Major TAVR products worldwide

Company	Edwards Lifesciences				Medtronic			Boston Scientific		Abbott	Venus Medtech	Jiecheng Medical	MicroPort
Product	SAPIEN	SAPIEN XT	SAPIEN 3	Centera	Core Valve	Evolut R	Evolut Pro	Lotus Edge	ACURATE neo	Portico	VenusA-Valve	J-Valve	VitaFlow
													
FDA Approval	2011	2014	2015	/	2014	2015	2017	2019	/	/	/	/	/
CE Mark	2007	2010	2014	2018	2011	2014	2017	2016	2014	2012	/	/	/
NMPA Approval	/	/	/	/	/	/	/	/	/	/	2017	2017	2019
Expanding Mechanism	BE	BE	BE	SE	SE	SE	SE	ME	SE	SE	SE	SE	SE
Pericardium Material	BP	BP	BP	BP	PP	PP	PP	BP	PP	PP	PP	PP	BP
Vascular Approach	TF/TA	TF/TA	TF/TA	TF	TF	TF	TF	TF	TF/TA	TF	TF	TA	TF
Anti-PVL Design	-	-	+	-	+	+	+	+	+	+	+	+	+
Retreivability	-	-	-	+	-	+	+	+	-	+	-	-	-
Price per unit to patient	N/A	~USD32,000		N/A	N/A	~US$30,000		N/A			~RMB250,000	~RMB290,000	~RMB180,000
Maket share (2018)	67.1% in US				32.9% in US			N/A			79.3% in China	20.7% in China	N/A

Note: BE=Balloon-expending; SE=Self-expanding; ME=Mechanically-expanding; BP=Bovine Pericardium; PP=Porcine Pericardium; TF=Transfemoral (经股动脉); TA=Transapical (经心尖)

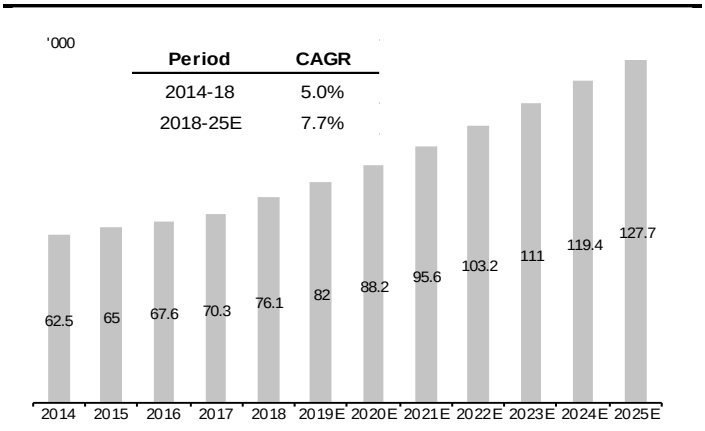
Source: Company data, MicroPort, CMBIS

TPVR is a niche market with unmet clinical need

Currently the major standard of care for patients with RVOTD after receiving TAP treatment in China and other major markets is SPVR. Compared to TPVR, SPVR induce large trauma, slow recovery and high risk, since patients may undergo a second open-chest operation after their surgery for RVOT repair. Based on the existing clinical evidence, TPVR can improve patients' heart functions, relieve symptoms and enhance their quality of life. Therefore, the use of TPVR is a shift in treatment paradigm. Currently, there are three marketed TPVRs worldwide and five candidates at the clinical trial stage. To date, there is no TPVR approved by NMPA in China. The treatment cost per TPVR procedure in US was ~US$126,000, while SPVR procedure costed ~US$80,000.

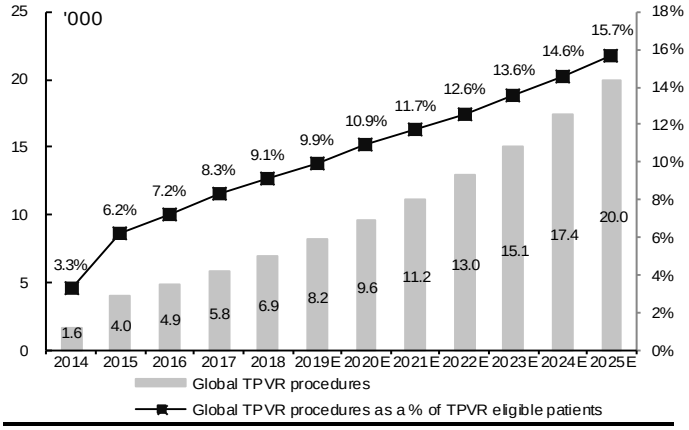
F&S forecasts that globally, mainly driven by the increase in the number of ToF and other RVOTD patients, the number of TPVR eligible patients increased from 62,500 in 2014 to 76,100 in 2018 and may increase to 127,700 in 2025E.

Figure 33: Global eligible patients for TPVR (2014-25E)



Source: F&S, CMBIS

Figure 34: Global TPVR procedures and penetration rate (2014-25E)

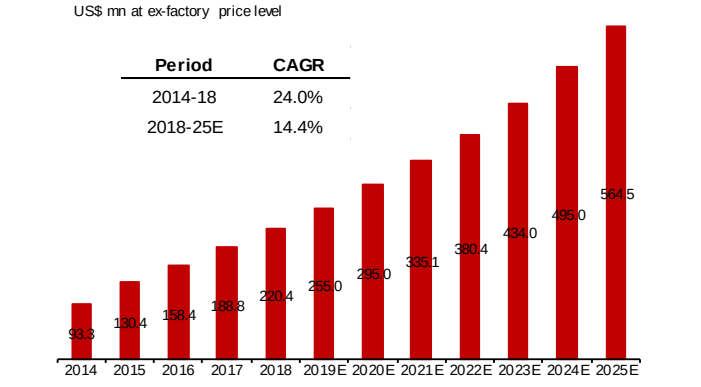


Source: F&S, CMBIS

According to F&S, the number of TPVR procedures conducted globally has increased rapidly at a CAGR of 24.5% from 2014-18 and may further grow at a CAGR of 16.4% in 2018-25E.

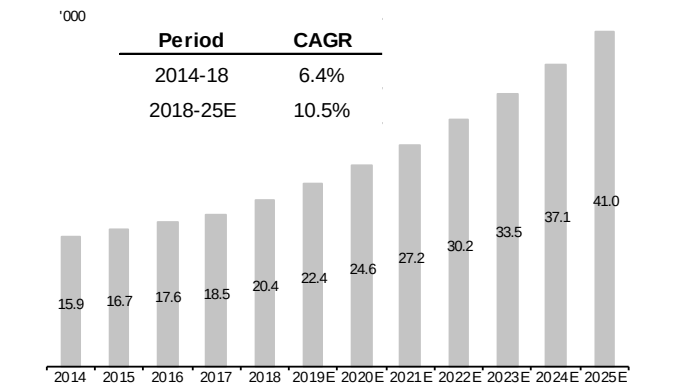
F&S estimates that the TPV market size increased from US$93.3mn in 2014 to US$220.4mn in 2018 and may increase to US$564.5mn in 2025E.

Figure 35: Global market size of TPV (2014-25E)



Source: F&S, CMBIS

Figure 36: Total eligible patients for TPVR in China (2014-25E)



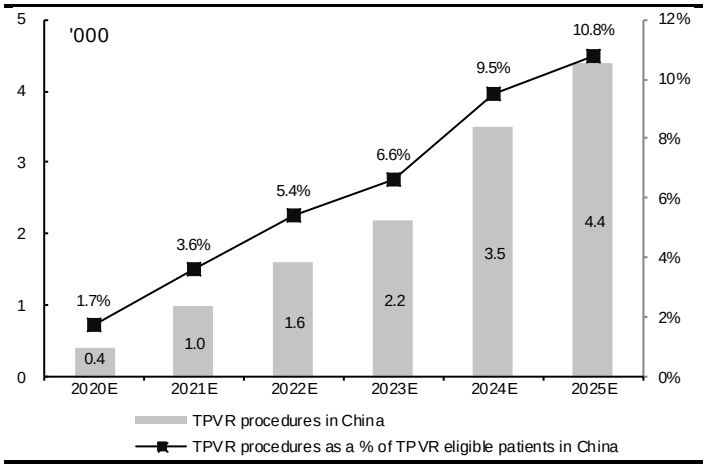
Source: F&S, CMBIS

Meanwhile, F&S forecasts the number of TPVR eligible patients in China to increase from 20,400 in 2018 to 41,000 in 2025E.

There's currently no TPVR products commercialized in China. F&S expects the number of TPVR procedures to reach 4,400 in 2025E driven by approval of TPVR products by the NMPA.

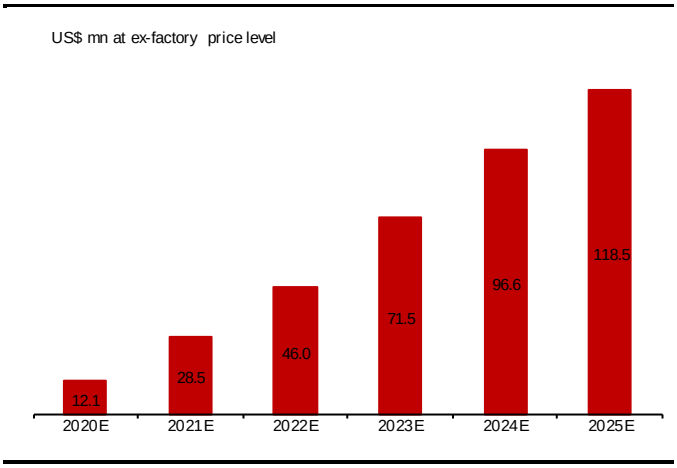
The TPV market in China is expected to increase from US$12.1mn in 2020E to US$118.5mn in 2025E, according to F&S.

Figure 37: TPVR procedures and penetration rate in China (2020-25E)



Source: F&S, CMBIS

Figure 38: Market size of TPV in China (2020-25E)



Source: F&S, CMBIS

VenusP-Valve is designed to treat patients with pulmonary regurgitation (肺动脉瓣反流) which is mainly caused by degeneration of RVOT from a previous repair to treat tetralogy of fallot (ToF, 法洛氏四联症) patients and other congenital heart diseases. With the increasing number of ToF and other RVOTD patients, demand for TPVR products may increase. According to F&S, globally, the number of TPVR eligible patients increased from 62,500 in 2014 to 76,100 in 2018, and is expected to increase to 127,700 in 2025E. In China, the number of eligible patients increased from 15,900 in 2014 to 20,400 in 2018, and is expected to increase to 41,000 in 2025E.

Currently, there are three FDA or CE approved TPVR products including SAPIEN and SAPIEN XT from Edwards Lifesciences and Melody from Medtronic. There are five product candidates at the clinical trial stage. Compared to Melody and Sapien XT, VenusP-Valve is more tailored to Chinese patients. More than 85% of ToF patients in China that went through RVOT enlargement procedures are treated with the transvalvular patch method (跨瓣补片法), and the diameter of their pulmonary valve ring is larger than 22mm, making VenusP-Valve the only viable option among the three competing products.

