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## Peijia Medical Limited

### 沛嘉醫療有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9996)

## INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED JUNE 30, 2022

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce the unaudited consolidated results of our Group for the six months ended June 30, 2022, together with the unaudited comparative figures for the six months ended June 30, 2021.

### FINANCIAL HIGHLIGHTS

	Six months ended June 30,		Period-to-period change
	2022	2021	
	RMB'000	RMB'000	
	(Unaudited)	(Unaudited)	
Revenue	118,799	51,689	129.8%
Gross profit	83,202	37,400	122.5%
Loss before income tax	(91,794)	(175,174)	(47.6%)
Loss for the period and attributable to the owners of the Company	(91,986)	(175,174)	(47.5%)
Cash, cash equivalents and term deposits	2,057,886	3,024,659	(32.0%)
Research and development expenses	(83,428)	(131,291)	(36.5%)
Including: One-time expensing BD payments	(12,343)	(79,739)	(84.5%)

For the six months ended June 30, 2022, our Group recorded revenue of RMB118.8 million, as compared to RMB51.7 million for the same period in 2021, representing an increase of 129.8% in revenue as compared to the same period in 2021; and loss for the period and attributable to the owners of the Company of RMB92.0 million, as compared to RMB175.2 million for the same period in 2021.

The increase in revenue was primarily attributable to: (i) commercialization of the second generation retrievable TAVR product TaurusElite®; (ii) increased sales revenue from existing neurointerventional products including Tethys® Intermediate Catheter and SacSpeed® Balloon Dilation Catheter; and (iii) commercialization of multiple new neurointerventional products including Jasper® SS Detachable Coil, etc.

## **BUSINESS HIGHLIGHTS**

- 1. Rooted in outstanding product performance as well as professional market education and promotion, both product adoption by new hospitals and the utilization rate of our products in the adopted hospitals have accelerated for our Transcatheter Valve Therapeutic Business.*

Good progress was achieved in product adoption by hospitals in 2022. As of July 31, 2022, our products entered 209 hospitals, representing an increase in 114 hospitals as compared to the end of 2021.

Although the overall market has been affected by the COVID-19 pandemic, the sales and implantation of our TaurusOne® and TaurusElite® products were in good progress, repeatedly setting new monthly highs in implantation volume. For the six months ended June 30, 2022, the revenue of the Transcatheter Valve Therapeutic Business increased by 455.4% as compared to the same period in 2021, and the total implantation volume for this period has far exceeded that for the whole year of 2021.

The Transcatheter Valve Therapeutic Business has progressed rapidly since its commercial launch, thanks to our cross functional teams comprised of marketing, sales and medical professionals. The all-round support ranges from academic promotion to new technology cooperation, from patient identification to physician training, and from preoperative, intraoperative and postoperative clinical support to meticulous sales service. The product adoption by new hospitals and the utilization rate in the adopted hospitals, especially in core hospitals, continued rising. The rapid advancement of commercialization has laid a solid cash foundation for the long-term development of the Company.

2. ***With the successive launch of four ischemic products of our Neurointerventional Business in the first half of 2022, the product portfolio for our ischemic product line has been preliminarily established, with all major devices readily in place. Continued enrichment of the ischemic product line, coupled with the hemorrhagic product line with the first mover advantages, will further diversify the revenue composition of the Neurointerventional Business.***

In the first half of 2022, the registration applications of four products have been approved by the NMPA, namely, Syphonet® Stent Retriever, Tethys AS® Aspiration Catheter, Fastunnel® Delivery Balloon Dilation Catheter and Fluxcap® Balloon Guide Catheter. The product portfolio for our ischemic product line has been preliminarily established, with all major devices readily in place.

The newly approved Syphonet® Stent Retriever, Tethys AS® Aspiration Catheter and Fluxcap® Balloon Guide Catheter, together with the existing products including Tethys® Intermediate Catheter and Presgo® Microcatheter, formed a complete solution for AIS patients. The unique “zero exchange” technology of Fastunnel® Delivery Balloon Dilation Catheter ushered a new era of ICAD treatment. Together with SacSpeed® Balloon Dilatation Catheter, we hope to benefit more patients with ICAD.

In the first half of 2022, we continued increasing sales and expanding our share in the sizable hemorrhagic market. Thanks to our continued efforts in product upgrades and long-established sales relationships, the revenue generated from the Neurointerventional Business for the six months ended June 30, 2022 increased by 57.6% as compared to the same period in 2021. Our revenue from hemorrhagic products, ischemic products and vascular access products accounted for 44.2%, 25.0% and 30.6% of the revenue from the Neurointerventional Business, respectively. With increasing sales from hemorrhagic products and upcoming commercialization of recently approved ischemic products, the revenue composition of our Neurointervention Business will further diversify. This will not only build our resilience in times of change and uncertainty, but also enhance the attractiveness and synergy of our product portfolio among physicians and distributors.

3. *Pioneering in the next-generation technologies of transcatheter valve therapies, we have developed a competitive and comprehensive pipeline with innovative technologies to meet the huge market needs. Both BD and internally developed projects are progressing smoothly. The Neurointerventional Business focuses on innovative products suitable for Chinese patients and physicians, through the cooperation between medical and engineering professionals.*

*In terms of the Transcatheter Valve Therapeutic Business, we have developed a strong product pipeline with a wide range of innovative product candidates through external acquisitions and internal development. Our strategy is to employ both approaches to differentiate us from the peers and strengthen our competitiveness in the next-generation technologies. As of the date of this announcement, the Company has four BD projects, which are deployed in the fields of aortic valve replacement for AR, mitral valve replacement, tricuspid valve replacement and mitral valve coaptation augmentation, respectively:*

- 1) Trilogy™ Heart Valve System of JenaValve Technology Inc. (“**JenaValve**”) is the first and the only transfemoral device of its kind to receive CE Mark approval for the treatment of both severe symptomatic aortic regurgitation and aortic stenosis as of the date of this announcement. We entered into a series of agreements with JenaValve in December 2021, for an exclusive license regarding Trilogy™ Heart Valve System for the treatment of AR and AS in the Greater China region. The transaction will enable us to have the most comprehensive TAVR pipeline covering major aortic valve diseases, as compared to other players in China. As of the date of this announcement, the technology transfer of the product is progressing smoothly. We plan to carry out registration clinical trial in 2023. Since the product has obtained CE Mark, we are preparing the implantation of Trilogy™ in Hong Kong and Macau or the rest of the Greater Bay Area within the Greater China region.
- 2) HighLife® TSMVR System is a leading product candidate in the field of mitral valve replacement in terms of technical route and clinical progress in the world. HighLife® TSMVR System adopted the unique “Valve-in-Ring” concept, allowing the system to realize self-centering and self-alignment. We entered into an exclusive license agreement with HighLife SAS (“**HighLife**”) in the fourth quarter of 2020 and completed the technology transfer in 2021. As of the date of this announcement, the product is in the process of a research clinical trial conducted by West China Hospital of Sichuan University.

- 3) MonarQ TTVR system of inQB8 Medical Technologies, LLC (“**inQB8**”) is one of the most important product candidates being developed in the field of transcatheter tricuspid valve treatment. We entered into a series of agreements with inQB8 in May 2021, a U.S.-based medical technology incubator, to explore innovative solutions for treating structural heart diseases. The transaction includes our acquisition of MonarQ TTVR technology from inQB8, for which inQB8 will continue with the device development in partnership with us. As of the date of this announcement, MonarQ is in the pre-clinical evaluation stage and we are currently preparing for FIM clinical trial.
- 4) The Sutra Hemi Valve of Sutra Medical Inc. (“**Sutra**”) is a hybrid transcatheter mitral valve coaptation augmentation treatment system between valve replacement and repair technology. Our initial closing of the purchase and sale of shares of Sutra took place in August 2021. As of the date of this announcement, we are launching animal studies for the Sutra Hemi Valve.

*In addition to BD projects, our internally developed projects are also progressing smoothly. Areas we are exploring include improving the durability of prosthetic valves, creating non-implant treatment solution for valve diseases and developing innovative mitral valve repair products:*

- 1) TaurusNXT<sup>®</sup> is our internally developed third-generation TAVR system. TaurusNXT<sup>®</sup> incorporates our patented non-glutaraldehyde bio-tissue crosslinking technology that removes the root cause of valve calcification. The technology is expected to greatly enhance the durability and biocompatibility of the PAV. Furthermore, comparing to the traditional dry tissue technology using glycerin, TaurusNXT<sup>®</sup> adopts an ultra-low temperature vacuum freeze-drying technology to maintain the physical integrity of the valve tissue while allowing the PAV to be preloaded onto the delivery catheter system. As of the date of this announcement, the multi-center registration clinical trial for TaurusNXT<sup>®</sup> is in progress.
- 2) TaurusApex<sup>®</sup> is our internally developed fourth-generation aortic valve replacement system. By replacing bio-materials with high strength, stable and soft polymer materials, we could further improve durability and biocompatibility of prosthetic valves. TaurusApex<sup>®</sup> could also significantly simplify the product manufacturing process and reduce production cost. The development of TaurusApex<sup>®</sup> is a significant step that we take to explore innovative solutions to improve the durability of prosthetic valves. As of the date of this announcement, we are conducting animal studies and associated long-term follow-up evaluation on TaurusApex<sup>®</sup>, with promising results.

- 3) TaurusWave<sup>®</sup> Lithotripsy Valvuloplasty System is our internally developed non-implant solution, using shockwave technology to remodel calcification on the heart valves. After the treatment, the mobility of native leaflets could be significantly increased, thereby improving the hemodynamics performance. The system can be used as a stand-alone TAV treatment or prior to TAVR, in order to alleviate valve stenosis. As of the date of this announcement, the FIM clinical trial for TaurusWave<sup>®</sup> is in progress.
- 4) GeminiOne<sup>®</sup> is our internally developed transcatheter TEER device. The product has a unique design, which enables a longer coaptation length while still maintaining smaller implant size and delivery system. Other innovations include its independent leaflet grasp that reduces the complexity of the procedure, auto-locking mechanism that avoids repeatedly lock & unlock during the procedure, as well as multi-angular detachment that copes with a wider range of anatomy. GeminiOne<sup>®</sup> is designed to treat mitral valve and tricuspid valve diseases. As of the date of this announcement, GeminiOne<sup>®</sup> is in the pre-clinical preparation stage.

*For our Neurointerventional Business, we have four ischemic products approved by the NMPA in the first half of 2022, providing more innovative and optimized treatment solutions for ICAD and AIS:*

- 1) Fastunnel<sup>®</sup> Delivery Balloon Dilation Catheter is the first medical device in China which can realize balloon dilation and stent delivery in one device. The innovative design can reduce the number of device exchanges as required in a traditional ICAD procedure, shorten procedure time and improve the safety of the procedure.
- 2) Syphonet<sup>®</sup> Stent Retriever is an internally developed product based on clinical feedbacks. The product has various specifications, all compatible with 0.017-inch microcatheter. The stent is also designed with optimized radial force to maintain the integrity of the lumen, even in tortuous vessels, ensuring a smooth procedure. The product's unique design features a capture basket at the distal end, which can effectively prevent the thrombus fragments from dislodging into the blood stream, thereby improving the removal of the thrombus. Radiopaque wires in the stent and a radiopaque marker on the distal end allow for visualization of the entire retriever, facilitating physicians with better visual guidance.

- 3) Tethys AS<sup>®</sup> Aspiration Catheter is indicated for thrombus aspiration, featuring large lumen, great deliverability and high compressive strength. The 0.071-inch large lumen of Tethys AS<sup>®</sup> largely increases the aspiration force, which can significantly shorten the procedure time. It features a 20cm soft segment at the distal end, which better conforms to the vessels and largely enhances its deliverability to the distal vessels. The device adopts a double-layer design with outer braids and inner coils, which allows high compressive strength and helps maintain lumen integrity.
- 4) Fluxcap<sup>®</sup> Balloon Guide Catheter is an optimized product based on clinical feedbacks. Featuring 0.087-inch large lumen, the catheter is compatible with all 6F intermediate catheters or aspiration catheters on the market, as well as 8F introducer sheaths. The product addresses the challenge of poor compatibility of balloon guide catheters on the market and can significantly reduce the occurrence of vascular injury.

