

CONNECTED TRANSACTIONS

Upon [REDACTED], transactions entered into between us and our connected persons will constitute connected transactions or continuing connected transactions under Chapter 14A of the Listing Rules.

OUR CONNECTED PERSONS

Lepu Medical is one of our substantial Shareholders. Accordingly, Lepu Medical and its subsidiaries (other than our Group) will become our connected persons for the purposes of connected transactions under Chapter 14A of the Listing Rules upon the [REDACTED].

SUMMARY OF OUR CONTINUING CONNECTED TRANSACTIONS

Fully Exempt Continuing Connected Transactions

Transactions	Applicable Listing Rules	Waivers sought	Historical amounts (RMB)	Proposed annual caps (RMB)
<i>1. Purchase of Parts Framework Agreement (expense-based)</i>				
The Group purchasing certain parts from the Retained Lepu Medical Group for production of our products	14A.34, 14A.52, 14A.53 and 14A.76	N/A	2019: 0.8 million 2020: 1.1 million 2021: 2.3 million Six months ended June 30, 2022: 0.6 million	2022: 2.0 million 2023: 1.6 million 2024: 1.3 million
<i>2. Lease Agreement with Lepu (Shanghai) (revenue-based)</i>				
Shanghai Shape Memory Alloy leasing certain property to Lepu Medical Technology (Shanghai) Co., Ltd. (樂普(上海)醫療器械有限公司) (“Lepu (Shanghai)”)	14A.34, 14A.52, 14A.53 and 14A.76	N/A	2019: 0.6 million 2020: 0.5 million 2021: 0.5 million Six months ended June 30, 2022: 0.2 million	2022: 1.2 million 2023: 1.2 million 2024: 1.2 million

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Partially-Exempt Continuing Connected Transaction

Transaction	Applicable Listing Rules	Waivers sought	Historical amounts (RMB)	Proposed annual caps (RMB)
<i>1. Clinical Trial Service Framework Agreement (expense-based)</i>				
The Retained Lepu Medical Group providing the Group with clinical trail services	14A.34, 14A.35 and 14A.76	Requirements as to announcement under Chapter 14A of the Listing Rules	2019: 0.016 million 2020: nil 2021: 1.3 million Six months ended June 30, 2022: 0.7 million	2022: 9.0 million 2023: 9.5 million 2024: 9.5 million

Non-exempt Continuing Connected Transactions

Transactions	Applicable Listing Rules	Waivers sought	Historical amounts (RMB)	Proposed annual caps (RMB)
<i>1. Sale of Products Framework Agreement (revenue-based)</i>				
The Group selling occluder and occluder related products system to the Retained Lepu Medical Group for distribution	14A.34, 14A.35, 14A.36, 14A.49, 14A.52 to 14A.59 and 14A.71	Requirements as to announcement, circular, shareholders’ approval, terms not exceeding three years and annual caps under Chapter 14A of the Listing Rules	2019: 10.2 million 2020: 31.0 million 2021: 15.7 million Six months ended June 30, 2022: 2.0 million	2022: 14.3 million 2023: 17.9 million 2024: 20.4 million

2. Entrusted Products Related Framework Agreement (expense-based)

Lepu Medical conducting research, development and registration of the Entrusted Products under the directions of the Group	14A.34, 14A.35, 14A.36, 14A.49, 14A.52 to 14A.59 and 14A.71	Requirements as to announcement, circular, shareholders’ approval, terms not exceeding three years and annual caps under Chapter 14A of the Listing Rules	2019: Nil 2020: Nil 2021: 28.7 million Six months ended June 30, 2022: 16.1 million	2022: 28.0 million 2023: 18.0 million 2024: 11.0 million
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FULLY EXEMPT CONTINUING CONNECTED TRANSACTIONS

1. Purchase of Parts Framework Agreement

Description of the agreement

On [●] 2022, our Company entered into a purchase of parts framework agreement with Lepu Medical (the “Purchase of Parts Framework Agreement”), pursuant to which our Group will purchase customized parts for producing (1) congenital heart disease occluders and congenital heart disease occluder delivery systems, (2) snares, (3) LAA occluder systems, and (4) biodegradable delivery systems. We may enter into individual agreements separately with the Retained Lepu Medical Group with respect to different transactions which provide for specific terms and conditions including products, price, payment and other terms in accordance with the Purchase of Parts Framework Agreement and applicable laws. The term of the Purchase of Parts Framework Agreement shall commence from the [REDACTED] and expire on December 31, 2024, subject to renewal upon mutual consent of both parties.