Figure 39: Comparison between three TPVR products

	Melody	SAPIEN XT	VenusP-Valve (Not marketed yet)
Company	Medtronic	Edwards	(Venus MedTech)
Market status	Approved in US and EU	Approved in US	Pending approval in China and EU
Expanding Mechanism	Balloon-expanding	Balloon-expanding	Self-expanding
Materials of Scaffolds	Platinum-Iridium alloy	Cobalt-chromium alloy	Nickel-titanium alloy
Materials of Valves	Bovine jugular vein	Bovine Pericardium	Porcine Pericardium
Application Range of Pulmonary Rings	16~22mm	16~22mm	16~27mm
Shape of Valve	Straight	Straight	Double trumpet-shaped
Specification	A bracket is needed to be pre-implanted on RVOT and 2 expansion balloons are also necessary, resulting in the high cost.		Both bracket and expansion balloons are not needed, more convenient and economical.
Price per unit to patients	~US$30,000	~US$30,000	N/A

Source: F&S, CMBIS

Comprehensive product portfolio

VenusA-Valve: the first-to-market TAVR product in China

VenusA-Valve received marketing approval from the NMPA in Apr 2017, and was launched in Aug 2017, becoming the first TAVR product launched in China. The Company also registered VenusA-Valve in Colombia in Apr 2018 and commercialized the product in Philippines in 3Q19. In addition, the Company is applying for the registration of VenusA-Valve in Brazil and Taiwan.

Product structure of VenusA-Valve

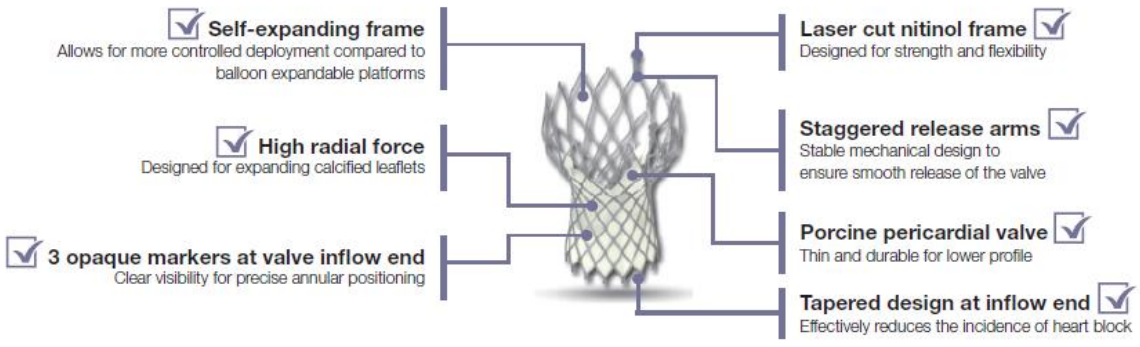
VenusA-Valve is a supra annular aortic valve comprised of a percutaneous aortic valve (PAV), a delivery catheter system (DCS) and a compression loading system (CLS).

The PAV consists of a self-expanding frame made of nickel-titanium alloy stent and three pieces of single-layer porcine pericardium leaflets attached to a porcine pericardium fan skirt. The skirt is attached to the frame with PTFE sutures. The frame is made of laser-cut nitinol tube, which helps ensure the valve's strength, durability and flexibility. There are three X-ray-opaque markers at the valve inflow end. The stent is visible during the entire operation, which provides additional visual guidance for the implantation of the valve.

Compared with balloon expandable valve, the self-expanding frame has lower requirement for the accuracy of positioning when the valve is released and reduces the risk of vascular complication. The diamond structure of the frame provides three-dimensional radial force, which helps to push aside the calcified leaflet, increasing the success rate of replacing the valve for patients with such condition. The high radial force can also reduce the incidence of paravalvular leakage after the procedure.

VenusA-Valve uses porcine pericardium as valve tissue instead of bovine pericardium which lowers Transmissible spongiform encephalopathies (TSE) risk. In addition, porcine pericardium is thinner than bovine pericardium which allows PAV to be delivered with a smaller catheter and reduces the difficulty of introducing the valve and the incidence of complications at the puncture site.

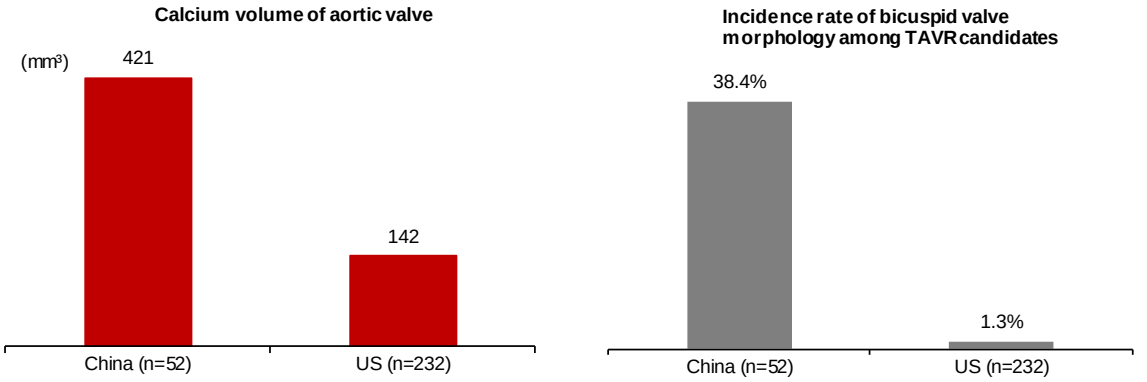
Figure 40: Illustration of PAV of VenusA-Valve



Source: Company data, CMBIS

Compared with patients in the US, aortic stenosis patients in China typically require treatment with special features such as having relatively strong bottom radial support due to high calcium volume and high percentage of bicuspid valve morphology. VenusA-Valve is specially designed for patients with high calcification and bicuspid valves, thereby making it suitable for China's patients.

Figure 41: Comparison between China and US regarding calcium volume and the bicuspid valve morphology incidence rates



Source: F&S, CMBIS

Satisfying clinical data of VenusA-Valve

Venus Medtech has completed a multi-center, single arm, open-label, pivotal trial in China to evaluate the efficacy and safety of VenusA-Valve. The procedures were completed in five centers, with Chinese Academy of Medical Sciences-Fuwai Cardiovascular Hospital as the leading research institution. Taking the foregoing factors into consideration, throughout the follow-up period, the subjects' cardiac function improved significantly.

From Sep 2012 to Jan 2015, 101 subjects were admitted to the trial. The primary safety endpoint is the all-cause mortality and the major stroke incidence at different times. As of Nov 2019, the Company has completed 48-month follow-up with the 101 patients. The success rate of the TAVR procedures was 95.0% at the time of discharge from procedures. The all-cause mortality rate for the 101 subjects was 5.0% at 30 days, 5.9% at 12 months, 8.9% at 24 months, 12.9% at 36 months and 14.9% at 48 months. The stroke rate for the 101 subjects was 1.0% at 30 days, 1.0% at 12 months, 1.0% at 24 months, 1.0% at 36 months and 3.0% at 48 months.

Compared with clinical outcomes of other TAVR products for high-risk severe AS patients, Venus A-Valve delivered comparable all-cause mortality rates and a lower rate of stoke. Nevertheless, we also noticed significant differences in baseline situation of enrolled patients, which may lead to different clinical outcomes.

Figure 42: Clinical data of VenueA-Valve versus peers

	VenusA-Valve			VitaFlow-Valve			TaurusOne		SAPIEN 3	
	30-Day	12-Month	60-Month	30-Day	6-Month	12-Month	30-Day	6-Month	30-Day	12-Month
Company	Venus Medtech			Microport			Peijia		Edwards Lifesciences	
N	101			110			125		583	
Age (yr)	75.4 ± 6.4			77.7 ± 4.8			N/A		82.6 ± 8.1	
STS score	6.7 ± 3.7			8.84 ± 5.58			N/A		8.6 ± 3.7	
Death	**5 (5.0%)**	**6 (6.0%)**	**21**	**2 (1.8%)**	**3 (2.7%)**	**3 (2.7%)**	**2 (1.6%)**	**4 (3.2%)**	**13 (2.2%)**	**82 (14.4%)**
Cardiogenic death	3 (3.0%)	4 (4.0%)	15	2 (1.8%)	2 (1.8%)	2 (1.8%)			8 (1.4%)	45 (8.1%)
Myocardial infarction	**2 (2.0%)**	**2 (2.0%)**	**5**	**2 (1.8%)**	**2 (1.8%)**	**2 (1.8%)**	**N/A**	**N/A**	**3 (0.5%)**	**N/A**
Stroke	**1 (1.0%)**	**1 (1.0%)**	**4**	**3 (2.7%)**	**5 (4.5%)**	**6 (4.5%)**			**9 (1.5%)**	**23 (4.3%)**
Major stroke	1 (1.0%)	1 (1.0%)	2				N/A	N/A		13 (2.4%)
Permanent pacemaker implantation	**19 (18.8%)**	**19 (18.8%)**	**20**	**18 (16.4%)**	**21 (19.1%)**	**21 (19.1%)**	**N/A**	**N/A**	**76 (13.0%)**	**96 (16.8%)**
Cardiovascular surgery	**3 (3.0%)**	**3 (3.0%)**	**3**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
Major vascular complications	**6 (5.9%)**	**6 (5.9%)**	**N/A**	**2 (1.8%)**	**2 (1.8%)**	**2 (1.8%)**	**N/A**	**N/A**	**29 (5.0%)**	**N/A**
Renal failure	**2 (2.0%)**	**2 (2.0%)**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**

Source: Company data, CMBIS, Peijia Prospectus, Edward Lifesciences
Note: N/A represents not applicable or undisclosed.

As of Nov 2019, VenusA-Valve had been used in 2,260 TAVR procedures since its commercialization in Aug 2017 with outstanding clinical performance. The incidence rate of all events at 30 days, 6 months and 12 months after the procedure was lower than such incidence rate among the 101 subjects in the clinical trial at each follow-up time respectively.

Figure 43: Post-market clinical data of VenusA-Valve (as of Nov 2019)

N=2,260	30 Days	6 Months	12 Months
Death			
Cardiogenic death	7 (0.3%)	7 (0.3%)	7 (0.3%)
Myocardial infarction	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**
Stroke			
Major	0 (0.0%)	0 (0.0%)	0 (0.0%)
Minor	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular surgery	**13 (0.6%)**	**13 (0.6%)**	**13 (0.6%)**

Source: Company data, CMBIS

Potent efficacy of VenusA-Valve

The efficacy endpoint is evaluated based on the relevant physical conditions of the subjects. Subjects' symptoms were relieved and their cardiac functions improved after the procedure. For the follow-up within 12 months after the TAVR procedure, subjects' cardiac function is mainly evaluated by the left ventricular ejection fraction (LVEF, 左心室射血分数), aortic valve pressure gradient (主动脉瓣压力梯度) and peak aortic valve velocity (峰值主动脉瓣血流速度), and proportion of patients with a level III or IV cardiac function under the NYHA classification prior to the procedure (术前及随访期 NYHA 分级中 III 或 IV 级心功能患者的比例而评估) during the follow-up period. Subjects' long-term cardiac function

during the 60-month follow-up period is evaluated by their mean aortic valve pressure gradient, the size of the effective orifice area (有效瓣口面积大小) and the incidence and severity of PVL (瓣周漏).