4. ***We are making continuous efforts in optimizing supply chain and improving production process for long-term success.***

*Main accomplishments include:*

- 1) Expanding production capacity and improving productivity to support business growth;
- 2) Introducing and verifying more key raw material suppliers to enhance the supply chain security;
- 3) Optimizing the in-house manufacturing process of self-produced raw materials, focusing on mass production and product yield. In this way, we can ensure the stability of our raw material supply chain while keeping overall cost in check;
- 4) Automating and optimizing our manufacturing process. Through these, we have lowered our production cost with improved operating efficiency, increased product yield and reduced wastage;
- 5) Continuously investing in personnel training, including mentoring programs, to shorten the learning curve of employees.

# MANAGEMENT DISCUSSION AND ANALYSIS

## I. BUSINESS REVIEW

### Overview

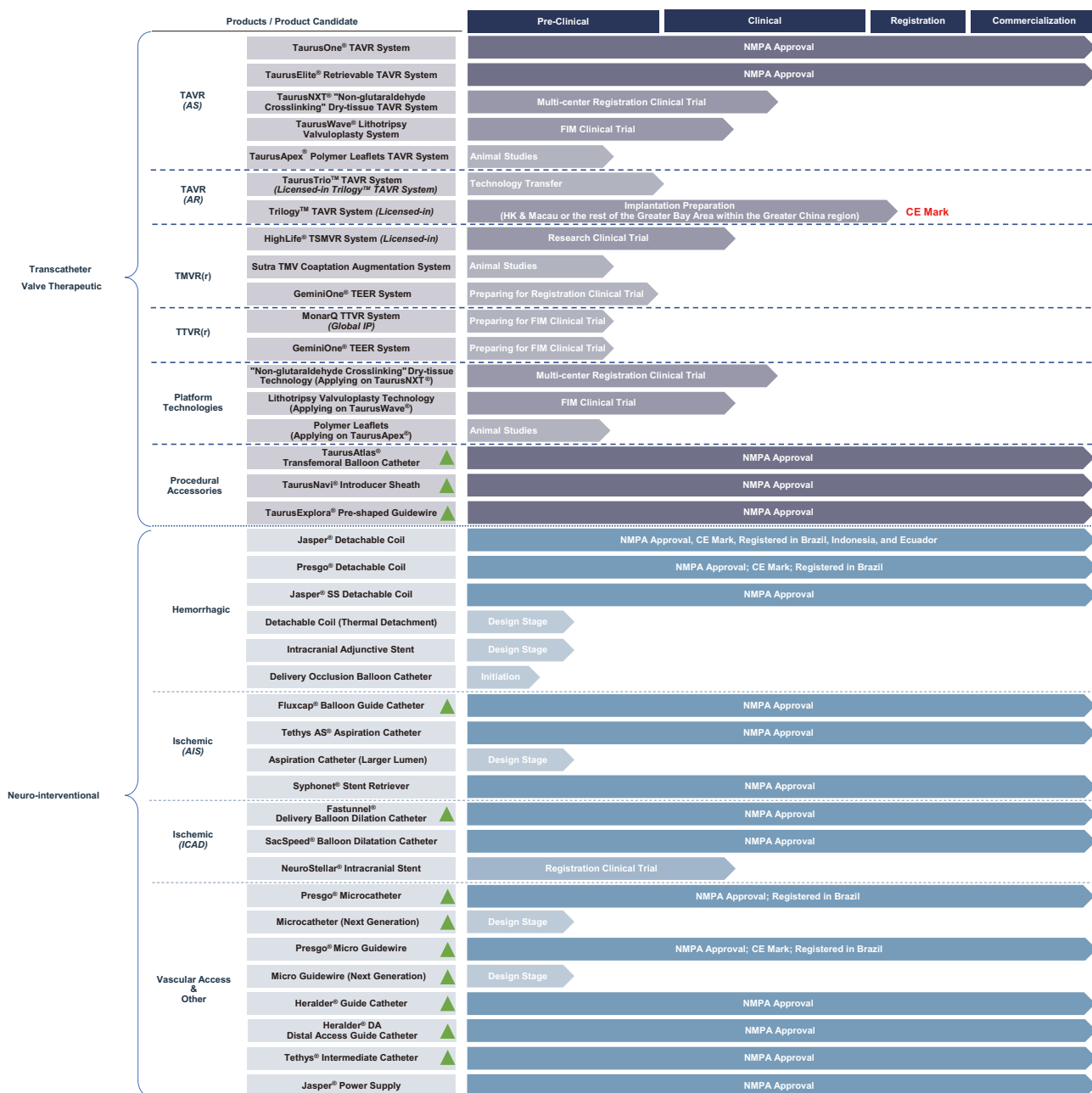
We have built a medtech platform that focuses on the high-growth interventional procedural medical device markets in China and globally. Our products and product candidates target the vast, fast-growing and under-penetrated markets with high entry barriers, including transcatheter valve therapeutic medical device market and neurointerventional procedural medical device market.

### Products and Pipeline

For the six months ended June 30, 2022, we obtained registration approvals from the NMPA for four neurointerventional products, namely, Syphonet<sup>®</sup> Stent Retriever, Tethys AS<sup>®</sup> Aspiration Catheter, Fastunnel<sup>®</sup> Delivery Balloon Dilation Catheter (formerly named as Neway Balloon Microcatheter) and Fluxcap<sup>®</sup> Balloon Guide Catheter.



As of the date of this announcement, for our Transcatheter Valve Therapeutic Business, we had five registered products and nine product candidates at various development stages. For our Neurointerventional Business, we had fourteen registered products and seven product candidates at various development stages. The following chart summarizes the current development status of our product portfolio:



▲ Among our products, these devices are exempted from clinical trial requirements in accordance with the Catalogue of Medical Device Exempted from Clinical Trials (免於臨床評價醫療器械目錄) promulgated by the NMPA, as amended.

## **Transcatheter Valve Therapeutic Products and Product Candidates**

Our Transcatheter Valve Therapeutic Business focuses on treating the most prevalent heart valve diseases, including AS, AR, MR and TR, via transcatheter approaches.

We have a comprehensive portfolio of registered and pipeline products. For the six months ended June 30, 2022, our revenue generated from the sales of transcatheter valve therapeutic products amounted to RMB52.1 million, representing an increase of 455.4% from approximately RMB9.4 million recorded for the six months ended June 30, 2021.

### **TAV Replacement and Repair Products and Product Candidates**

#### ***TaurusOne® — First-Generation TAVR System***

TaurusOne® is our internally developed first-generation TAVR product, and is designed to treat aortic valve stenosis using a catheter-based approach. The product consists of a PAV, a delivery catheter system and a loading system. The PAV includes bovine pericardial leaflets, a nitinol frame, and a sealing skirt to prevent paravalvular leakage. Compared to porcine pericardial leaflets, bovine pericardial leaflets are generally more durable and perform better in terms of hemodynamic profile. The clinical trial of TaurusOne® was the first ever TAVR product registration clinical trial which is completed solely by Chinese physicians. It is also the first domestic TAVR product whose clinical results were published in the top quartile research journal. We received NMPA approval for the registration application of TaurusOne® in April 2021.

#### ***TaurusElite® — Second-Generation Retrievable TAVR System***

TaurusElite® is our internally developed second-generation retrievable TAVR product. TaurusElite® has a valve design similar to that of TaurusOne®, and yet it features a key upgrade in its delivery catheter system that allows physicians to retrieve and reposition the PAV when placing it. The feature of retrievability can largely address the challenge of valve positioning. This can improve the success rate of the TAVR procedure and the long-term benefit to patients, and through this, promote wider clinical adoption. Through the innovative design of inner and outer tubes, the pushability and flexibility of the delivery catheter system are further enhanced, effectively coping with the challenges of complex anatomy of aortic arch and horizontal aorta. The TaurusElite® delivery catheter system is also available in an inline sheath model to meet the diverse needs of doctors and for patients with complicated vascular anatomy.

We received the NMPA approval for the registration application of TaurusElite® in June 2021 and commercially launched the product in July 2021. TaurusElite® is the record-breaking domestic retrievable TAVR product in terms of the approval time as of the date of this announcement.

In addition to the products mentioned above, we also received NMPA approvals for the registration application of a number of procedural accessories in 2021, including TaurusAtlas® Transfemoral Balloon Catheter, TaurusNavi® Introducer Sheath and TaurusExplora® Pre-shaped Guidewire. These are important accessories to help physicians perform the TAVR procedures using Taurus-series products.

We have successfully achieved commercial implantation of our TAVR products in 209 hospitals as of July 31, 2022, benefiting from the increasing number of experienced physicians and hospitals, the positive user experience of our products, and our dedicated marketing and sales capabilities for TAVR products. The product adoption by new hospitals and the utilization rate in the adopted hospitals, continued rising, repeatedly setting new monthly highs in implantation volume. For the six months ended June 30, 2022, the sales from TaurusElite® comprised the majority of our sales of the Transcatheter Valve Therapeutic Business.

### ***TaurusNXT® — Third-Generation “Non-glutaraldehyde Crosslinking” Dry-tissue TAVR System***

TaurusNXT® is our internally developed third-generation TAVR system, and has significantly different tissue and structure from TaurusOne® and TaurusElite®. TaurusNXT® incorporates our patented non-glutaraldehyde bio-tissue crosslinking technology that removes the root cause of valve calcification, the number one cause of prosthetic valve degeneration. The technology is expected to greatly enhance the durability and biocompatibility of the PAV. Furthermore, comparing to the traditional dry tissue technology using glycerin, TaurusNXT® adopts an ultra-low temperature vacuum freeze-drying technology to maintain the physical integrity of the valve tissue while allowing the PAV to be pre-loaded onto the delivery catheter system. The delivery catheter system of TaurusNXT® is both retrievable and steerable, making it much easier for physicians to guide the PAV to its target position, thereby further improving the safety of the procedure. The first patient implant of TaurusNXT® was completed in September 2021. We are currently carrying out the multi-center registration clinical trial for TaurusNXT®.

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

***TaurusApex® — Polymer Leaflets TAVR System***

TaurusApex® is our internally developed fourth-generation TAVR system featuring the polymer leaflets instead of biological tissue. By replacing bio-materials with high strength, stable and soft polymer materials, we could further improve durability and biocompatibility of the prosthetic valves. The leaflets of TaurusApex® adopt the multi-layer bionic composite braided structure which better mimics the features and hemodynamic performance of human's native valves. Polymer leaflets excel biological tissue in durability, tear resistance and wear resistance.

The manufacturing process of TaurusApex® is hand-sewing free. This can not only enable precise cutting and complete edge sealing, but can also result in lower production cost. The development of TaurusApex® is a significant step that we take to explore innovative solutions to improve the durability of the prosthetic valve. We are currently conducting animal studies and associated long-term follow-up evaluation on TaurusApex®, with promising results.

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

***TaurusWave® — Lithotripsy Valvuloplasty System***

Our TaurusWave® Lithotripsy Valvuloplasty System applies shockwave technology to remodel calcification on the heart valves. After the treatment, the mobility of the native valve could be improved, leading to better hemodynamic performance. The system can be used as a stand-alone TAV treatment or be used prior to TAVR, in order to alleviate valve stenosis. The first patient treatment using TaurusWave® was completed in October 2021. We are currently proceeding with FIM clinical trial for this product.

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

***TaurusTrio™ TAVR System — Licensed-in Trilogy™ TAVR Product for Aortic Regurgitation Indication***

We entered into a collaboration and license agreement, a service agreement and a stock purchase agreement with JenaValve, a U.S.-based medical device company, in December 2021. Pursuant to these agreements, JenaValve has granted us an exclusive license regarding Trilogy™ Heart Valve System for the treatment of AR and AS. We are entitled to develop, manufacture, and commercialize the product in the Greater China region and JenaValve agreed to provide services, assisting us to exploit the value of the product within the region. For further details, please also refer to our announcement dated January 14, 2022.