Reasons for and benefits of entering into the transaction

We have procurement needs for essential parts for producing (1) congenital heart disease occluders and congenital heart disease occluder delivery systems, (2) snares, (3) LAA occluder systems, and (4) biodegradable delivery systems. Historically we have been procuring from the Retained Lepu Medical Group such parts with customized processing. The Retained Lepu Medical Group is equipped with facilities that are able to meet our needs and is most familiar with our demand for the parts we procure from it. While our Directors believe that there are alternative third party suppliers of such parts at a comparable price in the market considering the entry barrier (being the intellectual properties and techniques involved with the parts procured from the Retained Lepu Medical Group) is not high, switching to other suppliers will cause uncertainty in the orderly delivery and quality stableness in the parts we procure, and therefore possible unnecessary disruption to our business, and extra costs during the transitional period given such parts need to be customized to our specifications.

Pricing policies

The amounts to be paid by our Group to the Retained Lepu Medical Group under the Purchase of Parts Framework Agreement will be determined on normal commercial terms after arm’s length negotiations between the relevant parties, taking into consideration a number of factors including (1) the cost incurred by the Retained Lepu Medical Group, including raw materials, labor and packaging; and (2) a profit rate of 10% determined with reference to Provisions on Certain Specific Issues of Value-added Tax (《增值税若干具體問題的規定》) issued by the State Administration of Taxation in December 1993 which suggested 10% as a presumed profit rate for goods that are sold at a significantly low price or with no definitive selling price. The price to be determined shall be fair and reasonable, and in the best interests

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of the shareholders of our Group and the Retained Lepu Medical Group. The Directors are of the view that such reference is reasonable because there is normally no definitive selling price for the parts with customize processing that the Group purchased from the Retained Lepu Medical Group.

Historical transaction amounts

For the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, the aggregate transaction amounts were approximately RMB0.8 million, RMB1.1 million, RMB2.3 million and RMB0.6 million, respectively.

Annual caps

The proposed annual caps in respect of the transactions contemplated under the Purchase of Parts Framework Agreement are approximately RMB2.0 million, RMB1.6 million and RMB1.3 million for the three years ending December 31, 2022, 2023 and 2024, respectively. We expect the annual cap to decrease for the relevant period because we expect to produce an increasing number of such parts on our own that we currently procure from the Retained Lepu Medical Group.

Basis of caps

The above proposed annual caps are determined with reference to the following factors: (1) the historical transaction amounts paid by our Group to the Retained Lepu Medical Group; (2) expected number of parts needed for production of our the occluders; (3) the expected number of parts needed for our clinical trials on new generation of delivery systems and (4) unit price of the parts agreed between the Retained Lepu Medical Group and us in the existing agreements.

Implications under the Listing Rules

Since the highest applicable percentage ratio in respect of the Purchase of Parts Framework Agreement will be less than 5% and the total consideration will be less than HK\$3,000,000, each on an annual basis, the Purchase of Parts Framework Agreement will fall within the de minimis threshold under Rule 14A.76(1)(c) of the Listing Rules and will be fully exempt from reporting, annual review, announcement, circular and independent shareholders' approval requirements under Chapter 14A of the Listing Rules pursuant to Rule 14A.76(1) of the Listing Rules.