For patients treated with VenusA-Valve, the majority of the subjects didn't experience paravalvular leakage (PVL, 瓣周漏) or only suffered from a trace or mild PVL during the follow-up period after the procedure. The percentage of patients without or with a trace or a mild PVL among the subjects remained consistently over 90.0% during the follow-up period.

Figure 44: Subjects with PVL for VenusA-Valve and VitaFlow-Valve

	VenusA-Valve				VitaFlow-Valve			
	12-Month	24-Month	36-Month	48-Month	Discharge	30-Day	6-Month	12-Month
# of subjects	**95**	**91**	**87**	**84**	**110**	**108**	**102**	**105**
None or Trace	69.4%	66.8%	60.2%	53.0%	71%	71%	71%	71%
Mild	26.3%	27.9%	32.4%	38.8%	27%	26%	29%	29%
Moderate or Severe	4.2%	5.3%	7.4%	8.2%	2%	2%	0%	2%

Source: Company data, CIT 2018, CMBIS

For VenueA-Valve, the proportion of subjects with a level III or IV cardiac function under NYHA classification decreased significantly after the procedure and reached 8.6% at 12 months.

Figure 45: Change in subjects' NYHA level

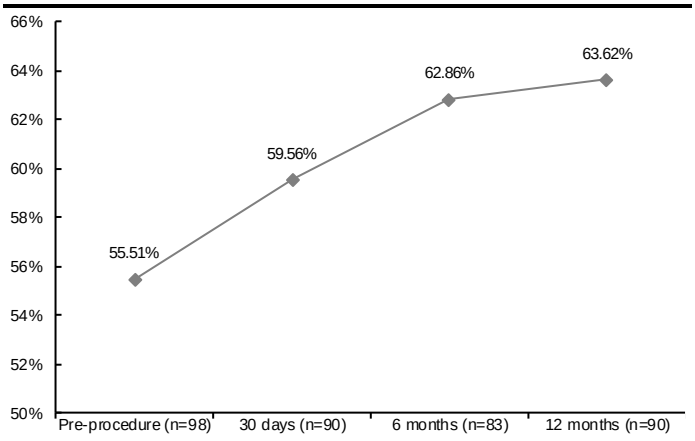
	VenusA-Valve				VitaFlow-Valve				TaurusOne	
	Baseline	30-Day	6-Month	12-Month	Baseline	30-Day	6-Month	12-Month	Baseline	30-Day
Number of Subjects	**101**	**95**	**93**	**93**	**110**	**109**	**106**	**107**	**10**	**9**
Level I	2 (2%)	40 (42.1%)	66 (71%)	74 (79.6%)	0 (0%)	29 (27%)	50 (47%)	76 (71%)	0 (0%)	8 (88.9%)
Level II	19 (18.8%)	41 (43.2%)	21 (22.6%)	11 (11.8%)	21 (19%)	61 (56%)	51 (48%)	28 (26%)	0 (0%)	1 (11.1%)
Level III	50 (49.5%)	12 (12.6%)	6 (6.5%)	8 (8.6%)	65 (59%)	18 (16%)	4 (4%)	2 (2%)	10 (100%)	0 (0%)
Level IV	30 (29.7%)	2 (2.1%)	0 (0%)	0 (0%)	30 (22%)	1 (1%)	1 (1%)	1 (1%)	0 (0%)	0 (0%)

Source: Company data, Peijia Prospectus, CIT 2018, CMBIS

The subjects' LVEF increased after the procedure, from 55.51% prior to the procedure, to 59.56% at 30 days and to 62.86% at 6 months after the procedure, and gradually stabilized at 63.62% at 12 months after the procedure.

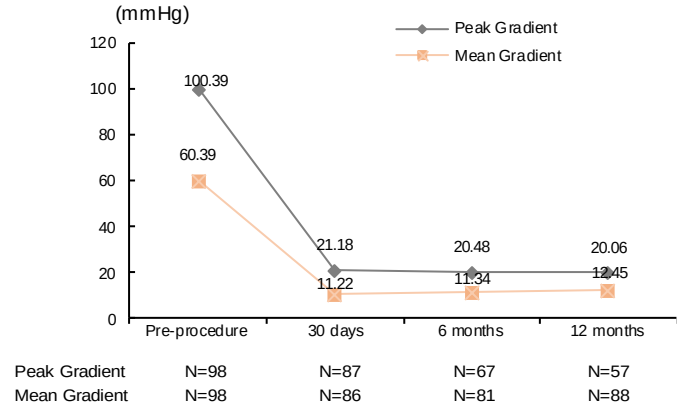
The subjects' aortic valve pressure gradient substantially decreased after the procedure in both peak pressure gradient and the mean pressure gradient. The aortic valve peak pressure of the subjects significantly decreased from 100.39mmHg prior to the procedure to 21.18mmHg at 30 days after the procedure, and remained around 20mmHg, respectively, at 6 months' and 12 months' follow-up after the procedure.

Figure 46: Change in the subjects' LVEF (%)



Source: Company data, CMBIS

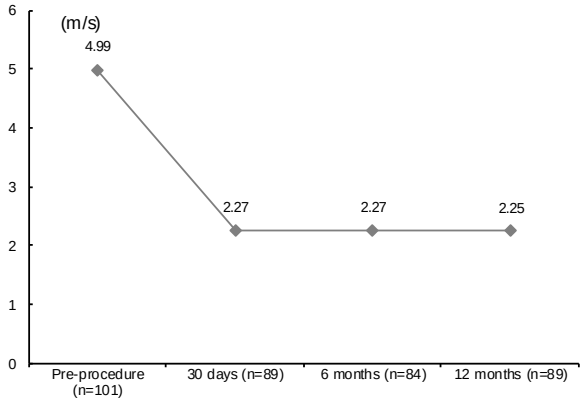
Figure 47: Change in the subjects' aortic valve pressure gradient



Source: Company data, CMBIS

The peak aortic valve velocity decreased from 4.99m/s prior to the procedure to 2.27m/s at 30 days after the procedure and remained at 2.27m/s at 6 months after procedure and 2.25m/s at 12 months after procedure.

Figure 48: Change in the subjects' peak aortic valve velocity

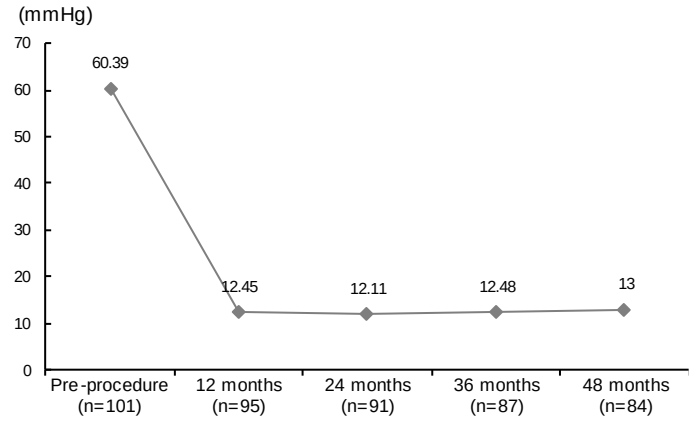


Source: Company data, CMBIS

In terms of long-term follow-up data, the subjects' mean aortic valve pressure gradient decreased significantly after the procedure and decreased gradually thereafter. The subjects' mean aortic valve pressure gradient decreased from 60.39mmHg before the procedure to 12.45mmHg at 12 months, 12.11mmHg at 24 months, 12.48mmHg at 36 months and 13.00mmHg at 48 months, respectively, after the procedure.

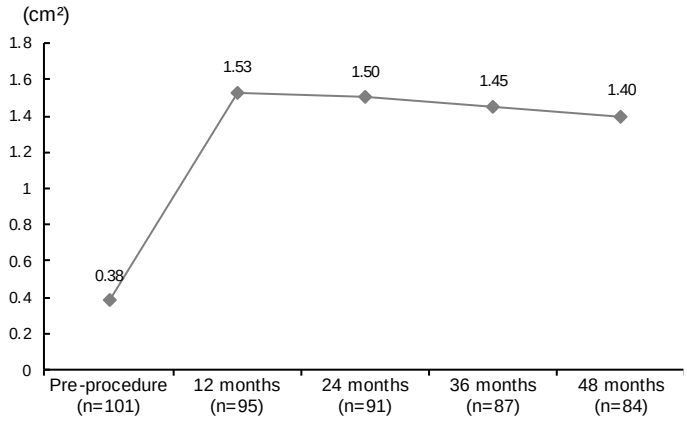
The subjects' effective orifice area (有效瓣口面积) increased after the procedure and decreased gradually thereafter, but in general remained relatively stable during the follow-up period.

Figure 49: Change in the subjects' mean aortic valve pressure gradient



Source: Company data, CMBIS

Figure 50: Change in the subjects' effective orifice area



Source: Company data, CMBIS

VenusA-Plus: the potential first retrievable TAVR product in China

VenusA-Plus is an upgraded product based on VenusA-Valve. Compared to VenusA-Valve, VenusA-Plus contains a DCS with retrieving function. In May 2018, the Company submitted to the NMPA an application for VenusA-Plus as an amendment to the VenusA-Valve registration. VenusA-Plus could be the first retrievable TAVR product in China.

Venus Medtech submitted the GMP application for the manufacturing system of VenusA-Plus in Brazil in Aug 2018 and is currently preparing the application for product registration in Brazil.

Retrieving function of VenusA-Plus makes the procedure easily operated

VenusA-Plus is a supra annular aortic valve comprised of a PAV, a DCS and a CLS. The PAV has similar structure as that of VenusA-Valve. The valve is delivered by using an 18-19Fr delivery system. It also has similar features of VenusA-Valve, including the high radial force, self-expanding frame and the thin and elastic porcine pericardial valve tissue, which contribute to its advantage in accurate positioning, treating patients with highly calcified valve leaflets and lowering the incidence of complication.

Unlike VenusA-Valve, the DCS of the VenusA-Plus system possesses a retrieving function. It enables physicians to retrieve the PAV during a TAVR procedure before the PAV is fully released, if the PAV is not placed accurately at the designated position. When starting release the PAV, the physician can pause when the valve is released for up to 2/3 of its size and conduct an angiography in the root of aorta to evaluate the PAV's position. If the positioning is not ideal, the physician can reversely rotate the catheter handle to retrieve the PAV.

Hence, physicians are given multiple opportunities to adjust the positioning of the PAV until it is placed at the designated location. Inaccurate positioning of the artificial valve has become a major issue in TAVR procedures, because of the difficulty of physicians to monitor and control the positioning throughout the process, which leads to an increasing incidence of PPM (永久心脏起搏器植入), PVL or death.