AR is one of the most common types of aortic valve diseases. According to Frost & Sullivan, there were approximately 27.0 million patients worldwide and 3.9 million patients in China in 2020, suffering from AR. As of the date of this announcement, Trilogy™ Heart Valve System is the first and the only transfemoral device of its kind to receive CE Mark approval for the treatment of both severe symptomatic AR and AS. It was also granted the Breakthrough Device Designation by the United States Food and Drug Administration.

We consider this transaction an important step to strengthen our TAVR pipeline by adding first-in-class aortic valve regurgitation treatment system, hoping to benefit more patients in China by expanding indications to AR with clinically proven minimally invasive option. The transaction will enable us to have the most comprehensive TAVR pipeline covering major aortic valve diseases, as compared to other players in China. The technology transfer is in progress as of the date of this announcement. We are preparing the implantation of Trilogy™ in Hong Kong and Macau or the rest of the Greater Bay Area within the Greater China region.

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

**TMV Replacement and Repair Product Candidates**

***HighLife® — Licensed-in TSMVR Product***

We entered into an exclusive license agreement with HighLife, a French-based medical device company focusing on the development of a novel transseptal replacement system for treating mitral valve regurgitation, in December 2020. Pursuant to the agreement, we are entitled to, among other things, manufacture, develop, and commercialize the HighLife® TSMVR device in the Greater China region. Mr. Georg BÖRTLEIN, the founder of HighLife, is also the co-founder of CoreValve, a pioneer company focusing on TAVR which was acquired by Medtronic in 2009.

The field of TMVR still faces many technical difficulties, including access to the target site, anchoring and the risk of paravalvular leakage and LVOT obstruction. Most existing approaches are either transapical or anchoring using radial force. HighLife® TSMVR product adopted the unique “Valve-in-Ring” concept, allowing the system to realize self-centering and self-alignment. This system separates the valve from its anchoring ring and delivers the two components through the femoral vein and femoral artery, respectively, through a simple three-step procedure. The 2-component design respectful for mitral valve anatomy helps to mitigate the risk of paravalvular leakage and effectively reduces catheter size. The procedure can be successfully completed using teleproctoring support. The learning curve is relatively short, evidenced by significant reduction of procedure time by the same physician.

The technology transfer of this product was completed in the third quarter of 2021, and local manufacturing in China has been established. The first mitral valve replacement procedure using HighLife® TSMVR device was completed by West China Hospital of Sichuan University in December 2021, which is also the first application of TSMVR technology in Asia. The product is currently in the process of research clinical trial.

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

***GeminiOne® — TEER System***

GeminiOne® is our internally developed TEER device. The product has a unique design, which enables a longer coaptation length while still maintaining smaller implant size and delivery system. Other innovations include its independent leaflet grasp that reduces the complexity of the procedure, auto-locking mechanism that avoids repeatedly lock & unlock during the procedure, as well as multi-angular detachment that copes with a wider range of anatomy. GeminiOne® is designed to treat mitral valve and tricuspid valve diseases. The product is currently in the pre-clinical evaluation stage.

Dr. Saibal KAR, who is one of the early advocates for TEER technique and a world-leading doctor specializing in TEER procedure, and Dr. Khung Keong YEO, a renowned interventional cardiologist from Singapore, are our medical consultants for GeminiOne®.

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

***Sutra — TMV Coaptation Augmentation System***

In April 2021, we entered into a stock purchase agreement with Sutra, a U.S.-based medical device company that designs and develops transcatheter solutions to treat valvular heart diseases. Sutra's key product candidate, Sutra Hemi Valve, is a transcatheter mitral valve therapeutic device that adopts a hybrid approach between valve replacement and repair technology. The device is designed to treat mitral valve regurgitation using a coaptation augmentation technology that targets only the posterior mitral valve leaflet. Sutra Hemi Valve is currently in the animal studies stage.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET Sutra Hemi Valve SUCCESSFULLY.**

## **TTV Replacement and Repair Product Candidates**

### ***MonarQ — Acquired TTVR Product***

We entered into an IP acquisition agreement, a service agreement and a stock purchase agreement with inQB8 in May 2021, a U.S.-based medical technology incubator, to explore innovative solutions for treating structural heart diseases. The transaction includes our acquisition of a TTVR technology, namely MonarQ, from inQB8, and for which inQB8 will continue with the device development in partnership with us. MonarQ is currently in the pre-clinical evaluation stage.

In addition, we are exploring the application of GeminiOne<sup>®</sup> TEER technology in treating tricuspid valve disease. The FIM clinical trial is currently under preparation.

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

## **Platform Technologies**

We are committed to constantly explore platform technologies which can be applied to various therapies. As of June 30, 2022, we have three patented platform technologies, namely Non-glutaraldehyde Crosslinking Dry-tissue Technology, Polymer Leaflets Technology and Lithotripsy Valvuloplasty Technology.

Non-glutaraldehyde Crosslinking Dry-tissue Technology and Polymer Leaflets Technology are currently applied in our third-generation TAVR product TaurusNXT<sup>®</sup> and our fourth-generation TAVR product TaurusApex<sup>®</sup>, respectively. These technologies can also be applied to other TAVR, TMVR or TTVR product candidates.

Lithotripsy Valvuloplasty Technology, currently applied in TaurusWave<sup>®</sup>, is our non-implant solution to treat AS by remodeling the severe calcification. We are currently carrying out FIM clinical trial for the technology. The initial results indicate the safety and efficacy of the technology. The technology can be applied on a stand-alone basis or as a pre-implantation step during the transcatheter valve replacement procedure.

## **Neurointerventional Products and Product Candidates**

We have a comprehensive portfolio of registered and pipeline products that target both hemorrhagic and ischemic stroke markets. For the six months ended June 30, 2022, our revenue generated from the sales of neurointerventional products amounted to RMB66.7 million, representing an increase of 57.6% from approximately RMB42.3 million for the six months ended June 30, 2021.

## **Hemorrhagic Products and Product Candidates**

For the six months ended June 30, 2022, our revenue generated from the sales of hemorrhagic products amounted to RMB29.5 million, representing an increase from approximately RMB25.5 million for the six months ended June 30, 2021 and accounting for 44.2% of the total revenue of the Neurointerventional Business.

***Detachable Coils:*** we have three registered detachable coil products, namely, Jasper<sup>®</sup> Detachable Coil, Presgo<sup>®</sup> Detachable Coil and Jasper<sup>®</sup> SS Detachable Coils, with different detachment methods. We received NMPA approval for the registration application of Jasper<sup>®</sup> SS Detachable Coil, our latest generation detachable coil, in June 2021. The detachment process of Jasper<sup>®</sup> SS Detachable Coil is the same as that of the previous generation, Jasper<sup>®</sup> Detachable Coil, whereas Jasper<sup>®</sup> SS Detachable Coil is much softer in order to address specific clinical needs during the fill and finish processes of a cerebral aneurysm endovascular coiling procedure.

We are also in the process of developing coil product that can be thermally detached. The coil is designed for framing, filling and finishing. It is an important addition to our existing product offering of embolization coils, providing an alternative and easier detachment method to physicians.

***Intracranial Adjunctive Stent:*** Intracranial Adjunctive Stent is indicated for use with neurovascular embolization coils in the endovascular treatment of intracranial aneurysms. Stent-assisted coil embolization allows endovascular treatment of complex shaped and wide necked intracranial aneurysms. The product is currently in the design stage.

***Delivery Occlusion Balloon Catheter:*** Balloon-assisted coil embolization is a technique involving the intra-procedural remodeling of the aneurysm neck, through the inflation of balloon across the aneurysm neck. By ensuring the framing stability and even distribution of the coils, packing density can be largely improved with proper remodeling of the aneurysm neck, thus reducing the chances of endovascular stent implantation. In addition, if the aneurysm neck requires permanent support after the coil embolization procedure, the endovascular stent can be delivered directly through the inner lumen of the catheter. The catheter provides an alternative treatment solution to physicians while simplifying the procedure.



## **Ischemic Products and Product Candidates**

For the six months ended June 30, 2022, our revenue generated from the sales of ischemic products amounted to RMB16.6 million, representing an increase of 101.9% from approximately RMB8.2 million for the six months ended June 30, 2021 and accounting for 25.0% of the total revenue of the Neurointerventional Business.

### ***Products Designed for Treating AIS***

***Syphonet® Stent Retriever*** (formerly named as Shenyi® in English): Syphonet® Stent Retriever is an important product designed for removing thrombus in intracranial vessels in a mechanical thrombectomy procedure for patients with AIS. The product's unique design features a capture basket at the distal end, which can effectively prevent the thrombus debris from dislodging into the blood stream, thereby improving the removal of the thrombus. The stent is also designed with optimized radial force to maintain the integrity of the lumen, even in tortuous vessels. Radiopaque wires in the stent and a radiopaque marker on the distal end allow for visualization of the entire retriever, facilitating physicians with better visual guidance. The Syphonet® Stent Retriever has various specifications, all compatible with 0.017-inch microcatheter. The compatibility will improve the success rate of deployment and reduce procedure time. We received NMPA approval for the registration application of Syphonet® Stent Retriever in February 2022. The product has been commercially launched in the Reporting Period.

***Tethys AS® Aspiration Catheter***: our Tethys AS® Aspiration Catheter is specially designed for direct aspiration in mechanical thrombectomy. The 0.071-inch large lumen of the product largely increases the aspiration force, which can significantly shorten procedure time. It features a 20cm soft segment at the distal end, which conforms to the tortuous vessels and largely enhances its deliverability to the distal vessels. The optimized design of the transitional structure improves the trackability of the catheter, allowing the device to be delivered to the target vessel more easily. The entire device adopts a double-layer design with outer braids and inner coils, which allows high compressive strength and helps maintain lumen integrity. We received NMPA approval for the registration application of Tethys AS® Aspiration Catheter in May 2022.

***Fluxcap® Balloon Guide Catheter:*** Fluxcap® Balloon Guide Catheter has 0.087-inch large lumen and is compatible with 6F intermediate catheters or aspiration catheters. The reinforced layer with transition zones leads to a balance of proximal support and distal flexibility, offering a stable passage for intracranial devices. The 0.75mm non-radiopaque segment at the tip can reduce the blind spots of the physicians and thus, improving the safety of the procedure. The compliant balloon at its tip can block proximal flow and effectively prevent the thrombus from dislodging into the distal vessels. We received NMPA approval for the registration application of Fluxcap® Balloon Guide Catheter in June 2022.

With the successive launch of Syphonet® Stent Retriever, Tethys AS® Aspiration Catheter and Fluxcap® Balloon Guide Catheter, we are able to provide physicians a fully integrated solution for mechanical thrombectomy. Physicians can rely on our product combinations for different procedures, based on the clinical manifestations of patients.

***Aspiration Catheter (Larger Lumen):*** Aspiration Catheter (Larger Lumen) is a product candidate for treating AIS, which is in the design stage. The product features large lumen to improve aspiration capacity and efficiency, with 8F outer diameter and 0.097-inch inner diameter.

### ***Products Designed for Treating ICAD***

***SacSpeed® Balloon Dilatation Catheter:*** we commercially launched SacSpeed® Balloon Dilatation Catheter in the fourth quarter of 2020. The Catheter is used for dilating stenosis to help with intracranial blood supply, while treating ICAD.

***Fastunnel® Delivery Balloon Dilation Catheter (formerly named as Neway Balloon Microcatheter):*** Fastunnel® Delivery Balloon Dilation Catheter is designed for treating ICAD. As the first medical device in China which can realize balloon dilation and stent delivery in one device, its unique “zero exchange” technology ushered a new era of ICAD treatment. The product adopts an integrated design combining the features of both balloon dilation catheter and microcatheter, which can reduce the number of device exchanges and improve the safety of the procedure. The balloon uses Pebax® semi-compliant materials to achieve steady shape and safe expansion. Meanwhile, the stainless steel structure reinforces the entire device, and thus improves the trackability of the catheter and the deliverability of the intracranial stent system. In addition, the 150cm delivery system is compatible with intermediate catheters length of 135cm and below. We received NMPA approval for the registration application of Fastunnel® Delivery Balloon Dilation Catheter in May 2022.