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2. Lease Agreement with Lepu Shanghai

Description of the agreement

On [●] 2022, Shanghai Shape Memory Alloy entered into a lease agreement with Lepu Shanghai (the “Lease Agreement with Lepu Shanghai”), pursuant to which Shanghai Shape Memory Alloy agreed to lease to Lepu Shanghai certain premises located at 258 Xin Zhuan Road, Songjiang District, Shanghai, with a total gross floor area of 950.05 square meters. Such premises will be used by Lepu Shanghai for administrative, testing and research and development purposes. The term of the Lease Agreement with Lepu Shanghai shall commence on the [REDACTED] and expire on December 31, 2024, subject to renewal upon mutual consent of both parties.

Reasons for and benefits of entering into the transaction

The Group believes that it will benefit from the transaction due to the following reasons: (1) the Group will earn rental fee incomes which are at the prevailing market rates; and (2) all the utility fees and property management fees relating to the above mentioned property will be borne by Lepu Shanghai.

The Lepu Medical Group has been leasing and using the above-mentioned property for its business operation prior to and throughout the Track Record period. Any relocation may cause unnecessary disruption to Lepu Shanghai’s business.

Pricing policies

The rent is calculated at a rate of RMB1.6 per square meter per day. The amounts to be paid by Lepu Shanghai to our Group under the Lease Agreement with Lepu Shanghai was determined on normal commercial terms after arm’s length negotiations between the relevant parties with reference to the market price of properties of comparable size and use in the vicinity.

Historical transaction amounts

For the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, the aggregate transaction amounts were approximately RMB0.6 million, RMB0.5 million, RMB0.5 million and RMB0.2 million, respectively.

Annual caps

The proposed annual caps in respect of the transactions contemplated under the Lease Agreement with Lepu Shanghai are RMB1.2 million, RMB1.2 million and RMB1.2 million for the three years ending December 31, 2022, 2023 and 2024, respectively.

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Basis of caps

The above proposed annual caps are determined with reference to (1) the floor area and agreed and unit price of the relevant premises; (2) the rentals of the existing property leases according to the existing lease agreements; (3) the estimated rentals of the property leases to be entered into for the expanded floor area; and (4) estimated utility bill amount relating to the leased property.

We have engaged an independent property valuer who has reviewed the terms of the Lease Agreement with Lepu Shanghai with reference to comparable market rental transactions for their assessment of the market rent of a property. The independent property valuer is of the view that (1) the Lease Agreement with Lepu Shanghai is entered into on arm’s length basis and on normal commercial terms, (2) the considerations in formulating the proposed annual caps are fair and reasonable, reflecting the current prevailing market rates for the similar premises in the vicinity of the relevant property in the PRC, and (3) the terms of the Lease Agreement with Lepu Shanghai are no less favorable to our Group than what we can get from parties who are independent third parties.

Implications under the Listing Rules

Since the highest applicable percentage ratio in respect of the Lease Agreement with Lepu Shanghai will be less than 5% and the total consideration will be less than HK\$3,000,000, each on an annual basis, the Lease Agreement with Lepu Shanghai will fall within the *de minimis* threshold under Rule 14A.76(1)(c) of the Listing Rules and will be fully exempt from reporting, annual review, announcement, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules pursuant to Rule 14A.76(1) of the Listing Rules.

PARTIALLY-EXEMPT CONTINUING CONNECTED TRANSACTION

We set out below details of the partially-exempt continuing connected transaction (the “Partially-exempt Continuing Connected Transaction”) for our Group, which are subject to the announcement, reporting and annual review requirements under Chapter 14A of the Listing Rules but will be exempted from the circular and independent shareholders’ approval requirement under Chapter 14A of the Listing Rules.

1. Clinical Trial Service Framework Agreement

Description of the agreement

On [●] 2022, our Company entered into a clinical trial service framework agreement with Lepu Medical (the “Clinical Trial Service Framework Agreement”), pursuant to which the Retained Lepu Medical Group agreed to provide clinical trial services on our products that enter into clinical trial stage from time to time for our Group. We may enter into individual agreements separately with the Retained Lepu Medical Group with respect to different

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transactions which provide for specific terms and conditions including products, price, payment and other terms in accordance with the Clinical Trial Service Framework Agreement and applicable laws. The term of the Clinical Trial Service Framework Agreement shall commence from the [REDACTED] and expire on December 31, 2024, subject to renewal upon mutual consent of both parties.