More importantly, thanks to the retrieving function, the physicians could operate the TAVR procedure more easily. This will significantly save the time for physician training for TAVR procedure and expedite the penetration of TAVR products in hospitals.

Smooth progress of clinical trials

Venus Medtech has conducted a multi-center, single arm, open-label clinical trial in four hospitals in China, led by the Second Affiliated Hospital of Zhejiang University School of Medicine. The purpose is to evaluate the safety and efficacy of VenusA-Plus, compared to the clinical results of VenusA-Valve.

The trial was started in Apr 2018 and enrolled 62 subjects. The trial was completed in Nov 2019 and the Company has submitted the clinical report to NMPA.

The incidence rate of each adverse event during the follow-up period was below 5.0%, except for the implantation of permanent pacemaker.

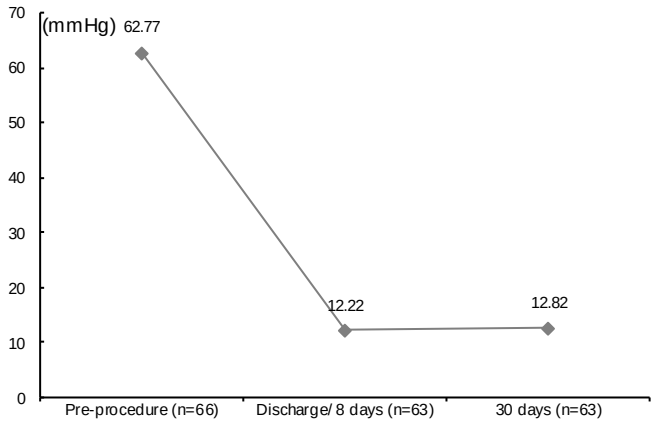
Figure 51: Safety endpoint of VenusA-Plus Valve

(N=62)	30 Days Subjects	% of total subjects
All-cause Mortality	3	4.8%
Myocardial Infarction	0	0.0%
Major Stroke	1	1.6%
Permanent Pacemaker Implantation	6	9.7%
Cardiovascular Surgery	0	0.0%

Source: Company data, CMBIS

The efficacy endpoint is evaluated based on the relevant physical conditions of the subjects. The mean aortic valve pressure gradient of the subjects significantly decreased from 62.77mmHg prior to the procedure to 12.22mmHg at the earlier of discharge or eight days after the procedure and remained relatively stable at 12.82mmHg at 30 days after the procedure.

Figure 52: Change in subjects' aortic valve area and mean aortic gradient



Source: Company data, CMBIS

Meanwhile, the proportion of subjects with a level III or IV cardiac function under NYHA classification decreased from 80.7% prior to the procedure to 20.7% 30 days after the procedure.

Figure 53: Change in subjects' aortic valve area and mean aortic gradient

	Pre-procedure	30 days
Number of subjects	**62**	**58**
Level I	0 (0.0%)	46 (79.3%)
Level II	12 (19.4%)	0 (0.0%)
Level III	30 (48.4%)	12 (20.7%)
Level IV	20 (32.3%)	0 (0.0%)

Source: Company data, CMBIS

VenusA-Pilot: the next generation TAVR product

VenusA-Pilot is the Company's next generation product for TAVR treatment with further improvements to the DCS function of VenusA-Plus. The DCS of VenusA-Pilot is designed to have retrieving and steering functions, which can improve the accuracy of positioning the valve. VenusA-Pilot is in under animal studies. We expect the Company to submit the NMPA application for VenusA-Pilot as an amendment to the VenusA-Valve registration upon completion of clinical trials.

Compared with VenusA-Valve, VenusA-Pilot is designed to contain a DCS with not only retrieving but also steering functions. Physicians can use the DCS to retrieve the PAV during a TAVR procedure if it is not released accurately to the designated position. Besides the retrieving function, physicians can use the DCS to steer the position of the PAV during a TAVR procedure. The valve is delivered by using an 18-19Fr delivery system.

VenusA-Pilot further reduces the complexity of a TAVR procedure. We think the potential commercialization of VenusA-Pilot will help to extend the life-cycle of Venus Medtech's overall TAVR portfolio.

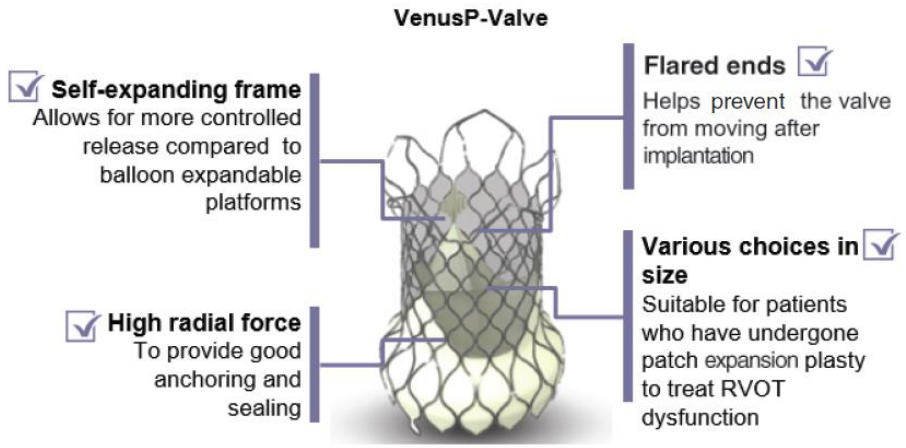
VenusP-Valve: the potential first-to-market TPVR product in China

VenusP-Valve is a transcatheter pulmonary valve system which is designed for percutaneous implantation via cardia catheterization into the right ventribular outflow tract (RVOT, 右心室流出道) to treat the dysfunction of RVOT (RVOTD, 右心室流出道障碍) including pulmonary valve backflow as a result of treatment for patients with congenital heart disease.

The Company has completed the clinical trial in China for VenusP-Valve. In Apr 2019, VenusP-Valve was granted Special Approval Procedures of Innovative Medical Devices by the NMPA and may be approved by NMPA in 2021E. Venus Medtech submitted the application for the CE Marking in Apr 2019 and may be approved by EMA in 2H20E. In addition, VenusP-Valve is in the process of animal trials in the US.

We expect VenusP-Valve to become the first-to-market TPVR product in China and the first TPVR product for patients with RVOTD after receiving transannular patching (TAP, 跨瓣环修补) treatment globally, and the first self-expanding TPVR product globally.

Figure 54: Illustrative structure of VenusP-Valve



Source: Company data, CMBIS

China pivotal clinical trial completed

Venus Medtech has completed a multi-center, single-arm, open-label, pivotal trial in China to evaluate the safety and efficacy of VenusP-Valve, involving 55 subjects. As of Nov 2019, it was the only completed clinical trial in China for TPVR products. The trial was started in May 2014 and was completed in Jan 2018.

The safety of applying VenusP-Valve in TPVR procedures is evaluated by the incidence of all-cause mortality, stroke and cardiovascular surgery among the subjects at 30 days, 6 months, 12 months, 24 months, 36 months, 48 months and 60 months after the procedure.

There was no incidence of stroke at the 24 months after the procedure and there were only two cardiogenic deaths during the 24 months after the procedure. Only one patient needed another TPVR procedure to reposition the implanted PPV, after which, the subject's cardiac function remained effective and stable during the follow-up period.

Figure 55: Safety endpoint of VenusP-Valve

(N=55)	30 days	6 months	12 months	24 months
Death				
Cardiogenic death	0 (0.0%)	2 (3.6%)	2 (3.6%)	2 (3.6%)
Non-cardiogenic death	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Stroke	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular Surgery	1 (1.8%)	1 (1.8%)	1 (1.8%)	1 (1.8%)

Source: Company data, CMBIS

The success rate of the placement and the implantation of PPV was 100%. Among the 55 subjects, 53 patients survived 24 months after the procedure. Most of the subjects had different degrees of improvement in their cardiac function after the TPVR procedure, reflected by the improvement in their right ventricular end-diastolic volume index (RVEDVI, 右心室舒张末容积指数). The improvement rate of the subjects' RVEDVI was 98.0% at 6 months after the procedure.

The subjects' cardiac function level under NYHA classification improved during the 12 months after the procedure. During the follow-up period, the proportion of patients with level I cardiac function under NYHA classification increased to over 90%, and there has not been any patient with cardiac function level lower than level II after the procedure.

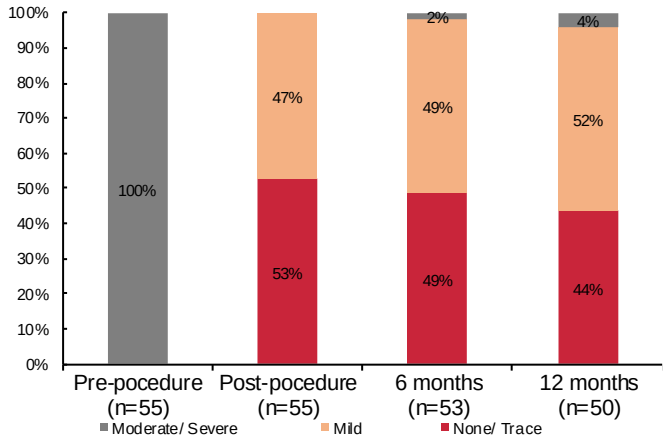
Figure 56: Subjects' NYHA level before and after the VenusP-Valve procedure

	Before Procedure	30 days	6 Months	12 Months
Number of subjects	55	55	53	53
Level I	3 (5.5%)	47 (85.5%)	48 (90.6%)	50 (94.3%)
Level II	44 (80.0%)	8 (14.5%)	6 (9.4%)	3 (5.7%)
Level III	8 (14.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Level IV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Source: Company data, CMBIS

During the 12-month follow-up after the procedure, the pulmonary valve regurgitation (肺动脉瓣反流) in all surviving subjects improved to varying degrees. At the immediate evaluation after the procedure, all subjects' pulmonary valve regurgitation improved substantially. In general, the subjects' conditions remained stable during the 12-month follow-up, with no more than 4% of the subjects suffered from moderate or severe regurgitation.

Figure 57: Number of subjects with pulmonary regurgitation and the level of severity



Source: Company data, CMBIS

For the purpose of application for CE Marking, the Company has initiated a prospective, non-randomized, multi-center clinical investigation of VenusP-Valve for the treatment of pulmonary regurgitation with or without stenosis in patients with native outflow tracts. The trial was started in Sep 2016, and the enrollment and procedures were completed in Oct 2018 with a total of 79 subjects worldwide.

During the follow-up period, the proportion of the evaluated patients with a level I NYHA cardiac function increased from 26.7% to 87.2%, and no patient had a NYHA function level lower than level II after the procedure. The subjects with severe or moderate PV regurgitation decreased from 100% to 0% and remained 0% during the 12-month after the procedure.