### **Vascular Access Products and Product Candidates**

For the six months ended June 30, 2022, our revenue generated from the sales of vascular access products amounted to RMB20.4 million, representing an increase of 140.8% from approximately RMB8.5 million for the six months ended June 30, 2021 and accounting for 30.6% of the total revenue of the Neurointerventional Business in the Reporting Period.

***Tethys® Intermediate Catheter:*** we received NMPA approval for the registration application of Tethys® Intermediate Catheter in October 2020. Our Tethys® Intermediate Catheter assists the delivery of diagnostic devices and/or treatment devices to the neurovascular system and peripheral vascular system. It is applicable in various procedures, including aneurysm embolization procedures, mechanical thrombectomy procedures and ICAD procedures. The catheter provides strong support and stability, for stable operation of microcatheters, embolization coils, Stent Retrievers, and balloon dilation catheters in distal blood vessels.

***Heralder® DA Distal Access Catheter:*** we received NMPA approval for the registration application of Heraldier® DA Distal Access Catheter in June 2021, providing more options for the delivery of devices to different positions.

Other registered vascular access products include Presgo® Microcatheter, Presgo® Micro Guidewire and Heraldier® Guide Catheter.

Other vascular access product candidates include Micro Guidewire (Next Generation) and Microcatheter (Next Generation), both of which are in the design stage. The Micro Guidewire (Next Generation) is a newly designed micro guidewire that can be more easily handled by physicians, achieving 1:1 torque ratio. The Microcatheter (Next Generation) adopts more advanced cutting techniques for better support and pushability, applicable in endovascular procedures for both hemorrhagic and ischemic strokes.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP OR MARKET THE ABOVE PRODUCTS OR PRODUCT CANDIDATES SUCCESSFULLY.**

## **Research & Development**

Both in-house innovation and business development opportunities are crucial to our R&D efforts. Our core R&D team is led by Dr. Yi Zhang, our chairman of the Board and chief executive officer, Mr. Kongrong PAN, our chief operating officer and Dr. Jian Fong TAN, our chief technology officer. Each of them, as an industry veteran with impressive academic and professional background, has previously worked in managerial positions at various leading players in the medical device sector.

We have also developed deep relationship with global leaders in both the transcatheter valve therapeutic and neurointerventional domains, including world-class scientists, physicians and industry practitioners. Besides licensing in cutting-edge technologies, we have also been building up our overseas R&D capabilities through close collaboration:

We are Sutra's second largest shareholder after the founder, and has right of first offer if Sutra proposes to offer or sell any new securities, subject to certain customary exceptions. Sutra will share the R&D facilities with the Company in the United States, and will also assist us in expanding R&D presence in North America. The founding team of Sutra is composed of professionals with extensive experience in both academia and industry.

inQB8 is a medtech incubator in partnership with us. Under the partnership, in the joint development of novel products and solutions in the structural heart field, we will have exclusive privileges and rights to these technologies globally. The founding team of inQB8 has multidisciplinary backgrounds in medtech and engineering. Before founding inQB8, the team founded CardiAQ Valve Technologies (“**CardiAQ**”). CardiAQ developed the world’s first transcatheter TMVR system and was later acquired by Edwards Lifesciences.

We have established close working relationship with world-class consultants, who provide consultancy services exclusively for us in China. They are heavily involved in our R&D process, contributing significantly to our innovative aortic, mitral and tricuspid valve products:

Dr. Nicolo PIAZZA is a renowned interventional cardiologist at McGill University Health Center and the German Heart Center in Munich. He also served as the chairman or the core team member in many premier transcatheter valve therapeutics conferences, including EuroPCR, PCR London Valves and PCR-CIT China Chengdu Valves. He is actively involved in our overseas business development, product promotion and clinical trials, including the clinical trial and technology transfer of HighLife® as well as the clinical trial of TaurusWave®.

Dr. Saibal KAR became our consultant in September 2021. He is a world-leading doctor well-known for his research and achievements in the field of structural heart therapies, particularly in mitral repair space. Dr. Saibal KAR also serves as an external consultant for various multinational medical device companies such as Medtronic plc, Boston Scientific Corporation, and Abbott Vascular Inc. He worked as a principal investigator in a couple of multicenter studies and randomized studies for MitraClip™. Dr. Saibal KAR is currently advising the R&D of our mitral edge-to-edge therapies.

Dr. Khung Keong YEO became our consultant in April 2022. He is the deputy chief executive officer (data science and innovation) and a senior consultant with the Department of Cardiology at the National Heart Centre Singapore (NHCS). Dr. YEO currently leads the MitraClip™ program at NHCS, the first in Asia. He is advising the R&D of our mitral and tricuspid edge-to-edge repair therapies.

Suzhou SITRI Interventional Medtech Institute (“**IMI**”), an innovation incubation and investment platform dedicated in the field of vascular interventional medical devices, was established in October 2021. The IMI was proposed and funded by us together with Suzhou Industrial Park Administrative Committee, Suzhou Industrial Technology Research Institute, and IMI management team. The establishment of IMI will facilitate our R&D activities through providing us with access to emerging medical device technologies that might have significant global impact, which will benefit our future business expansion.

As of June 30, 2022, we had an in-house R&D team of 115 employees dedicated to the R&D of our transcatheter valve therapeutic products and neurointerventional products.

On March 1, 2022, TaurusNXT® was formally accepted by the Special Review and Approval Procedure for Innovative Medical Devices of the NMPA. Given this, we will enjoy advantages including expedited approval, as well as favorable policy support and market access. As of the date of this announcement, we have the highest number of medical devices accepted by the Special Review and Approval Procedure among Chinese listed transcatheter valve therapeutic peers, which once again proved our strong R&D capabilities and the innovativeness of our product pipeline.

## **Intellectual Property**

As of June 30, 2022, we had a robust intellectual property portfolio, consisting of a total of 89 granted and valid patents and 100 patents under application. Specifically, there are 53 granted and valid patents and 74 patents under application for our Transcatheter Valve Therapeutic Business, and 36 granted and valid patents and 26 patents under application for our Neurointerventional Business.

## **Manufacturing**

We manufacture, assemble and examine our products at two production facilities. One is located in our self-owned properties in Suzhou, Jiangsu province, with a total area of 18,843.9 sq.m., and the other one is located in our leased properties in Shanghai with a total area of 1,188.4 sq.m..

For our Neurointerventional Business, we currently manufacture Presgo® Detachable Coil, Presgo® Micro Guidewire, Presgo® Microcatheter, Jasper® Detachable Coil and Jasper® Power Supply in the leased properties in Shanghai. Herald® Guide Catheter, Tethys® Intermediate Catheter, SacSpeed® Ballon Dilatation Catheter, Jasper® SS Detachable Coil, Herald® DA Distal Access Catheter, Syphonet® Retriever Stent, Tethys AS® Aspiration Catheter, Fastunnel® Delivery Balloon Dilation Catheter and Fluxcap® Balloon Guide Catheter are manufactured in our Suzhou facility.

For our Transcatheter Valve Therapeutic Business, we have five registered products as of June 30, 2022. All of them, namely, TaurusOne®, TaurusElite®, our first and second generation TAVR products, TaurusAtlas® Transfemoral Balloon Catheter, TaurusNavi® Introducer Sheath and TaurusExplora® Pre-shaped Guidewire, are manufactured in our Suzhou facility. Our Suzhou facility is also equipped with multiple production lines dedicated to TaurusNXT®, TaurusWave®, HighLife® and other production lines for transcatheter valve therapeutic product candidates.

We monitor compliance with our quality control system at every phase in a product life cycle. We have developed the Risk Management and Control Procedures (《風險管理控制程序》), arranged risk control measures for all phases of the product lifecycle, and used scientific tools to identify, analyze, evaluate and control risks to ensure the safety and efficacy of medical devices.

We have established an advanced quality management system. It is our responsibility to develop products that allow patients to enjoy healthy lives and strictly abide by the Product Quality Law of the People's Republic of China (《中華人民共和國產品質量法》), Measures for the Supervision and Administration of Medical Device Production (《醫療器械生產監督管理辦法》), Good Manufacturing Practices for Medical Devices (《醫療器械生產質量管理規範》) and other laws and regulations. Our Quality Management System is aligned to relevant laws and international standards, including GMP standards and the ISO 13485:2016 Medical devices — Quality management systems.

Over the years, we continuously expand the production capacity to meet growing market demand. Our new headquarter in Suzhou Industrial Park is under construction. Phase I with a total construction area of around 77,600 m<sup>2</sup> will start being used in 2023.

## **Commercialization**

As of June 30, 2022, we had a sales and marketing team of 225 employees, with 151 of whom dedicated to the sales and marketing of our transcatheter valve therapeutic products and 74 focusing on the sales and marketing of neurointerventional products.

For our Transcatheter Valve Therapeutic Business, through well-planned internal training system and rigorous staff development plan, we have built up a professional sales and marketing team with leading expertise in academic education and marketing. Our team is comprised of:

- product specialists, who collaborate with R&D team to align product roadmap with the lifecycle of product portfolio to address unmet clinical needs;
- marketing specialists, who promote brand awareness, market education and connections with KOLs/hospitals;

- clinical support specialists, who provide seamless technical support and intensive involvement to ensure best patient outcome;
- frontline sales, who stay connected with physicians and hospitals to complete sales procedure.

In addition to the sales and marketing staff mentioned above, we also have a team of medical specialists. They are licensed physicians with extensive clinical experience and can provide full medical support for patient evaluation, procedure planning and other clinical needs.

To increase our academic influence in the industry, we actively participated in domestic and international academic conferences, as well as branded academic promotion activities organized by relevant associations in the cardiovascular field. We work closely with domestic and foreign experts and scholars, to promote the adoption of TAVR technology and increase regional implantation volume. At the same time, we have created a series of Peijia branded academic programs through the professional education platform of Yijia Institute and other digital academic media. In this way, we educate physicians about the Taurus-series products and increase the product adoption by new and emerging hospitals:

- Yijia Institute is a professional clinical education and training center under Peijia Medical that includes both online and offline channels. The aim of establishing Yijia Institute is to facilitate the adoption of TAVR technology through procedure demonstration, academic thematic discussion, case analysis, patient diagnosis and screening and etc.;
- Yijia Institute is equipped with facilities such as training classrooms, laboratories, operation rooms and etc. The institute can provide professional trainings, imaging trainings, live-streaming of procedures and other activities. The institute's online programs include Round Table Discussion, Cloud Classroom, Imaging interpretation competition and etc., helping more physicians to learn and communicate online;
- In June 2022, we launched the WeChat official and channel accounts for Yijia Institute. As a professional education platform, the accounts provide educational resources and the latest industry information of transcatheter heart valve interventions. By combining resources from both theory and practice, the platform can benefit the experts and physicians during their journey to TAVR technologies. Yijia Institute promotes the digital dissemination of professional education and industry information of transcatheter heart valve interventions in China, facilitating the development of the therapy.

Since the launch of these programs, more than 300 experts and physicians have participated in our activities as guest speakers, with more than 40,000 attendees. We also forge long-term ties with leading experts and scholars through these programs.

The three key building blocks for accelerated commercialization of our TAVR products are accurate product positioning and superior product performance, all-around marketing and sales support as well as high-touch sales model. We are dedicated to becoming the best product partner and service provider to physicians.

As of July 31, 2022, we had TAVR implantations in 209 hospitals, well ahead of schedule. We will continue to strengthen our research cooperation with TOP/KA hospitals and size up the sales team for more coverage and adoption of our TAVR products.

For our Neurointerventional Business, our experienced marketing team has tailored marketing strategies to maximize product visibility and penetration, based on the commercialization stage and design characteristics of each product. We work closely with KOLs and physicians in the industry. In addition to actively participating in academic and industry conferences on neurointerventional therapies, we live-streamed neurointerventional procedures conducted by physicians from top hospitals, which effectively enhanced our product reputation and brand awareness.