Reasons and benefits of entering into the transaction

We are a developer and manufacturer of occluders and occluder-related products and a developer of heart valve products. Clinical trial services are vital to our clinical studies for occluders and heart valve products as part of our development process. Hefei Hospital, a member of the Retained Lepu Medical Group, is a cardiovascular hospital equipped with the requisite qualification for providing clinical trial services and has a track record of having the capability of providing efficient clinical trial services since our cooperation with them in 2019. As such, we engage Hefei Hospital as one of the hospitals that provide clinical trial services for us.

Pricing policies

During the Track Record Period, the amounts paid by our Group to the Retained Lepu Medical Group under the Clinical Trial Service Framework Agreement was determined on normal commercial terms with reference to the price charged by Hefei Hospital to third-party medical device companies for its clinical trial services, as the Group was not able to obtain comparable quotations on the clinical trial services provided by Hefei Hospital to our Group due to the customization nature of such clinical trial services. During the term of the Clinical Trial Service Agreement, the price to be determined shall be based on the quotations provided by independent third-party suppliers if such suppliers are available. However, considering that the services have certain customization characteristics that third-party suppliers may not be available, then such price to be determined shall be with reference to the quotations provided by Hefei Hospital to its independent third-party customers which shall be fair and reasonable, comparable to (or better than) the price offered to independent third parties, and in the best interests of the shareholders of our Group.

Historical transaction amounts

For the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, the aggregate transaction amount was approximately RMB0.016 million, nil, RMB1.3 million and RMB0.7 million, respectively. The historical amount of RMB0.016 million incurred in 2019 was related to a then clinical trial project of fully biodegradable occluders which involved two participating subjects.

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Annual caps

The proposed annual caps in respect of the transactions contemplated under the Clinical Trial Service Framework Agreement are RMB9.0 million, RMB9.5 million and RMB9.5 million for the three years ending December 31, 2022, 2023 and 2024, respectively.

Basis of caps

The above proposed annual caps are determined with reference to the following factors: (1) the estimated number of the research and development projects of our occluders and heart valve products, and (2) the estimated number of participating subjects to be involved in the clinical trials to be conducted by Hefei Hospital.

Implications under the Listing Rules

Since the highest of all applicable percentage ratios in respect of the Clinical Trial Service Framework Agreement will be more than 0.1% but less than 5% on an annual basis, the Clinical Trial Service Framework Agreement will be subject to the announcement, reporting and annual review requirements under Chapter 14A of the Listing Rules but will be exempted from the circular and independent shareholders’ approval requirement under Chapter 14A of the Listing Rules. [We have applied for, and the Stock Exchange has granted, waivers from these requirements as described below.]

NON-EXEMPT CONTINUING CONNECTED TRANSACTIONS

We set out below details of the non-exempt continuing connected transactions (the “Non-exempt Continuing Connected Transactions”) for our Group, which are subject to the reporting, annual review, announcement and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

1. Sale of Products Framework Agreement

Description of the agreement

On [●] 2022, our Company entered into a sale of products framework agreement with Lepu Medical (the “Sale of Products Framework Agreement”), pursuant to which our Group may sell to (1) Lepu (Shanghai) and Anhui Magete certain products manufactured by our Group, namely, congenital heart disease occluders, congenital heart disease occluder delivery systems, LAA occluder systems, and snares, for distribution within the PRC; and (2) Lepu India congenital heart disease occluders, congenital heart disease occluder delivery systems and snares, for distribution in India. We may enter into individual agreements separately with Lepu (Shanghai), Anhui Magete and Lepu India with respect to different transactions which provide for specific terms and conditions including products, price, payment and other terms in accordance with the Sale of Products Framework Agreement and applicable laws. The term of the Sale of Products Framework Agreement shall commence from the [REDACTED] and expire on December 31, 2024, subject to renewal upon mutual consent of both parties.