Figure 58: Subjects' NYHA level after VenusP-Valve procedure

	Before Procedure	30 days	6 Months	12 Months
Number of subjects	60	67	67	39
Level I	16 (26.7%)	40 (59.7%)	41 (61.2%)	34 (87.2%)
Level II	39 (65.0%)	26 (38.8%)	24 (35.8%)	5 (12.8%)
Level III	5 (8.3%)	1 (1.5%)	1 (1.5%)	0 (0.0%)
Level IV	0 (0.0%)	0 (0.0%)	1 (1.5%)	0 (0.0%)

Source: Company data, CMBIS

Venus Mitral Valve and Venus Tricuspid Valve under develoment

Higher entry barriers for TMVR and TTVR market

TMVR and TTVR are difficult to develop due to 1) the position of TMVR and TTVR increase the difficulty of accurately positioning of artificial valves, which pose more stringent requirements for the valve delivery system, 2) if a large stent is implanted in a TMVR procedure to fit into the large-sized mitral annulus, it may cause adverse effects, such as left ventricular outflow, tract obstruction and thrombosis, and as a result, it poses more stringent requirements for the design of valve products, 3) the saddle-shaped mitral annulus may lead to higher risks of complications during and after TMVR procedures, 4) the mitral valve is more prone to degradation compared to the aortic valve, since it is affected by higher left ventricular systolic pressure.

Venus Mitral Valve: the TMVR product under development

Venus Medtech is developing Venus Mitral Valve for TMVR treatment of mitral regurgitation patients. As of Feb 2020, there was no TMVR product approved for marketing worldwide. In China, there's currently no TMVR pipeline product at the clinical stage. The TMV market remains a gap with significant growth potential to address the unmet needs of a vast population of mitral valve regurgitation patients. According to F&S, the global prevalence of mitral regurgitation is expected to reach 108.6mn in 2025E from 95.1mn in 2018.

Figure 59: Major TMVR pipeline candidates at the clinical stage globally

Company	Pipeline Products	Access/ approach	Regions
Abbott	Tendyne	Transapical	US
Direct Flow Medical	Direct Flow Medical Transcetheter Mitral Valve Replacement	Transapical	US
Edwards Lifesciences	FORTIS	Transapical	US
	CardiAQ-Edwards Transcatheter Mitral Valve	Transfemoral/ Transapical/ Transatrial	US
HighLife	HighLife transcatheter mitral valve replacement device	Transapical/ Transatrial	EU
LivaNova	Caisson TMVI system	Transapical	UK
Medtronic	Intrepid	Transapical	EU
MValve Technologies	Mvalve Docking Device	Transapical	EU
NaviGate Cardiac Structures	NAVI	Transapical	US
Neovasc	Tiara	Transapical	Canada

Source: F&S, CMBIS

Venus Tricuspid Valve: the TTVR product under development

Venus Medtech is developing Venus Tricuspid Valve for TTVR treatment of tricuspid regurgitation patients. As of Feb 2020, there was no TTVR pipeline product at the clinical trial stage worldwide. The TTV market remains blank with significant growth potential to address unmet demands of a vast population of tricuspid valve regurgitation patients. According to F&S, the global prevalence of tricuspid regurgitation is expected to reach 55.9mn in 2025E from 48.6mn in 2018.

Ancillary products to enrich prodcut line

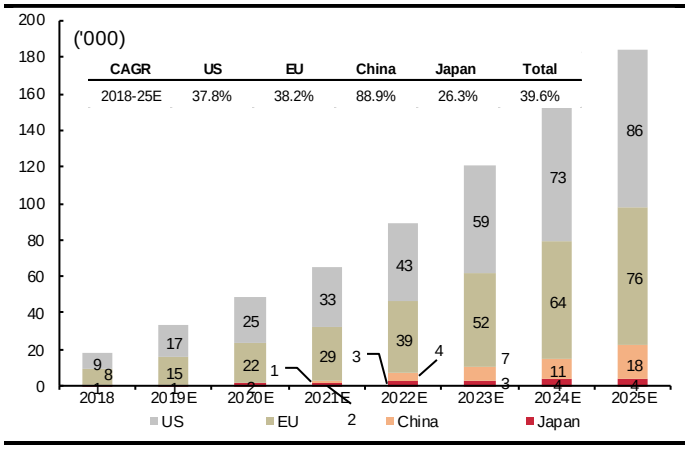
TriGUARD3: the CEP device

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 F&S.

Post-operative brain injury occurs in a significant proportion of patients undergoing cardiac surgeries, which severely affects the patient's morbidity, mortality and life quality. Such injury is often of ischemic origin, which leads to strokes. CEP devices are designed to decrease the incidence of stroke during TAVR procedures, where their usage has reduced the frequency of ischemic lesions. Given that the clinical data are still preliminary, routine clinical use of CEP devices has not yet been established.

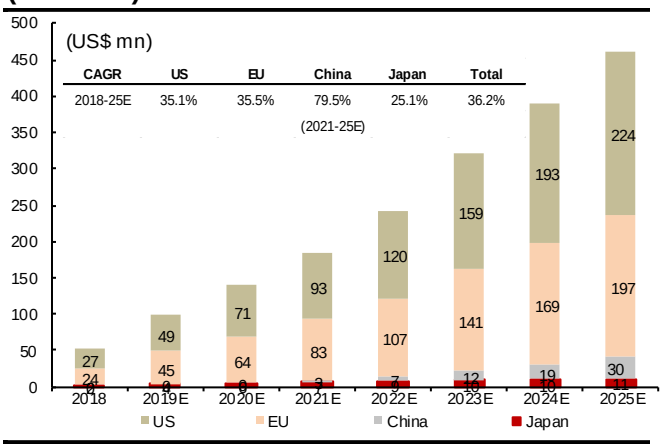
As the CEP device market is driven by the penetration and development of interventional procedures, especially TAVR, the number of CEP systems globally is expected to grow at a CAGR of 39.6% in 2018-25E.

Figure 60: Global CEP systems (2018-25E)



Source: F&S, CMBIS

Figure 61: Market size of global CEP systems (2018-25E)



Source: F&S, CMBIS

F&S also forecasts the global CEP device market size to reach US$461.0mn in 2025E with China accounting for 6.5% of the global market size.

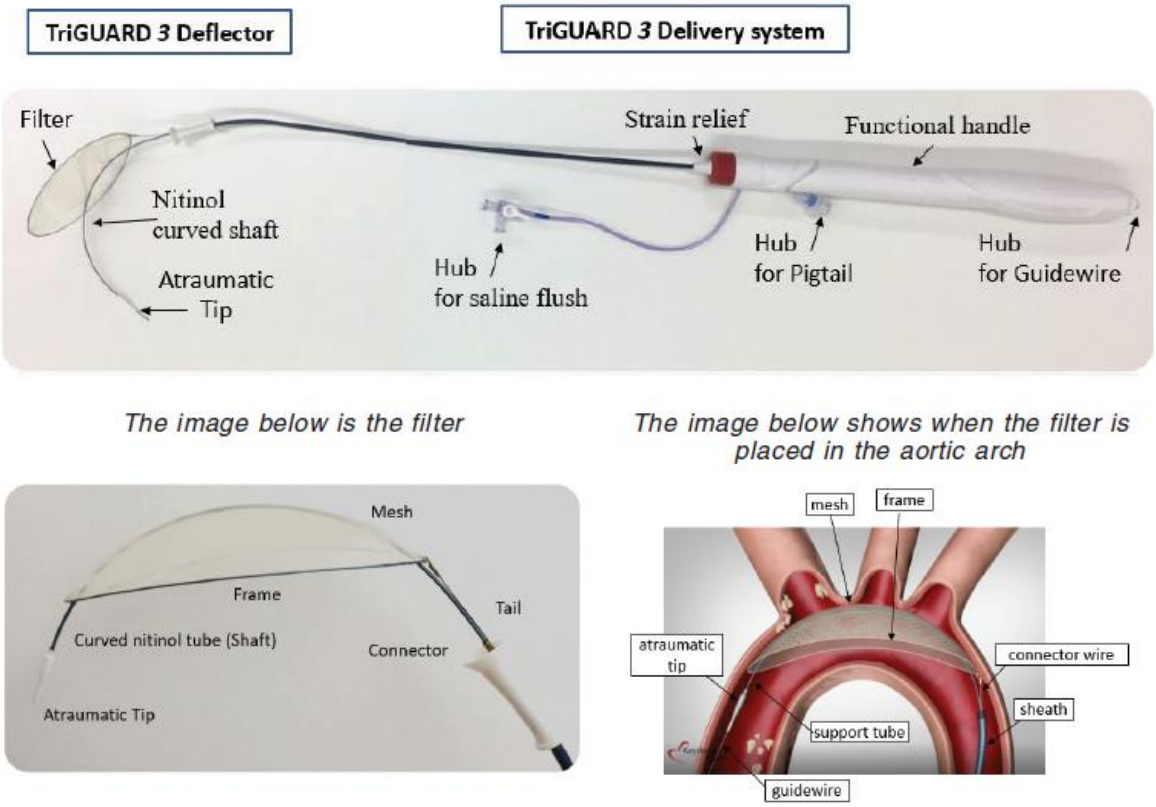
Venus Medtech completed the acquisition of Keystone with 100% stake in Dec 2018. Keystone Heart was incorporated in Israel in 2004 with one subsidiary incorporated in the US and one subsidiary incorporated in UK and focuses on the development of CEP devices. It has a R&D team of five members.

Keystone has developed three generations of CEP devices: TriGuard, TriGuard HDH and TriGUARD3. TriGuard HDH received CE Marking in 2013. Keystone started Phase II trial to evaluate TriGUARD3 in May 2018. The trial procedures and the follow-up with all the enrolled subjects were completed in Jun 2019. We expect the Company to file for FDA 510(k) clearance in the US for TriGUARD3 in 1H20E. Keystone submitted the application of CE Marking for TriGUARD3 in Feb 2018. The Company plans to apply for an import product license for TriGUARD3 with the NMPA after receipt of the CE Marking. We expect that it may get CE mark in 3Q20E and receive approvals from US FDA and NMPA in 2021E.

TriGUARD3 consists of a filter and a delivery system for the filter. The filter is shaped to accommodate anatomic variations of the aortic arch. It is designed to be placed in the aorta to cover all three cerebral arteries and protect aortic side branch vessels from embolic debris created during cardiovascular procedures such as TAVR, while diverting blood towards the side branch vessels, where the debris are either harmless or can be treated effectively.

TriGUARD3 is placed via one of the two femoral artery access ports typically used in TAVR procedures, eliminating the need for a third puncture site or cerebral vessel interaction.

Figure 62: Illustration of TriGUARD3



Source: Company data, CMBIS

There are four major CEP devices announced globally: Sentinel from Boston Scientific, TriGUARD3 from Venus Medtech, Embrella and Embol-X from Edwards Lifesciences. As of Nov 2019, Sentinel is the only US FDA approved CEP device in the market and TriGUARD3 is in the clinical development stage. Embrella and Embol-X currently have no ongoing registered clinical studies.

As compared to Sentinel, TriGUARD3 has advantages including its ability to self-position and self-stabilize, protection for the three major arteries that supply blood to the brain, instead of two, and the elimination of the need for a third puncture site or cerebral vessel interaction during a TAVR procedure, which leads to optimized safety.