At the same time, we have a sales team with strong product knowledge and clinical resources. Our sales team have established extensive and in-depth relationships with industry experts, physicians and hospitals, and maintained long-term cooperation with experienced distributors. Most of our products are sold directly to hospitals mainly through distributors. We believe that through a single-tier distribution system, we can leverage our distributors' local networks and expertise to reach a wider range of end customers. On the other hand, we can better adapt to changes in end-user demand and be more responsive to clinical feedback. The single-tier distribution system also enables a healthy channel inventory level, reduces channel costs and lowers product return rate as compared to multi-tier distribution system.

As of June 30, 2022, we had 177 distributors, covering more than 1,800 hospitals in 31 provinces nationwide. We will continue to build on our sales team and distributor coverage in response to our expanding ischemic product portfolio.



## **Impact of the COVID-19 Pandemic**

The Chinese government has strengthened the epidemic prevention and control since the outbreak of Delta variant and Omicron variant cases successively in 2021. Despite of the social restrictions imposed, our revenue for the six months ended June 30, 2022 increased by 129.8% to RMB118.8 million from RMB51.7 million for the six months ended June 30, 2021. The adverse impact on our product sales, financial condition and results of procedures were limited due to our prompt and proactive actions. We will continue to enhance remedial measures in line with the government's requirements in response to the ongoing situation.

## **Future Outlook**

In the future, we will uphold our corporate vision and continue our commitment to the development and commercialization of interventional solutions for structural heart and neurovascular diseases in China and globally. For our Transcatheter Valve Therapeutic Business, our sales and marketing team will focus on the commercialization of TaurusOne® and TaurusElite®. In addition, we will continue to actively launch clinical trials for a number of our pre-clinical stage product candidates, including GeminiOne® and MonarQ, and facilitate the progress of those that are currently in the clinical stage. We will facilitate the technology transfer of Trilogy™ from JenaValve and subsequent clinical trial. We are also in preparation of the implantations of Trilogy™ in Hong Kong and Macau or the rest of the Greater Bay Area within the Greater China region.

For our Neurointerventional Business, we intend to maintain the sales growth momentum through further penetration of our existing products. We are currently preparing for commercial launch of the products recently approved by the NMPA during the six months ended June 30, 2022, including Syphonet® Stent Retriever, Tethys AS® Aspiration Catheter, Fastunnel® Delivery Balloon Dilation Catheter and Fluxcap® Balloon Guide Catheter. Our dedicated sales team will make efforts to commercialize these newly approved products.

We will continue to enhance our pipeline, including TMV/TTV treatment device, and other transcatheter valve therapeutic and neurointerventional product candidates; strengthening our in-house R&D capabilities while seeking deeper cooperation and strategic partnership around the globe. We will continue to strengthen our international patent portfolio and further advance our globalization strategy.

## II. FINANCIAL REVIEW

### Revenue

For the six months ended June 30, 2022, our Group's revenue was RMB118.8 million, representing an increase of 129.8% as compared to RMB51.7 million for the six months ended June 30, 2021. Revenue from Transcatheter Valve Therapeutic Business and Neurointerventional Business were RMB52.1 million and RMB66.7 million, representing an increase of 455.4% and 57.6% as compared to RMB9.4 million and RMB42.3 million for the six months ended June 30, 2021, respectively.

The increase in revenue was primarily attributable to: (i) commercialization of the second generation retrievable TAVR product TaurusElite®; (ii) increased sales revenue from existing neurointerventional products including Tethy® Intermediate Catheter and SacSpeed® Balloon Dilation Catheter; and (iii) commercialization of multiple new neurointerventional products including Jasper® SS Detachable Coil, etc.

The following table sets forth a breakdown of our revenue generated from Neurointerventional Business for the periods indicated:

	Six months ended June 30,			
	2022		2021	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
	(Unaudited)		(Unaudited)	
Hemorrhagic	29,490	44.2	25,461	60.2
Vascular Access	20,414	30.6	8,476	20.0
Ischemic	16,647	25.0	8,247	19.5
Others	145	0.2	124	0.3
<b>Total</b>	<b>66,696</b>	<b>100.0</b>	<b>42,308</b>	<b>100.0</b>

### Cost of Sales

For the six months ended June 30, 2022, our Group's cost of sales was RMB35.6 million, representing an increase of 149.1% as compared to RMB14.3 million for the six months ended June 30, 2021. The increase was primarily attributable to the increase in the material costs, labor costs and overheads as a result of the increased sales volume of the Transcatheter Valve Therapeutic Business and Neurointerventional Business.

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

As a result of the aforementioned factors, our Group's gross profit increased by 122.5%, from RMB37.4 million for the six months ended June 30, 2021 to RMB83.2 million for the six months ended June 30, 2022, in line with the increase in sales revenue. Gross profit margin is calculated as gross profit divided by revenue and multiplying the result by 100%. Our Group's gross profit margin was 70.0% for the six months ended June 30, 2022, as compared to 72.4% for the six months ended June 30, 2021. The decrease in gross profit margin was primarily attributable to the amortization of technologies related to the products launched in the Reporting Period.

## **Selling and Distribution Expenses**

Selling and distribution expenses increased by 327.5% from RMB21.7 million for the six months ended June 30, 2021 to RMB92.7 million for the six months ended June 30, 2022. Such increase was primarily attributable to (i) increase in expenses due to market education, development of multiple distribution channels and sales promotion, in line with the increase in sales revenue; and (ii) increase in staff costs.

## **Administrative Expenses**

Administrative expenses increased by 12.3% from RMB53.1 million for the six months ended June 30, 2021 to RMB59.6 million for the six months ended June 30, 2022. The increase was primarily attributable to the increase in staff costs.

## **Research and Development Expenses**

Research and development expenses decreased by 36.5% from RMB131.3 million for the six months ended June 30, 2021 to RMB83.4 million for the six months ended June 30, 2022. Such decrease was primarily attributable to the expensing BD payments of RMB67.4 million for TAVR, TMVR and TTVR products.

For the six months ended June 30, 2022, R&D investment in Transcatheter Valve Therapeutic Business and Neurointerventional Business amounted to RMB58.4 million and RMB25.0 million, respectively. The following table sets forth the components of research and development expenses for the periods indicated:

	<b>Six months ended June 30,</b>			
	<b>2022</b>		<b>2021</b>	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
Service expenses for research and development	<b>25,488</b>	<b>30.6</b>	90,250	68.7
Employee benefits expenses	<b>35,082</b>	<b>42.1</b>	24,101	18.4
Raw materials and consumables used	<b>17,513</b>	<b>21.0</b>	12,679	9.7
Depreciation and amortization	<b>3,126</b>	<b>3.7</b>	2,738	2.1
Others	<b>2,219</b>	<b>2.6</b>	1,523	1.1
<b>Total</b>	<b><u>83,428</u></b>	<b><u>100.0</u></b>	<b><u>131,291</u></b>	<b><u>100.0</u></b>

### **Other Gains/(Losses) — net**

Other gains/(losses) — net increased from a net other losses of RMB21.4 million for the six months ended June 30, 2021 to a net other gains of RMB41.6 million for the six months ended June 30, 2022. The increase was mainly due to the foreign exchange gains.

### **Finance Income**

Finance income increased from RMB13.0 million for the six months ended June 30, 2021 to RMB18.1 million for the six months ended June 30, 2022. The increase was mainly due to the bank interest income.

### **Gearing Ratio**

Gearing ratio is calculated by dividing total liabilities by total equity and multiplying the result by 100%. As of June 30, 2022, the gearing ratio of our Group increased to 7.1% from 4.8% as of December 31, 2021.

### **Net Current Assets**

As of June 30, 2022, our Group's net current assets were RMB1,923.2 million, as compared with RMB2,307.7 million as of December 31, 2021.

### **Capital Management**

The primary goal of our Group's capital management is to maintain our Group's stability and growth, safeguard its normal operations and maximize Shareholders' value. Our Group reviews and manages its capital structure on a regular basis. Timely adjustments are made in light of changes in operating and market conditions.

## **Liquidity and Financial Resources**

As of June 30, 2022, our Group's total cash, cash equivalents and term deposits amounted to approximately RMB2,057.9 million, representing a decrease of 10.4% as compared to RMB2,296.1 million as of December 31, 2021. Our Group continues to maintain a strong financial position and is confident that it has sufficient funds to meet its daily business operation requirements.

We rely on capital contributions by our Shareholders as the major sources of liquidity. We also generate cash from our sales of existing commercialized products. As our business develops and expands, we expect to generate more net cash from our operating activities, through increasing sales revenue, lowering production costs and improving operating efficiency.

Our Group adopts conservative treasury policies in cash and financial management. To achieve better risk control and minimize the cost of funds, our Group's treasury is centralized. Cash is generally placed in deposits mostly denominated in U.S. Dollars, Hong Kong dollars and RMB. Our Group's liquidity and financing requirements are reviewed regularly.

## **Capital Expenditure**

For the Reporting Period, our Group's total capital expenditure amounted to approximately RMB121.0 million, which was mainly used in (i) the construction of new headquarter; (ii) equipment procurement; and (iii) technologies.

## **Significant Investment**

As of June 30, 2022, our Group did not have any significant investment.

## **Contingent Liabilities**

As of June 30, 2022, our Group did not have any significant contingent liabilities.

## **Material Acquisitions and Disposals**

As of June 30, 2022, our Group did not have any material acquisitions and disposals.

## **Charge on Assets**

As of June 30, 2022, certain land use right of our Group was mortgaged for a long-term bank facility, of which RMB9.0 million was drawn down.

## **Foreign Exchange Exposure**

Our Group has transactional currency exposures. Certain cash and cash equivalents as well as financial assets at fair value through profit or loss are dominated in foreign currencies and are exposed to foreign currency risk. Our management monitors foreign exchange exposure and the Company has entered into several forward exchange settlement agreements with reputable banks to hedge exchange rate risks.

## **Future Plans for Material Investments and Capital Asset**

Our Group had not authorized any plan for material investments or acquisitions as of the date of this announcement.

## **SUBSEQUENT EVENT AFTER THE REPORTING PERIOD**

Save as disclosed in this announcement, our Group is not aware of any material subsequent events after the Reporting Period.

## USE OF PROCEEDS FROM THE GLOBAL OFFERING

Net proceeds from the Global Offering and the Listing on the Listing Date, and the full exercise of the Over-allotment Option, after deduction of the underwriting fees and commissions and expenses of the Company in connection with the Global Offering was approximately HK\$2,587.98 million. Our Group would apply such proceeds in a manner consistent with the intended use of proceeds as disclosed in the Prospectus.

The table below sets forth the utilisation of the net proceeds from the Global Offering and the unutilized amount as of June 30, 2022:

Business objective as stated in the Prospectus	Percentage to total amount %	Net proceeds HK\$ million	Utilised	Unutilised	Expected timeline for unutilised amount
			amount as of June 30, 2022 HK\$ million	amount as of June 30, 2022 HK\$ million	
Development and commercialization of our Core Product and other major product candidates	65	1,682.18	326.43	1,355.75	Yr2025
Ongoing pre-clinical studies and planned clinical trials, preparation for registration filings and potential commercial launches (including sales and marketing) of our other product candidates in our pipeline	10	258.80	258.8	0	
Strengthen our research and development capabilities to enrich our product pipeline	8	207.04	57.87	149.17	Yr2024
Expand our product portfolio or intellectual property portfolio through potential strategic acquisitions, investments, partnerships and licensing opportunities	10	258.80	246.89	11.91	Yr2022
Working capital and other general corporate purposes	7	181.16	148.42	32.74	Yr2023
<b>Total</b>	<b>100</b>	<b>2,587.98</b>	<b>1,038.41</b>	<b>1,549.57</b>	

As of June 30, 2022, net proceeds from the Global Offering not yet utilized were deposited with certain licensed banks in Hong Kong or the PRC.

## **USE OF PROCEEDS FROM THE PLACING**

On January 22, 2021, the Company entered into the Placing Agreement with Morgan Stanley & Co. International plc, pursuant to which the Company appointed Morgan Stanley & Co. International plc as its placing agent to procure not less than six Placees who are Independent Third Parties to subscribe up to 33,800,000 Placing Shares at the placing price of HK\$29.38 per Placing Share in accordance with the terms and conditions of the Placing Agreement. The net placing price per Placing Share after deducting related fees and expenses is approximately HK\$28.74 per Share. The Placing Shares had a market value of approximately HK\$1,012.31 million based on the closing price of HK\$29.95 per Share as of January 21, 2021 and an aggregate nominal value of US\$3,380. The Placing Shares represented approximately 5.3% of the existing issued share capital of the Company as of the Placing Agreement date, and approximately 5.1% of the enlarged issued share capital of the Company immediately following the completion of the Placing.