Figure 63: Major global competitors of CEP device

Company	Device	Access	Delivery	Deployment	Stage
Boston Scientific / claret medical	Sentinel	Radial/brachial	6F	Two filters to brachiocephalic trunk and left common carotid	FDA Approved (2017)
启明医疗 VENUSMEDTECH / Keystone Heart	TriGUARD3	Femoral	8F	Aortic arch	FDA & CE Clinical trial
Edwards	Embrella Embol-X	Radial/brachial Direct aortic	6F 14F	Aortic arch Ascending aorta	No progress No progress

Source: F&S, CMBIS

V8 and TAV8: Unique aortic valvuloplasty balloons

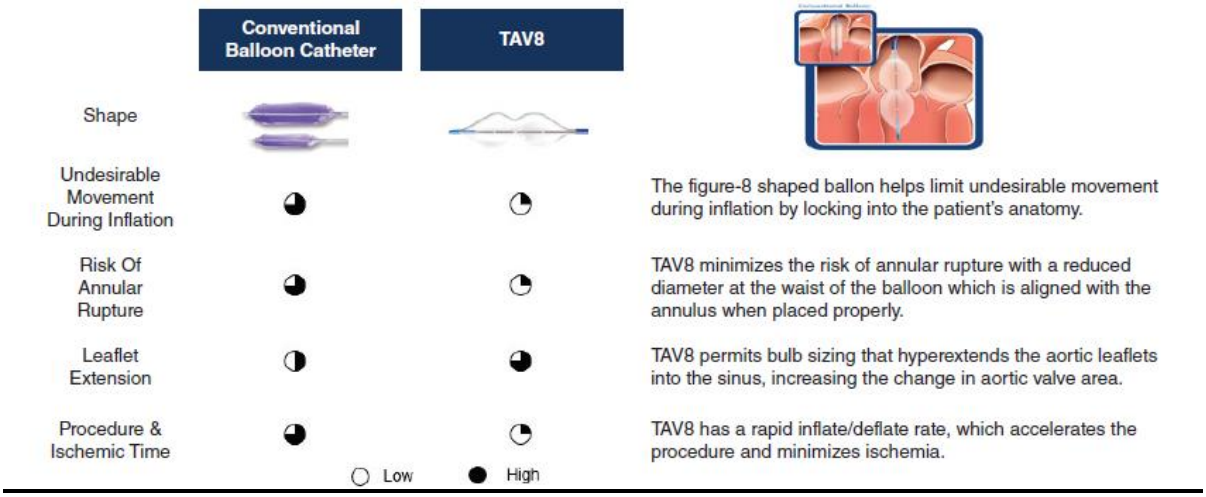
A balloon aortic valvuloplasty catheter system is designed to be used in stand-alone balloon aortic valvuloplasty procedures and the dilatation of aortic valve leaflets prior to and after TAVR procedure. InterVallve has developed two generations of bicuspid aortic valve catheter system, V8 and TAV8, both of which received FDA 510(k) clearance and CE Marking. In Nov 2016, InterValve assigned V8 and TAV8 related patents and transferred related regulatory approvals to Venus Medtech. Venus Medtech applied for an import product license with the NMPA for TAV8 in Feb 2018, and submitted clinical data from the post-market trial of TAV9 conducted in US in 2016 to NMPA in Oct 2019.

Clinical trials are not required to acquire FDA510(k) clearance or CE Marking approval for Venus Medtech's balloon aortic valvuloplasty catheter systems. To prove the efficacy of TAV8 when used for pre-dilatation of TAVR procedures and as required by the NMPA, the Company started a multi-center, single arm, open label clinical trial in China in Jun 2019 with 54 subjects to be enrolled. The trial may be completed in 2020E. We estimate TAV8 to be approved by NMPA in 2021E.

V8 and TAV8 both feature a figure "8" shaped dilatation balloon on the tip of a co-axial catheter. The balloon is shaped in figure "8", which limits undesirable movement during inflation by locking into the patient's anatomy, while the undersized waist segment attempts to limit excessive dilatation of the valve annulus. It is secured to help minimize slippage, which further reduces the need for rapid ventricular pacing.

The design of TAV8 was improved on V8's advantageous features. TAV8's 4mm distal bulb segment minimizes balloon engagement of the LVOT and could potentially limit conduction disturbances. TAV8 has a 15-20% lower inflation volume compared to V8, which decreases the time for inflation and deflation, shortens procedure time and reduces ischemia.

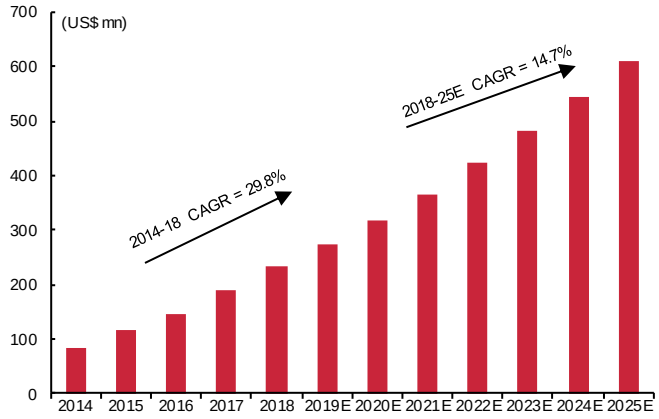
Figure 64: Comparison of conventional balloon and TAV8



Source: F&S, CMBIS

F&S estimates that the global market size for aortic valvuloplasty balloons increased at a CAGR of 29.8% and may increase at a CAGR of 14.7% from 2018 to 2025E and reach US$608mn by 2025E.

Figure 65: Global market size of aortic valvuloplasty balloons (2014-25E)



Source: F&S, CMBIS

Globally, there are five major balloon aortic valvuloplasty products competing against TAV8, which are Balloon Dialation Catheter from NuMED, Cristal Balloon from Balt Extrusion, Ascendra Ballon Aortic Valvuloplasty Catheter from Edwards Lifesciences, VIDA from Bard Peripheral Vascular and Z-MED from B Braun.

Figure 66: Major balloon aortic valvuloplasty products worldwide

	Company Name	Brand Name
China (NMPA)	NuMED	Balloon Dilatation Catheter
	Balt Extrusion	Cristal Balloon
US (FDA)	Intervalve	TAV8
	Edwards Lifesciences	Ascendra Balloon Aortic Valvuloplasty Catheter
	Bard Peripheral Vascular	VIDA
	B Braun	Z-MED

Source: F&S, CMBIS

Financial Analysis

Revenue to deliver 101% CAGR in FY18A-21E

We expect total revenue to grow 97%/ 79%/ 130% YoY to RMB227mn/ RMB407mn/ RMB934mn in FY19E/20E/21E, mainly driven by the fast-growing in VenusA-Valve and new product launches.

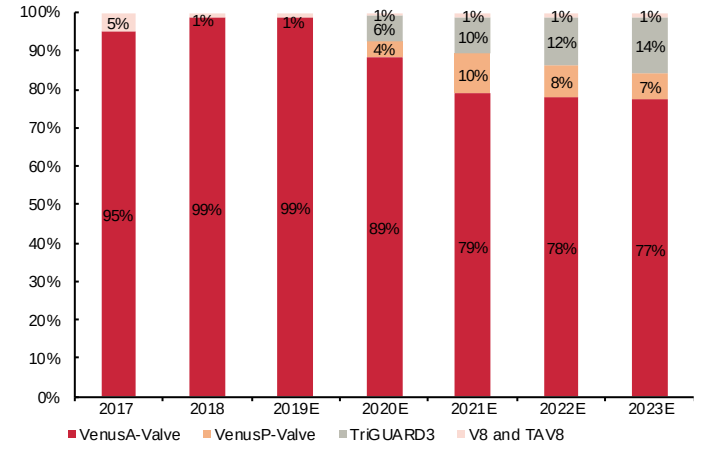
We expect VenusA-Valve will contribute the most revenue to the Company. We estimate VenusA-Valve will account for 99%/ 89%/ 79% of FY19E/20E/21E of the Company's total revenue and expect VenusA-Valve to record sales units of 1,550/ 2,700/ 6,000 in FY19E/20E/21E.

Figure 67: Revenue forecasts

(YE 31 Dec) (RMB mn)	2017	2018	2019E	2020E	2021E	2022E	2023E
Revenue of VenusA-Valve (RMB mn)	**17**	**114**	**225**	**360**	**737**	**1,152**	**1,587**
YoY		*557%*	*98%*	*60%*	*104%*	*56%*	*38%*
Unit sales (unit)	104	737	1,550	2,700	6,000	10,200	14,790
YoY		*609%*	*110%*	*74%*	*122%*	*70%*	*45%*
ASP ('000 RMB)	167	154	145	133	123	113	107
YoY		*-7%*	*-6%*	*-8%*	*-8%*	*-8%*	*-5%*
Revenue of VenusP-Valve (RMB mn)	**0**	**0**	**0**	**17**	**97**	**120**	**144**
YoY					*470%*	*24%*	*21%*
Unit sales (unit)	0	0	35	100	600	780	991
YoY				*186%*	*500%*	*30%*	*27%*
ASP ('000 RMB)	0	0	0	170	162	153	146
YoY					*-5%*	*-5%*	*-5%*
Revenue of TriGAURD3 (RMB mn)	**0**	**0**	**0**	**26**	**90**	**184**	**296**
YoY					*244%*	*105%*	*61%*
Unit sales (unit)	0	0	0	2,000	7,100	15,040	24,958
YoY					*255%*	*112%*	*66%*
ASP ('000 RMB)	0	0	0	13	13	12	12
YoY					*-3%*	*-3%*	*-3%*
Revenue of V8/TAV8 (RMB mn)	**1**	**2**	**3**	**3**	**11**	**17**	**23**
YoY		*91%*	*56%*	*31%*	*244%*	*50%*	*35%*
Unit sales (unit)	251	492	500	675	2,391	3,699	5,146
YoY		*96%*	*2%*	*35%*	*254%*	*55%*	*39%*
ASP ('000 RMB)	3	3	5	5	5	5	4
YoY		*-3%*	*54%*	*-3%*	*-3%*	*-3%*	*-3%*
Total Revenue	**18**	**115**	**227**	**407**	**934**	**1,473**	**2,051**
YoY		*535%*	*97%*	*79%*	*130%*	*58%*	*39%*

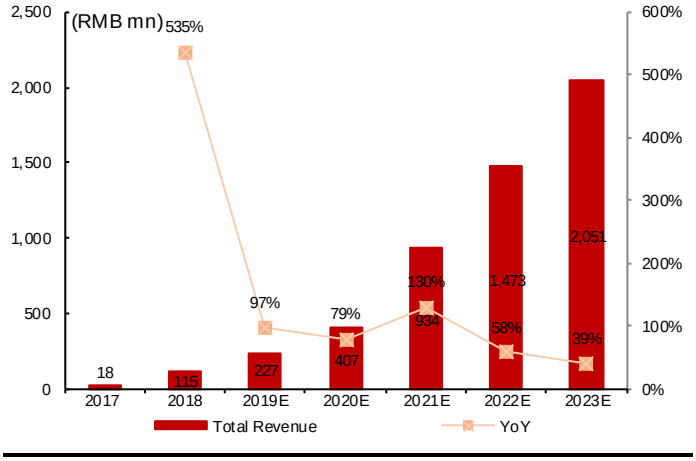
Source: Company data, CMBIS estimates

Figure 68: Revenue breakdown



Source: Company data, CMBIS estimates

Figure 69: Total revenue and growth forecasts



Source: Company data, CMBIS estimates

Turnaround from 2020E

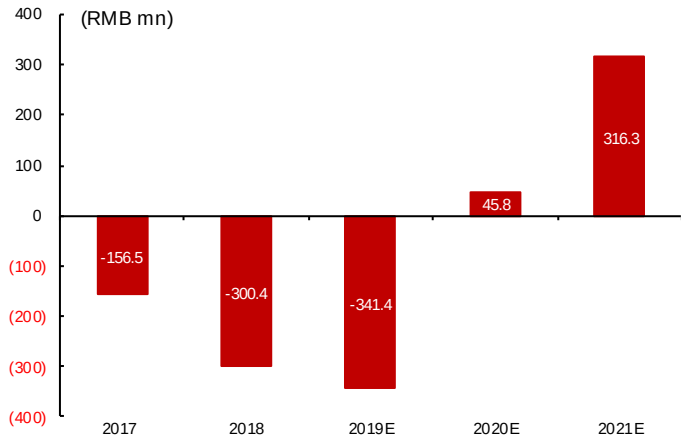
Venus Medtech recorded net losses of RMB157mn/ RMB300mn in FY17A/18A. We expect it to continue incur net loss of RMB341mn in FY19E and generate profit of RMB46mn/ RMB316mn in FY20E/21E.

Figure 70: P&L forecasts

(YE 31 Dec) (RMB mn)	2017	2018	2019E	2020E	2021E
Revenue	**18**	**115**	**227**	**407**	**934**
YoY		*535%*	*97%*	*79%*	*130%*
Cost of sales	(3)	(16)	(34)	(57)	(121)
% of revenue	*-17%*	*-14%*	*-15%*	*-14%*	*-13%*
Gross profit	**15**	**99**	**193**	**350**	**813**
GPM	*83%*	*86%*	*85%*	*86%*	*87%*
Other income and gains	5	13	2	2	2
% of revenue	*0*	*11%*	*1%*	*0%*	*0%*
Selling and distribution expenses	(36)	(67)	(82)	(130)	(280)
% of revenue	*-2*	*-58%*	*-36%*	*-32%*	*-30%*
Research and development costs	(117)	(105)	(180)	(100)	(93)
% of revenue	*-6*	*-91%*	*-79%*	*-25%*	*-10%*
Administrative expenses	(20)	(224)	(260)	(61)	(93)
% of revenue	*-1*	*-194%*	*-114%*	*-15%*	*-10%*
Other expenses	(2)	(11)	(10)	(10)	(10)
% of revenue	*0*	*-10%*	*-4%*	*-2%*	*-1%*
Profit from operations	(156)	(295)	(337)	51	338
% of revenue	*-9*	*-256%*	*-148%*	*12%*	*36%*
Impairment losses on financial assets, net	(0)	(2)	0	0	0
% of revenue	*0*	*-1%*	*0%*	*0%*	*0%*
Finance costs	(2)	(3)	(5)	(5)	(5)
% of revenue	*0*	*-3%*	*-2%*	*-1%*	*-1%*
Profit before taxation	(157)	(300)	(341)	46	333
% of revenue	*-9*	*-260%*	*-150%*	*11%*	*36%*
Income tax expense	(1)	(1)	0	0	(17)
Tax rate	*0%*	*0%*	*0%*	*0%*	*5%*
Profit (loss) for the year	**(158)**	**(301)**	**(341)**	**46**	**316**
Non-controlling interests	1	0	0	0	0
Profit (loss) attributable to shareholders	**(157)**	**(300)**	**(341)**	**46**	**316**
NPM	*N/A*	*N/A*	*N/A*	*11%*	*34%*
YoY		*N/A*	*N/A*	*N/A*	*N/A*

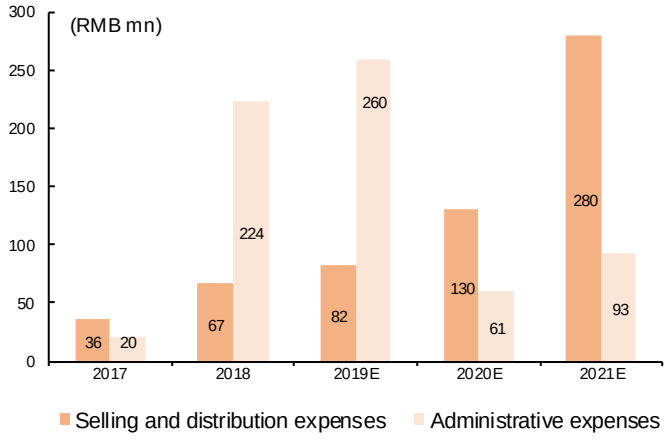
Source: Company data, CMBIS estimates

Figure 71: Net profit forecasts



Source: Company data, CMBIS estimates

Figure 72: SG&A expenses forecasts

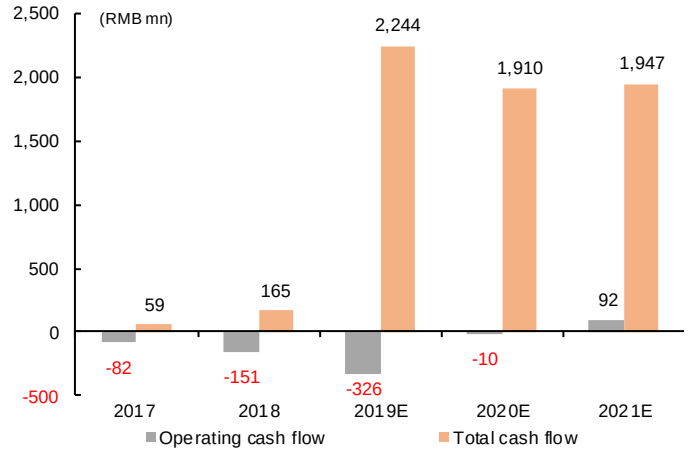


Source: Company data, CMBIS estimates

S&G spending to increase. Selling expenses were RMB36mn/ RMB67mn in FY17A/18A and we forecast selling expenses to increase to RMB82mn/ RMB130mn/ RMB280mn in FY19E/20E/21E, representing selling expenses ratios of 36%/ 32%/ 30%. Admin expenses were RMB20mn/ RMB224mn in FY17A/18A and the surge in FY18A was due to the share incentive expense of RMB180mn. We expect admin expenses to be RMB260mn/ RMB61mn/ RMB93mn in FY19E/20E/21E.

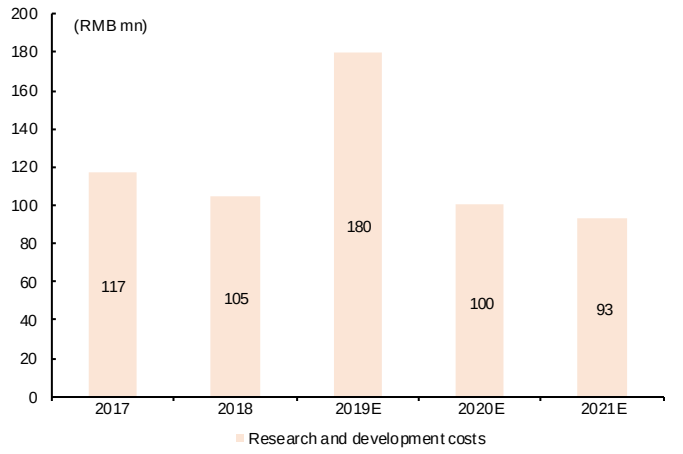
R&D spending to remain stable. We forecast R&D cost to increase from RMB117mn/ RMB105mn in FY17A/18A to RMB180mn / RMB100mn/ RMB93mn in FY19E/20E/21E.

Figure 73: Cash flows



Source: Company data, CMBIS estimates

Figure 74: R&D expenses



Source: Company data, CMBIS estimates

Financial Statments

Income statement

YE 31 Dec (RMB mn)	FY17A	FY18A	FY19E	FY20E	FY21E
Revenue	**18**	**115**	**227**	**407**	**934**
VenusA-Valve	17	114	225	360	737
VenusP-Valve	0	0	0	17	97
TriGUARD3	0	0	0	26	90
V8 and TAV8	1	2	3	3	11
Cost of sales	(3)	(16)	(34)	(57)	(121)
Gross profit	**15**	**99**	**193**	**350**	**813**
Other income	5	13	2	2	2
Selling & distribution expenses	(36)	(67)	(82)	(130)	(280)
Administrative expenses	(117)	(105)	(180)	(100)	(93)
R&D expenses	(20)	(224)	(260)	(61)	(93)
Other gains and losses	(2)	(11)	(10)	(10)	(10)
Operating profit	**(156)**	**(295)**	**(337)**	**51**	**338**
Net of impairment losses	(0)	(2)	0	0	0
Net finance costs	(2)	(3)	(5)	(5)	(5)
Pre-tax profit	**(157)**	**(300)**	**(341)**	**46**	**333**
Income tax	(1)	(1)	0	0	(17)
Minority interests	1	0	0	0	0
Net profit to shareholders	**(157)**	**(300)**	**(341)**	**46**	**316**

Cash flow summary

YE 31 Dec (RMB mn)	FY17A	FY18A	FY19E	FY20E	FY21E
Profit before tax	**(157)**	**(300)**	**(341)**	**46**	**333**
Depreciation and amortization	6	10	27	27	27
Change in working capital	(6)	(102)	(16)	(87)	(256)
Others	75	240	5	5	(12)
Net income tax paid	0	0	0	0	(17)
Net cash from operating	**(82)**	**(151)**	**(326)**	**(10)**	**92**
Capex	(19)	(27)	(40)	(50)	(50)
Acquisition of subsidiaries	0	0	(193)	(6)	0
Purchases of equity investments	(10)	0	0	0	0
Net purchases of financial assets	(13)	13	13	0	0
Others	(4)	(181)	179	(274)	0
Net cash from investing	(47)	(194)	(40)	(330)	(50)
Net proceeds from shares issued	146	445	2,450	0	0
Bank borrowing	30	19	0	0	0
Loans to related parties	0	0	0	0	0
Others	(3)	(11)	(5)	(5)	(5)
Net cash from financing	**173**	**453**	**2,445**	**(5)**	**(5)**
FX changes	2	(2)	0	0	0
Net change in cash	44	108	2,079	(344)	37
Cash at the beginning	13	59	165	2,244	1,900
Cash at the end	**59**	**165**	**2,244**	**1,900**	**1,937**