The Placing was completed on January 29, 2021. An aggregate of 33,800,000 Placing Shares have been successfully placed to not less than six Placees. The net proceeds from the Placing were approximately HK\$971.48 million, of which the intended use was set out in the announcement of the Company dated January 22, 2021. The Placing is being undertaken to strengthen our Group's financial position and for the long term funding of its business, expansion and growth plan. The table below sets forth the utilisation of the net proceeds from the Placing and the unutilized amount as of June 30, 2022:



Business objective as stated in the announcement of the Company dated January 22, 2021	Percentage to total amount %	Net proceeds HK\$ million	Utilised amount as of June 30, 2022 HK\$ million	Unutilised amount as of June 30, 2022 HK\$ million	Expected timeline for unutilized amount
To fund potential product licensing and possible merger and acquisition opportunities in the area of mitral valve replacement and repair treatment, including a collaboration and license agreement for transeptal mitral valve replacement with HighLife SAS dated December 18, 2020 (for further details, please refer to the voluntary announcement of the Company, published on December 21, 2020)	100	971.48	623.42	348.06	Yr2025
To fund potential product licensing and possible merger and acquisition opportunities in other areas including tricuspid valve replacement and repair treatment					
To fund ongoing technology transfer, product development, and research and development, across the Group					
For other general corporate purposes					
<b>Total</b>	<b>100</b>	<b>971.48</b>	<b>623.42</b>	<b>348.06</b>	

As of June 30, 2022, net proceeds from the Placing not yet utilized were deposited with certain licensed banks in Hong Kong or the PRC.

## HUMAN RESOURCES

As of June 30, 2022, our Group had 807 employees, who were all based in China. Our Group's total employee benefits for the six months ended June 30, 2022 were approximately RMB121.7 million, consisted of (i) wages, salaries and bonuses, (ii) social security costs and housing benefits, (iii) employee welfare and (iv) share-based compensation expenses.

We recruit our employees based on a number of factors, including work experience, educational background and the requirements of a relevant position. We invest in continuing education programs for our management staff and other employees to upgrade their skills and knowledge continuously. We provide our employees with regular feedback as well as internal and external training in various areas, such as product knowledge, project development and team building. We also assess our employees based on their performance to determine their salaries, promotion and career development.

In compliance with the relevant PRC labor laws, we enter into individual employment contracts with our employees covering matters such as terms, wages, bonuses, employee benefits, workplace safety, confidentiality obligations, non-competition and grounds for termination.

In addition, we are required under PRC law to make contributions to statutory employee benefit plans (including pension plans, medical insurance, work-related injury insurance, unemployment insurance, maternity insurance and housing funds) at a certain percentage of our employees' salaries, including bonus and allowances, up to a maximum amount specified by the local government.

## **INTERIM DIVIDEND**

The Board has resolved not to declare any interim dividend for the Reporting Period (six months ended June 30, 2021: nil).

## **CORPORATE GOVERNANCE PRACTICES**

The Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the Shareholders as a whole. The Company has adopted the code provisions as set out in the CG Code, as its own code to govern its corporate governance practices.

Under the code provision C.2.1 of the CG Code, the roles of chairman and chief executive should be separate and should not be performed by the same individual. Under the current organization structure of the Company, Dr. Zhang is the chairman of the Board and chief executive officer of the Company. With extensive experience in the medical devices industry and having served in the Company since its establishment, Dr. Zhang is in charge of overall management, business, strategic development and scientific R&D of our Group. The Board considers that vesting the roles of the chairman of the Board and the chief executive officer in the same person is beneficial to the management of our Group. The balance of power and authority is ensured by the operation of the Board, which comprises experienced and diverse individuals. The Board currently comprises three executive Directors (including Dr. Zhang), four non-executive Directors and four independent non-executive Directors, and therefore has a strong independent element in its composition.

Save as disclosed above, in the opinion of the Directors, the Company has complied with the relevant code provisions contained in the CG Code during the six months ended June 30, 2022.

The Board will continue to review and monitor the practices of the Company with an aim of maintaining a high standard of corporate governance.

## **MODEL CODE FOR SECURITIES TRANSACTIONS**

The Company has adopted the Model Code as its own code of conduct regarding dealings in the securities of the Company by the Directors and the Company's senior management who, because of his/her office or employment, is likely to possess inside information in relation to the Company's securities.

Upon specific enquiry, all Directors confirmed that they have complied with the Model Code during the six months ended June 30, 2022. In addition, the Company is not aware of any non-compliance of the Model Code by the senior management of our Group during the six months ended June 30, 2022.

## **PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES OF THE COMPANY**

As of June 30, 2022, the trustee of the RSU Scheme has purchased an aggregate of 5,472,000 Shares (representing approximately 0.81% of the total issued share capital of the Company) under the RSU Scheme.

As of June 30, 2022, a total of 205,935 Shares (representing approximately 0.03% of the total issued share capital of the Company) have been granted to two independent non-executive Directors, namely Dr. Stephen Newman OESTERLE and Mr. Robert Ralph PARKS, under the RSU Scheme.

As of June 30, 2022, a total of 202,310 Shares (representing approximately 0.03% of the total issued share capital of the Company) have been granted to an external consultant of our Group under the RSU Scheme.

Save as disclosed above, neither the Company nor any of its subsidiaries have purchased, sold or redeemed any of the Company's listed securities during the six months ended June 30, 2022.

## INTERIM CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

*For the six months ended June 30, 2022*

	<i>Note</i>	<b>Six months ended June 30,</b>	
		<b>2022</b>	<b>2021</b>
		<b>RMB'000</b>	<b>RMB'000</b>
		<b>(Unaudited)</b>	<b>(Unaudited)</b>
Revenue	5	<b>118,799</b>	51,689
Cost of sales	6	<b>(35,597)</b>	(14,289)
<b>Gross profit</b>		<b>83,202</b>	37,400
Selling and distribution expenses	6	<b>(92,670)</b>	(21,679)
Administrative expenses	6	<b>(59,609)</b>	(53,082)
Research and development expenses	6	<b>(83,428)</b>	(131,291)
Other income	7	<b>2,195</b>	2,237
Other gains/(losses) — net	8	<b>41,557</b>	(21,399)
<b>Operating loss</b>		<b>(108,753)</b>	(187,814)
Finance income	9	<b>18,080</b>	12,980
Finance costs	9	<b>(1,121)</b>	(340)
Finance income — net		<b>16,959</b>	12,640
<b>Loss before income tax</b>		<b>(91,794)</b>	(175,174)
Income tax expense	10	<b>(192)</b>	—
<b>Loss for the period and attributable to the owners of the Company</b>		<b><u>(91,986)</u></b>	<b><u>(175,174)</u></b>
<b>Total comprehensive loss for the period and attributable to the owners of the Company</b>		<b><u>(91,986)</u></b>	<b><u>(175,174)</u></b>
<b>Loss per share attributable to the owners of the Company</b>			
Basic and diluted loss per share <i>(in RMB per share)</i>	11	<b><u>(0.14)</u></b>	<b><u>(0.27)</u></b>

# INTERIM CONDENSED CONSOLIDATED BALANCE SHEET

As of June 30, 2022

		<b>June 30,</b>	December 31,
		<b>2022</b>	2021
	<i>Note</i>	<i>RMB'000</i>	<i>RMB'000</i>
		(Unaudited)	(Audited)
<b>ASSETS</b>			
<b>Non-current assets</b>			
Right-of-use assets		21,199	25,014
Property, plant and equipment		213,801	151,205
Investment properties		7,279	7,549
Intangible assets		399,471	276,502
Investment accounted for using equity method		500	—
Other receivables	12	12,644	—
Prepayments		3,193	52,613
Term deposits		170,000	—
Financial assets at fair value through profit or loss		236,241	224,424
<b>Total non-current assets</b>		<b>1,064,328</b>	<b>737,307</b>
<b>Current assets</b>			
Inventories		84,060	66,107
Trade and other receivables	12	64,854	33,333
Prepayments		56,960	30,809
Cash and cash equivalents		1,887,886	2,296,112
<b>Total current assets</b>		<b>2,093,760</b>	<b>2,426,361</b>
<b>Total assets</b>		<b>3,158,088</b>	<b>3,163,668</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity attribute to owners of the Company</b>			
Share capital and share premium		6,369,462	6,339,597
Treasury shares held in a trust		(84,507)	(84,549)
Other reserves		60,103	69,139
Accumulated losses		(3,396,988)	(3,305,002)
<b>Total equity</b>		<b>2,948,070</b>	<b>3,019,185</b>

		<b>June 30,</b>	December 31,
		<b>2022</b>	2021
	<i>Note</i>	<b>RMB'000</b>	<b>RMB'000</b>
		<b>(Unaudited)</b>	<b>(Audited)</b>
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Lease liabilities		2,614	4,082
Deferred tax liabilities		20,320	20,320
Borrowings		9,025	—
Other payables	13	6,246	—
Deferred income		1,220	1,374
		<hr/>	<hr/>
<b>Total non-current liabilities</b>		<b>39,425</b>	<b>25,776</b>
		<hr/>	<hr/>
<b>Current liabilities</b>			
Lease liabilities		1,928	3,545
Borrowings		56,000	—
Trade and other payables	13	112,208	115,162
Contract liabilities		457	—
		<hr/>	<hr/>
<b>Total current liabilities</b>		<b>170,593</b>	<b>118,707</b>
		<hr/>	<hr/>
<b>Total liabilities</b>		<b>210,018</b>	<b>144,483</b>
		<hr/>	<hr/>
<b>Total equity and liabilities</b>		<b><u>3,158,088</u></b>	<b><u>3,163,668</u></b>

# INTERIM CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the six months ended June 30, 2022

	Share capital and share premium RMB'000	Other reserves RMB'000	Treasury shares held in a trust RMB'000	Accumulated losses RMB'000	Total equity RMB'000
<b>Balance at January 1, 2021 (Audited)</b>	5,512,758	54,409	(23,126)	(2,730,786)	2,813,255
<b>Comprehensive loss:</b>					
Loss for the period	—	—	—	(175,174)	(175,174)
<b>Total comprehensive loss</b>	—	—	—	(175,174)	(175,174)
<b>Transactions with owners in their capacity as owners:</b>					
Issuance of ordinary shares	810,559	—	—	—	810,559
Acquisition of shares by the trust	—	—	(6,551)	—	(6,551)
Restricted share units granted	(57)	(742)	799	—	—
Share-based payments	—	10,010	—	—	10,010
<b>Balance at June 30, 2021 (Unaudited)</b>	<u>6,323,260</u>	<u>63,677</u>	<u>(28,878)</u>	<u>(2,905,960)</u>	<u>3,452,099</u>

	Share capital and share premium RMB'000	Other reserves RMB'000	Treasury shares held in a trust RMB'000	Accumulated losses RMB'000	Total equity RMB'000
<b>Balance at January 1, 2022 (Audited)</b>	<b>6,339,597</b>	<b>69,139</b>	<b>(84,549)</b>	<b>(3,305,002)</b>	<b>3,019,185</b>
Comprehensive loss:					
Loss for the period	—	—	—	(91,986)	(91,986)
<b>Total comprehensive loss</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>(91,986)</b>	<b>(91,986)</b>
<b>Transactions with owners in their capacity as owners:</b>					
Exercise of share options	31,159	(14,239)	—	—	16,920
Acquisition of shares under the RSU Scheme	—	—	(3,094)	—	(3,094)
Restricted share units granted	(1,294)	(1,842)	3,136	—	—
Share-based payments	—	7,045	—	—	7,045
<b>Balance at June 30, 2022 (Unaudited)</b>	<b><u>6,369,462</u></b>	<b><u>60,103</u></b>	<b><u>(84,507)</u></b>	<b><u>(3,396,988)</u></b>	<b><u>2,948,070</u></b>



# INTERIM CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

For the six months ended June 30, 2022

	<b>Six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<b>Cash flows from operating activities</b>		
Cash used in operations	(230,833)	(178,210)
Interest received	19,291	36,075
Interest paid	(141)	(42)
	<u>(211,683)</u>	<u>(142,177)</u>
<b>Net cash used in operating activities</b>		
<b>Cash flows from investing activities</b>		
Payments for property, plant and equipment	(50,619)	(28,364)
Payments for right-of-use assets	—	(8,300)
Payments for intangible assets	(70,349)	(1,108)
Payments for financial assets at fair value through profit or loss	—	(32,244)
Payments for investment accounted for using equity method	(500)	—
Payments for term deposits	(170,000)	—
Payments for settlement of foreign exchange forward contracts	(18,982)	—
Proceeds from disposal of property, plant and equipment	1	1
	<u>(310,449)</u>	<u>(70,015)</u>
<b>Net cash used in investing activities</b>		
<b>Cash flows from financing activities</b>		
Net proceeds from issue of ordinary shares	—	810,559
Proceeds from exercise of share options	762	—
Payments for listing expenses	—	(3,041)
Acquisition of shares under the RSU Scheme	(3,094)	(6,551)
Proceeds from bank borrowings	65,025	—
Interest paid to bank borrowings	(937)	—
Principal elements of lease payments	(1,431)	(827)
	<u>60,325</u>	<u>800,140</u>
<b>Net cash generated from financing activities</b>		
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>(461,807)</b>	<b>587,948</b>
Cash and cash equivalents at beginning of the period	2,296,112	2,458,161
Exchange gains/(losses) on cash and cash equivalents	53,581	(21,450)
	<u>1,887,886</u>	<u>3,024,659</u>
<b>Cash and cash equivalents at end of the period</b>		

# NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION

*For the six months ended June 30, 2022*

## 1 GENERAL INFORMATION

Peijia Medical Limited (the “**Company**”, or “**Peijia Medical**”) was incorporated in the Cayman Islands on May 30, 2012 as an exempted company with limited liability under the Company Law of the Cayman Islands. The Company and its subsidiaries (together, the “**Group**”) are principally engaged in the business of (i) research and development, manufacturing and sales of transcatheter valve therapeutic medical devices (“**Transcatheter Valve Therapeutic Business**”) and (ii) research and development, manufacturing and sales of neurointerventional procedural medical devices (“**Neurointerventional Business**”) in the People’s Republic of China (the “**PRC**”) and other countries. Transcatheter Valve Therapeutic Business is primarily operated by the subsidiaries of the Company mainly comprising of Peijia Medical Technology (Suzhou) Co., Ltd. (“**Peijia Suzhou**”) and Peijia Medical Technology (Shanghai) Co., Ltd. (“**Peijia Shanghai**”), and Neurointerventional Business is primarily operated by Achieva Medical Limited (“**Achieva Medical**”) together with its subsidiaries (“**Achieva Group**”).

The address of the Company’s registered office is Floor 4, Willow House, Cricket Square, Grand Cayman, KY1-9010 Cayman Islands.

The Company’s shares have been listed on the main board of the Stock Exchange of Hong Kong Limited since May 15, 2020.

This condensed consolidated interim financial information is presented in Renminbi (“**RMB**”). This condensed consolidated interim financial information has not been audited.

## 2 BASIS OF PREPARATION

The condensed consolidated interim financial information for the half-year reporting period ended June 30, 2022 has been prepared in accordance with International Accounting Standard 34 “Interim Financial Reporting”.

The interim report does not include all the notes of the type normally included in an annual financial report. Accordingly, this report is to be read in conjunction with the annual report for the year ended December 31, 2021 and any public announcements made by the Company during the interim reporting period.

### 3 ACCOUNTING POLICIES

The accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period, and the adoption of new and amended standards as set out below.

#### (a) New and amended standards adopted by the Group

The Group has applied the following standards and amendments for the first time for their annual reporting period commencing January 1, 2022:

Amendments to IFRS 3	Reference to the conceptual framework
Amendments to IAS 37	Onerous contracts — cost of fulfilling a contract
Amendments to IFRSs	Annual improvements to IFRS standards 2018–2020 cycle
Amendments to IAS 16	Property, plant and equipment: proceeds before intended use

The adoption of these amendments to standards and interpretations did not have any impact on the consolidated financial statements or result in any significant changes in the Group's significant accounting policies.

#### (b) New standards and interpretations not yet adopted

Standards and amendments to standards that have been issued but not yet effective and not been early adopted by the Group during the year are as follows:

		<b>Effective date</b>
IFRS 17	Insurance contracts	January 1, 2023
Amendments to IAS 1	Classification of liabilities as current or non-current	January 1, 2023
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies	January 1, 2023
Amendments to IAS 8	Definition of Accounting Estimates	January 1, 2023
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction	January 1, 2023
Amendments to IFRS 10 and IAS 28	Sale or contribution of assets between an investor and its associate or joint venture	To be determined

The Group has already commenced an assessment of the related impact of the above standards and amendments to standards which are relevant to the Group's operation.

There are no other standards that are not yet effective and that are expected to have a material impact on the Group's financial performance and position.

## 4 SEGMENT

The Group's business activities, for which discrete financial information is available, are regularly reviewed and evaluated by the Chief Operating Decision-Maker ("CODM"). The CODM, who is responsible for allocating resource and assessing performance of the operating segments, has been identified as the executive directors of the Company that make strategic decisions.

The CODM assessed the performance of the operation segments mainly based on segment revenues, cost of sales, selling and distribution expenses, administrative expenses, and research and development expenses of each operation segment. Thus, segment result would present revenues, cost of sales, selling and distribution expenses, administrative expenses, research and development expenses and gross profit for each segment, which is in line with CODM's performance review.

As a result of this evaluation, the Group determined that it has operating segments as follows:

### **Transcatheter Valve Therapeutic Business**

Transcatheter Valve Therapeutic Business is primarily operated by the subsidiaries of the Company mainly comprising of Peijia Suzhou and Peijia Shanghai, which is engaged in the business of research and development, manufacturing and sales of transcatheter valve therapeutic medical devices.

### **Neurointerventional Business**

Neurointerventional Business is primarily operated by Achieva Medical together with its subsidiaries, which is engaged in the business of research and development, manufacturing and sales of neurointerventional procedural medical devices.

There were no separate segment assets and segment liabilities information provided to the CODM, as CODM does not use this information to allocate resources to or evaluate the performance of the operating segments.

The revenue is mainly generated in China.

The segment information provided to the Group's CODM for reportable segments for the six months ended June 30, 2022 and 2021 is as follows:

	<b>Six months ended June 30, 2022</b>		
	<b>Transcatheter Valve Therapeutic Business</b>	<b>Neurointerventional Business</b>	<b>Total</b>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)	(Unaudited)
Revenue	52,103	66,696	118,799
Cost of sales	(11,365)	(24,232)	(35,597)
Selling and distribution expenses	(67,306)	(25,364)	(92,670)
Administrative expenses	(42,372)	(17,237)	(59,609)
Research and development expenses	(58,436)	(24,992)	(83,428)
Segment loss	<u>(127,376)</u>	<u>(25,129)</u>	<u>(152,505)</u>

	<b>Six months ended June 30, 2021</b>		
	<b>Transcatheter Valve Therapeutic Business</b>	<b>Neurointerventional Business</b>	<b>Total</b>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)	(Unaudited)
Revenue	9,381	42,308	51,689
Cost of sales	(1,907)	(12,382)	(14,289)
Selling and distribution expenses	(6,437)	(15,242)	(21,679)
Administrative expenses	(38,060)	(15,022)	(53,082)
Research and development expenses	(107,993)	(23,298)	(131,291)
Segment loss	<u>(145,016)</u>	<u>(23,636)</u>	<u>(168,652)</u>

## 5 REVENUE

	<b>Six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<i>RMB'000</i>	<i>RMB'000</i>
	(Unaudited)	(Unaudited)
Revenue from sales of goods		
— at a point in time	<u>118,799</u>	<u>51,689</u>

## 6 EXPENSES BY NATURE

	<b>Six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Change of work in process and finished goods	<b>(9,087)</b>	(10,296)
Raw materials and consumables used		
— Research and development expenses	<b>17,513</b>	13,125
— Cost of raw material	<b>17,544</b>	13,707
Service expenses for research and development	<b>26,652</b>	90,742
Employee benefits expenses	<b>121,739</b>	66,345
Promotion expenses	<b>21,133</b>	8,305
Professional services	<b>14,558</b>	5,899
Depreciation of property, plant and equipment	<b>9,842</b>	6,417
Utilities and office expenses	<b>8,208</b>	5,262
Amortisation of intangible assets	<b>6,025</b>	4,752
Entertainment expenses	<b>6,170</b>	3,584
Travelling and transportation expenses	<b>4,466</b>	3,741
Auditor's remuneration	<b>1,930</b>	2,007
Depreciation and amortisation of right-of-use assets	<b>1,592</b>	1,024
Depreciation and amortisation of investment properties	<b>270</b>	270
Others	<b>22,749</b>	5,457
	<hr/>	<hr/>
Total cost of sales, selling and distribution expenses, administrative expenses and research and development expenses	<b>271,304</b>	220,341
	<hr/> <hr/>	<hr/> <hr/>

**7 OTHER INCOME**

	<b>Six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Rental Income	452	357
Government grants-related to income	1,589	1,742
Government grants-related to assets	154	138
	<u>2,195</u>	<u>2,237</u>

**8 OTHER GAINS/(LOSSES) — NET**

	<b>Six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Foreign exchange gains/(losses) — net	60,900	(21,341)
Losses on disposal of property, plant and equipment	—	(102)
Losses on disposal of right-of-use assets	(397)	—
Loss from foreign exchange forward contracts	(18,982)	—
Others	36	44
	<u>41,557</u>	<u>(21,399)</u>

**9 FINANCE INCOME — NET**

	<b>Six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<b>Finance income:</b>		
Bank interest income	<u>18,080</u>	<u>12,980</u>
	<b><u>18,080</u></b>	<b><u>12,980</u></b>
<b>Finance costs:</b>		
Interest expense on lease liabilities	(141)	(42)
Interest expense on bank borrowings	(980)	—
Exchange losses on financial assets at fair value through profit or loss	<u>—</u>	<u>(298)</u>
	<b><u>(1,121)</u></b>	<b><u>(340)</u></b>
<b>Finance income — net</b>	<b><u>16,959</u></b>	<b><u>12,640</u></b>

**10 INCOME TAX EXPENSE**

	<b>Six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Current income tax	(192)	—
Deferred income tax	<u>—</u>	<u>—</u>
<b>Income tax expense</b>	<b><u>(192)</u></b>	<b><u>—</u></b>



The Group's principal applicable taxes and tax rates are as follows:

**(a) Mainland China**

No provision for Mainland China income tax has been provided for at a rate of 25% or 15% pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), as the Group's PRC entities have no estimated assessable profits.

According to the relevant laws and regulations promulgated by the State Administration of Taxation of the PRC that has been effective from 2018 onwards, enterprise engaging in research and development activities are entitled to claim 175%–200% of their research and development expenses incurred as tax deductible expenses when determining their assessable profits for that period.

**(b) Hong Kong**

No provision for Hong Kong profits tax has been provided for at the rate of 16.5% as the Group has no estimated assessable profit.

**(c)** Enterprises incorporated in other places are subject to income tax rates of 0%–0.26% prevailing in the places in which the Group operated.

**11 LOSS PER SHARE**

Basic loss per share is calculated by dividing the loss of the Group attributable to owners of the Company by weighted average number of ordinary shares issued during the period.

	<b>Six months ended June 30,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
Numerator:		
Loss for the period and attributable to owners of the Company (RMB'000)	<b>91,986</b>	175,174
Denominator:		
Weighted average number of ordinary shares in issue (thousand)	<b>672,171</b>	659,910
Basic loss per share (RMB)	<b><u>0.14</u></b>	<b><u>0.27</u></b>

(i) Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares. For the six months periods ended June 30, 2022 and 2021, the Company had one category of potential ordinary shares: the stock options granted to employees. As the Group incurred losses for the six months periods ended June 30, 2022 and 2021, the potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the respective six months periods ended June 30, 2022 and 2021 are the same as basic loss per share.