Balance sheet

YE 31 Dec (RMB mn)	FY17A	FY18A	FY19E	FY20E	FY21E
Non-current assets	**72**	**744**	**757**	**1,060**	**1,083**
PP&E	19	47	69	111	153
Goodwill	0	472	472	472	472
Other intangible assets	24	191	182	443	424
Deferred tax assets	0	3	3	3	3
Equity investments at fair value	28	29	29	29	29
Prepayments, other receivables and other assets	2	2	2	2	2
Current assets	**122**	**291**	**2,391**	**2,137**	**2,442**
Inventories	9	17	17	28	61
Trade receivables	18	81	101	181	415
Prepayments, other receivables and other assets	22	28	28	28	28
Cash and cash equivalents	59	166	2,245	1,901	1,938
Others	13	0	0	0	0
Current liabilities	**96**	**496**	**501**	**505**	**515**
Trade payables	3	1	6	9	20
Lease liabilities	2	6	6	6	6
Other payables and accruals	43	381	381	381	381
Due to a related party	2	1	1	1	1
Bank borrowing	30	80	80	80	80
Others	15	28	28	28	28
Non-current liabilities	**17**	**68**	**68**	**68**	**68**
Lease liabilities	4	15	15	15	15
Deferred tax liabilities	0	39	39	39	39
Others	13	14	14	14	14
Total net assets	**81**	**470**	**2,579**	**2,625**	**2,941**
Minority interest	9	9	9	9	9
Shareholders' equity	**72**	**462**	**2,570**	**2,616**	**2,932**

Key ratios

YE 31 Dec	FY17A	FY18A	FY19E	FY20E	FY21E
Sales mix (%)					
VenusA-Valve	95	99	99	89	79
VenusP-Valve	0	0	0	4	10
TriGUARD3	0	0	0	6	10
V8 and TAV8	5	1	1	1	1
Total	100	100	100	100	100
Profit & loss ratios (%)					
Gross margin	83	86	85	86	87
EBITDA margin	N/A	N/A	N/A	19	39
Pre-tax margin	N/A	N/A	N/A	11	36
Net margin	N/A	N/A	N/A	11	34
Effective tax rate	N/A	N/A	0	0	5
Balance sheet ratios					
Current ratio (x)	1	1	5	4	5
Trade receivables turnover	60	156	160	160	160
Trade payables turnover	70	30	60	60	60
Net debt to total equity	Net	Net	Net	Net	Net
Returns (%)					
ROE	N/A	N/A	N/A	2	11
ROA	N/A	N/A	N/A	1	9
Per share data					
EPS (RMB)	N/A	N/A	(0.84)	0.11	0.78
DPS (RMB)	N/A	N/A	0.00	0.00	0.00
BVPS (RMB)	N/A	N/A	6.38	6.49	7.27

Source: Company data, CMBIS estimates

Valuation

TP of HK$54.9 based on DCF model

Venus Medtech commercialized the first product, VenusA-Valve, in 2017 and its future cash flow will rely on sales ramp up of VenusA-Valve and future commercialization of pipeline products. We believe DCF would be a reasonable valuation method to value the Company. We derive TP of HK$54.9 based on a 11-year DCF valuation (WACC: 10.6%, terminal growth rate: 4.0%).

Figure 75: Base case valuation on risk-adjusted DCF valuation

DCF Valuation (in Rmb mn)	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	51	338	603	894	1,177	1,486	1,809	2,145	2,479	2,791	3,060
Tax rate	0%	5%	15%	15%	15%	15%	15%	15%	15%	15%	15%
EBIT*(1-tax rate)	51	321	513	760	1,000	1,263	1,537	1,823	2,107	2,372	2,601
+ D&A	27	27	27	27	27	27	27	27	27	27	27
- Change in working capital	(87)	(256)	(258)	(280)	(282)	(298)	(339)	(354)	(352)	(329)	(284)
- Capx	(50)	(50)	(80)	(80)	(80)	(80)	(80)	(80)	(80)	(80)	(80)
FCFF	**(60)**	**42**	**202**	**427**	**665**	**912**	**1,145**	**1,416**	**1,702**	**1,991**	**2,265**
Terminal value											**35,523**
FCF + Terminal value	(60)	42	202	427	665	912	1,145	1,416	1,702	1,991	37,788
Discount factor	100%	90%	82%	74%	67%	60%	55%	49%	45%	40%	36%
PV of FCF	(60)	**38**	**165**	**316**	**444**	**550**	**625**	**698**	**759**	**802**	**13,760**

Present value of enterprise (RMB mn)	18,097
Net Debt	(1,821)
Equity value (RMB mn)	19,917
Equity value (HK$ mn)	**22,204**
# of shares outstanding (mn)	**404**
Price per share (HK$)	**54.9**
Terminal growth rate	**4.0%**
WACC	**10.6%**
Cost of Equity	13.0%
Cost of Debt	6.0%
Equity Beta	1.0
Risk Free Rate	3.0%
Market Risk Premium	10.0%
Target Debt to Asset ratio	30.0%
Effective Corporate Tax Rate	15.0%

Source: CMBIS estimates

Figure 76: Sensitivity analysis (HK$)

	WACC				
Terminal growth rate	**9.63%**	**10.13%**	**10.63%**	**11.13%**	**11.63%**
5.0%	76.6	68.4	61.6	56.0	51.3
4.5%	70.9	63.8	58.0	53.0	48.8
4.0%	66.2	60.0	**54.9**	50.5	46.7
3.5%	62.2	56.8	52.2	48.3	44.8
3.0%	58.8	54.1	49.9	46.3	43.2

Source: Company data, CMBIS estimates

Figure 77: Peers' valuation

Company	Ticker	Price HK$	Mkt cap HK$ mn	PER(x) FY19E	PER(x) FY20E	PER(x) FY21E	PBR(x) FY19E	PBR(x) FY20E	PBR(x) FY21E	EV/EBITDA (x) FY19E	EV/EBITDA (x) FY20E	EV/EBITDA (x) FY21E	ROE % FY19E	ROE % FY20E	ROE % FY21E
Venue Medtech H-share	**2500**	**44.60**	**18,039**	**N/A**	**362.9**	**52.5**	**N/A**	**6.3**	**5.6**	**N/A**	**292.5**	**43.7**	**N/A**	**1.7**	**10.8**
AK Medical	1789	13.98	14,717	62.0	47.2	35.5	12.6	11.4	8.5	46.4	35.8	23.3	26.0	29.2	31.4
Chunli Medical	1858	72.60	10,044	42.9	28.8	31.4	10.5	7.9	7.3	36.9	30.0	24.5	29.9	33.6	25.9
Weigao Group	1066	10.04	45,404	21.6	18.3	15.7	2.5	2.3	2.0	14.1	12.1	10.4	12.4	13.0	13.3
Microport	853	9.41	15,328	46.6	44.9	32.7	3.7	3.6	3.3	20.0	22.1	19.4	11.1	9.0	12.5
Lifetech	1302	1.53	6,610	37.2	29.3	25.5	4.6	4.6	3.4	N/A	N/A	N/A	12.2	14.8	15.3
Kindly Medical	1501	40.30	6,690	64.8	41.2	31.0	4.9	4.6	4.2	N/A	N/A	N/A	11.0	11.0	14.0
			Average :	**45.9**	**34.9**	**28.6**	**6.5**	**5.7**	**4.8**	**29.4**	**25.0**	**19.4**	**17.1**	**18.4**	**18.7**

Source: Bloomberg, CMBIS estimates

Investment Risks

Sales mainly rely on one product, VenusA-Valve

Sales of VenusA-Valve accounted for 95.4%/ 98.6%/ 99.4% of total revenue in FY17/FY18/5M19. We expect that sales of VenusA-Valve will continue to account for a significant portion of total sales in the near future. Revenue from VenusA-Valve may be adversely affected by many factors, including downward pricing pressure caused by changes in market competition, expiration of patent protection, introduction of substitute products marketed by competitors, disruptions in manufacturing or sales, issues with respect to product quality or severe adverse events incurred after the procedure, coverage of medical insurance and disputes over intellectual property or other matters with third parties.

Growth depends on the success of pipeline product candidates

Venus's future growth depends on the successful development, regulatory approval and commercialization of pipeline product candidates (VenusA-Plus, VenusP-Valve, TriGUARD3, etc.), which are still in clinical development or design stage. If Venus is unable to successfully complete clinical development, obtain regulatory approval and commercialize product candidates, or experience significant delays in doing so, its business will be materially harmed.

Relatively limited experience in marketing and sales of products

Venus started marketing the first approved product, VenusA-Valve, in Aug 2017. It has relatively limited experience in launching and commercializing product candidates. It has limited experience in building a commercial team, conducting a comprehensive market analysis, obtaining licenses and approvals, or managing distributors and sales force. Venus may be able to develop and successfully maintain its in-house sales and commercial distribution capabilities or establish or maintain relationships with physicians, hospitals and other third parties to successfully commercialize products.

Fierce competition and downward pricing pressure

The development and commercialization of new products is highly competitive. Venus faces competition from major transcatheter heart valve replacement device companies worldwide, such as Edward Lifesciences, Medtronic, Boston Scientific, Abbott, Suzhou Jiecheng, MicroPort, etc. Venus's commercial opportunities could be reduced if competitors market products that are safer, more effective, have fewer severe adverse events, are more convenient or are less expensive than its.

Along with the increasing TAVR market and more TAVR products available, the government may issue price guidance or introduce tender process for TAVR products. Unexpected significantly price erosion may affect ex-factory price of Venus's products. Fierce competition may also lead to significant price cuts of the Company's TAVR products.

Limited reimbursement may restrict volume growth

Sales growth of drug and device in China are heavily related to the availability of governmental and private medical insurance. China has a complex medical insurance system that is undergoing reform. The governmental insurance coverage or reimbursement level in China for new products is subject to significant uncertainty and varies from region to region. The absence of sufficient medical insurance coverage for TAVR products may reduce demand for TAVR procedures.

Appendix: Company Profile

Figure 78: Management profile

Name	Age	Position	Roles and Responsibilities	Date of Joining	Date of First Appointment
Mr. Min Frank Zeng (曾敏)	57	Chairman of the Board of Director; Executive Director	Responsible for the overall management, business strategies, regulatory approvals and commercial suitability and sustainability of products of the Group.	2013/06/21	2018/11/26
Mr. Zhenjun Zi (訾振军)	50	Executive Director; General Manager	Responsible for the overall management, business strategies, regulatory approvals and commercial suitability and sustainability of products of the Group.	2012/11/21	2012/11/21
Mr. Lim Hou-Sen (Lin Haosheng) (林浩升)	46	Executive Director; Chief Operating Officer; Chief Technology Officer	Responsible for the business operations, regulatory approvals, quality control and commercial suitability and sustainability of products of the Group.	2018/11/26; 2018/06/05; 2016/12/01	2016/12/01
Mr. Haiyue Ma (马海越)	42	Chief Financial Officer; Joint Company Secretary	Responsible for the management of finance of the Company		2018/06/17; 2019/07/02

Source: Company data

Figure 79: Employee structure (as of Nov 2019)

Function	Number of full-time employees	% of total employees
Manufacturing	193	44%
Sales and marketing	77	18%
Product development	65	15%
Quality control	34	8%
General	69	16%
Total	**438**	**100%**

Source: Company data

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