## 12 TRADE AND OTHER RECEIVABLES

	<b>June 30, 2022 RMB'000 (Unaudited)</b>	December 31, 2021 RMB'000 (Audited)
Trade receivables from third parties (a)	16,227	—
Other receivables from employees (b)	28,802	—
Other receivables from third parties	7,962	3,639
Value-added tax recoverable	9,603	14,550
Interest receivables	4,264	5,475
Deposits	1,441	1,926
Others	9,199	7,743
	<hr/>	<hr/>
<b>Total</b>	<b>77,498</b>	<b>33,333</b>
Less: non-current portion	<b>(12,644)</b>	—
	<hr/>	<hr/>
Current portion	<b>64,854</b>	<b>33,333</b>
	<hr/> <hr/>	<hr/> <hr/>

- (a) At June 30, 2022 and December 31, 2021, the ageing analysis of the trade receivables based on invoice date were as follows:

	<b>June 30, 2022 RMB'000 (Unaudited)</b>	December 31, 2021 RMB'000 (Audited)
Within 6 months	<b>16,227</b>	—
	<hr/> <hr/>	<hr/> <hr/>

- (b) Other receivables from employees included a loan to an employee amounted to RMB12,644,000, of which the nominal value was HKD16,000,000 (equivalent to RMB13,372,000). The loan was interest-free and will be repayable in March 2024.

### 13 TRADE AND OTHER PAYABLES

	<b>June 30, 2022 RMB'000 (Unaudited)</b>	December 31, 2021 RMB'000 (Audited)
Trade payables to third parties	10,445	54,168
Other payables to third parties	57,443	31,116
Staff salaries, bonus and welfare payables	32,468	24,490
Interest payable	65	—
Accrued taxes other than income tax	18,033	5,388
	<hr/>	<hr/>
<b>Total</b>	<b>118,454</b>	115,162
Less: non-current position	(6,246)	—
	<hr/>	<hr/>
Current position	<b>112,208</b>	<b>115,162</b>
	<hr/> <hr/>	<hr/> <hr/>

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

	<b>June 30, 2022 RMB'000 (Unaudited)</b>	December 31, 2021 RMB'000 (Audited)
Within 1 year	10,315	54,003
More than 1 year	130	165
	<hr/>	<hr/>
	<b>10,445</b>	<b>54,168</b>
	<hr/> <hr/>	<hr/> <hr/>

### 14 DIVIDEND

The Board does not recommend the payment of an interim dividend for the six months ended June 30, 2022 (six months ended June 30, 2021: nil).

## **REVIEW OF FINANCIAL INFORMATION**

### **Audit Committee**

The Company has established an Audit Committee with written terms of reference in accordance with the Listing Rules. As of the date of this announcement, the Audit Committee comprises one non-executive Director, namely Mr. Jifeng GUAN, and three independent non-executive Directors, namely, Mr. Robert Ralph PARKS, Mr. Wai Ming YIP and Mr. Huacheng WEI. Mr. Wai Ming YIP is the chairman of the Audit Committee.

The Audit Committee has held relevant discussions with the Company's management, and reviewed the unaudited interim financial statements of our Group for the Reporting Period. The Audit Committee considered that the interim results of our Group for the Reporting Period are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof.

## **PUBLICATION OF RESULTS ANNOUNCEMENT AND INTERIM REPORT**

This announcement is published on the website of the Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company's website ([www.peijiamedical.com](http://www.peijiamedical.com)). The interim report of the Company for the Reporting Period containing all the information required by the Listing Rules will be dispatched to Shareholders and published on the above websites in due course.

## **APPRECIATION**

On behalf of the Board, I would like to thank all our colleagues for their diligence, dedication, loyalty and integrity. I would also like to thank all our Shareholders, customers, bankers and other business associates for their trust and support.

## **DEFINITIONS**

In this interim results announcement, the following expressions shall have the meanings set out below, unless the context otherwise requires:

“Achieva” or “Achieva Group” includes Achieva Medical and its subsidiaries, i.e., Achieva HK, Achieva Shanghai, Achieva Suzhou and Jiangxi Zhisheng

“Achieva Medical” Achieva Medical Limited, an exempt limited liability company incorporated under the laws of the Cayman Islands on November 2, 2005, being a wholly-owned subsidiary of our Company

“AIS”	acute ischemic stroke, a disease occurs when the blood flow through the cerebral arteries is blocked by a clot (i.e., a large amount of thickened blood)
“aortic valve”	a valve in the human heart between the left ventricle and the aorta
“AR”	aortic regurgitation
“AS”	aortic stenosis
“Audit Committee”	the audit committee of the Board
“BD”	business development
“CG Code”	the Corporate Governance Code as set out in Appendix 14 to the Listing Rules
“China” or “PRC”	the People’s Republic of China, which for the purpose of this announcement and for geographical reference only, Hong Kong, Macau and Taiwan
“CODM”	chief operating decision-maker
“Company” or “our Company”	Peijia Medical Limited (沛嘉醫療有限公司), an exempt limited liability company incorporated under the laws of the Cayman Islands on May 30, 2012
“confirmatory clinical trial”	a controlled clinical trial of a medical device product designed to demonstrate statistically significant clinical efficacy and safety of such product as used in human patients (in conjunction with the performance of a therapeutic procedure), for regulatory approval of such product
“Core Product”	has the meaning ascribed thereto in Chapter 18A of the Listing Rules, which, for purposes of this announcement, refers to TaurusOne®
“delivery catheter system”	an integral delivery catheter with a tip, a sheath tube, a catheter and a handle system used to deliver and release the PAV to the target position

“Director(s)”	the director(s) of the Company
“Dr. Zhang”	Dr. Yi Zhang, one of our Founders, and our chairman, Chief Executive Officer, an executive Director of our Company and our substantial shareholder upon Listing
“FIM”	First-in-man, a stage of clinical trial
“Frost & Sullivan”	a research & consulting firm which specialized in producing industry research reports
“Global Offering”	has the meaning as ascribed to it under the Prospectus
“Group,” “our Group,” “our,” “we,” or “us”	our Company and all of its subsidiaries (including but not limited to Achieva), or any one of them as the context may require or, where the context refers to any time prior to its incorporation or the Share Swap, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong dollars”, “HKD” or “HK\$”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
“ICAD”	intracranial atherosclerotic disease, a disease occurs when plaque (cholesterol, fatty deposits and other materials) builds up in the blood vessels at the base of the brain, causing them to narrow and harden
“IFRS”	International Financial Reporting Standards, as issued from time to time by the International Accounting Standards Board
“Independent Third Party” or “Independent Third Parties”	a person or entity who is not a connected person of our Company under the Listing Rules

“KOL(s)”	Key Opinion Leader(s), renowned physicians that are able to influence their peers’ medical practice
“Listing”	the listing of the Shares on the Main Board of the Stock Exchange
“Listing Date”	the date, Friday, May 15, 2020, on which the Shares were listed and dealings in the Shares first commence on the Stock Exchange
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (as amended, supplemented or otherwise modified from time to time)
“LVOT”	Left ventricular outflow tract
“mechanical thrombectomy”	a type of minimally-invasive therapy in which blood clot is removed from arteries using imaging techniques guiding medical devices through patients’ arteries to the blood clot
“mitral valve”	the valve that lets blood flow from one chamber of the heart, the left atrium, to another called the left ventricle
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 to the Listing Rules
“MR”	mitral regurgitation
“MS”	mitral stenosis
“Neurointerventional Business”	the business of our Group in research and development of neurointerventional procedural medical devices
“neurointerventional procedural medical devices”	medical devices for treatment of neurovascular diseases using interventional endovascular technique
“neurovascular diseases”	also known as cerebrovascular diseases, including any abnormality of the blood vessels within the brain and spine or abnormality with supplying blood to such areas

“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局), formerly known as the China Food and Drug Administration or the CFDA
“Over-allotment Option”	has the meaning as ascribed to it under the Prospectus
“PAV”	prosthetic aortic valve, the artificial valve of our TAVR Products
“Peijia Shanghai”	Peijia Medical Technology (Shanghai) Co., Ltd. (沛嘉醫療科技(上海)有限公司), a limited liability company incorporated under the laws of PRC on February 24, 2012, being an indirect wholly-owned subsidiary of our Company
“Peijia Suzhou”	Peijia Medical Technology (Suzhou) Co., Ltd. (沛嘉醫療科技(蘇州)有限公司), a limited liability company incorporated under the laws of PRC on March 4, 2013, being an indirect wholly-owned subsidiary of our Company
“Placee(s)”	any individuals, corporate, institutional or other investor(s) procured by the Placing Agent or their respective agents to subscribe for any of the Placing Shares pursuant to the Placing Agreement
“Placing”	the placing of 33,800,000 Placing Shares pursuant to the terms of the Placing Agreement
“Placing Agreement”	the conditional placing agreement entered into between the Company and Morgan Stanley & Co. International plc dated January 22, 2021 in relation to the Placing
“Prospectus”	the prospectus of the Company dated May 5, 2020, in relation to the Global Offering
“Remuneration Committee”	the remuneration committee of the Board
“Reporting Period”	the six months ended June 30, 2022
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC



“RSU Scheme”	the restricted share unit award scheme of the Company conditionally approved and adopted by our Shareholders on April 28, 2020, the principal terms of which are set out in Prospectus
“R&D”	research and development
“Share Option Scheme”	the share option scheme conditionally adopted by the Company on April 28, 2020, a summary of the principal terms of which is set forth in the paragraph headed “Appendix IV — Statutory and General Information — D. Share Incentive Schemes” in the Prospectus
“Share(s)”	ordinary share(s) with nominal value of US\$0.0001 each in the share capital of the Company
“Shareholder(s)”	holder(s) of the Share(s)
“sq.m.”	square meter, a unit of area
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“subsidiary”	has the meaning ascribed thereto under the Listing Rules
“TAVR”	transcatheter aortic valve replacement, a catheter-based technique to implant a new aortic valve in an interventional procedure that does not involve open-chest surgery
“TEER”	transcatheter edge-to-edge repair
“TMVR”	transcatheter mitral valve replacement, a catheter-based technique to implant a new mitral valve in an interventional procedure that does not involve open-chest surgery
“TOP/KA hospitals”	hospitals in China which complete at least 100 (TOP) or 50 (KA) TAVR procedures each year
“transcatheter valve therapeutic medical devices”	medical devices for the treatment of valvular heart diseases using cardiovascular interventional technique by implanting a prosthetic valve through an artery

“tricuspid valve”	the valve on the right dorsal side of the mammalian heart, between the right atrium and the right ventricle, the function of which is to prevent back flow of blood from the right ventricle into the right atriums
“TSMVR”	transseptal mitral value replacement
“TTVR”	transcatheter tricuspid valve replacement, a catheterbased technique to implant a new tricuspid valve in an interventional procedure that does not involve open-chest surgery
“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“U.S. dollars”, “US\$” or “USD”	United States dollars, the lawful currency of the United States
“valvular heart diseases”	the failure or dysfunction of one or more of the four heart valves, where the valves become too narrow and hardened to open fully, or are unable to close completely
“valvuloplasty”	a procedure using balloons to repair a heart valve with a narrowed opening and to improve blood flow through the valve
“%”	per cent

By order of the Board  
**Peijia Medical Limited**  
**Dr. Yi Zhang**  
*Chairman and Executive Director*

Hong Kong, August 19, 2022

*As of the date of this announcement, the Board comprises Dr. Yi Zhang, Mrs. Ping Ye Zhang and Ms. Hong Ye as executive Directors, Dr. Zhiyun Yu, Mr. Jifeng Guan, Mr. Fei Chen, Mr. Jun Yang as non-executive Directors, and Dr. Stephen Newman Oesterle, Mr. Robert Ralph Parks, Mr. Wai Ming Yip and Mr. Huacheng Wei as independent non-executive Directors.*