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Reasons for and benefits of entering into the transaction

- (a) Our principal business is the production and sales of occluder and occluder-related devices and it is in our ordinary and usual course of business to sell occluder delivery systems to other parties for distribution;
- (b) Since 2012, we have been distributing our occluders through the Retained Lepu Medical Group with its wide and developed distribution network. We have been steadily ramping up our distribution qualification and capability by means including applying for our own distribution licenses. While we have established our own sales capability, a portion of the sales of our products will be conducted through members of the Retained Lepu Medical Group as our distributors; and
- (c) Certain of the requisite certificates for conducting sales in India were registered by Lepu India. We will continue to engage them as our distribution channel in India, where the Medical Devices Rules, which were published by the central government of India in 2016 and became effective in 2017, forbid the application by a foreign entity from applying for a license for importing medical devices. It is not practicably feasible and unduly burdensome for us to establish an Indian entity within the near future to carry out as efficiently the role currently undertaken by Lepu India, due to our unfamiliarity with the local regulatory environment and the current pandemic situation caused by COVID-19.

Pricing policies

The amounts to be paid by the Retained Lepu Medical Group to our Group under the Sale of Products Framework Agreement will be determined (1) with reference to the procurement prices announced by competent local authorities, namely, the provincial tendering offices in the PRC; and (2) with reference to our sales price in other comparable regions and taking into account the sales price of similar products set by other companies comparable to us for sales in India. The price to be determined shall be fair and reasonable, comparable to (or better for the Company than) the price offered to independent third parties, and in the interests of the Company and the Shareholders.

Historical transaction amounts

For the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, the aggregate transaction amount was approximately RMB10.2 million, RMB31.0 million, RMB15.7 million and RMB2.0 million, respectively. Out of such transaction amount, the aggregate transaction amount of sales in India for the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022 accounted for 23.5%, 8.9%, 1.9% and 23.6%, respectively. Our gross profit margin generated from sales in India for the years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022 was in general consistent with our gross profit margin for sales to the Retained Lepu Medical Group for the same period, which was approximately 64.4%, 91.4%, 90.0% and 84.8%, respectively, as there was no material difference in the cost structure.

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Since 2012, we have been selling a portion of our products including occluders and delivery system through the Retained Lepu Medical Group, for both domestic and overseas distribution. In the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, our revenue generated from such sales from the Retained Lepu Medical Group contributed to 8.8%, 20.9%, 4.5% and 2.1% of our total revenue for the same periods, respectively. With the improvement of our overseas brand recognition, by the beginning of 2020, the contribution from Retained Lepu Medical Group had been reduced to our overseas distribution to an extent that its involvement and functions became similar to our PRC distributors in terms of domestic sales. Therefore, we and the Retained Lepu Medical Group adjusted the pricing model accordingly (the “Adjustment”) so that the consideration paid by the Retained Lepu Medical Group since the beginning of 2020 has been the net amount of the sales price of our products by the Lepu Medical Group to the overseas distributors deducting a profit to the Retained Lepu Medical Group calculated at a margin rate that is consistent with the prevailing market rate. The gross margin that we generated from our sales to the Retained Lepu Medical Group in 2020 has been 91.4%, which was comparable with that of the gross margin of the sales to our other distributors that are independent third parties for the same period, being approximately 88.6%.

We have engaged the transfer pricing team from one of the “big-four” accounting firms (“Tax Consultant”) to analyse and assess the reasonableness of the pricing in our connected transactions with the Retained Lepu Medical Group. Since the Adjustment, the Retained Lepu Medical Group has been receiving a proportion of the sales amount of our products, as its gross profit, at a rate comparable to that received by our other distributors that are independent third parties. As verified by the functional analysis and value chain analysis conducted by the Tax Consultant, we have been undertaking the research and development, production and operation, while the Retained Lepu Medical Group has been merely our distributor, which has less exposure to commercial risks and plays a relatively less important part compared to us. Utilising the resale price method introduced by the Measures for the Administration of Adjustments under Special Tax Investigation and Mutual Consultation Procedures (特別納稅調查調整及相互協商程序管理辦法) and OECD Transfer Pricing Guidelines (OECD轉讓定價指南), the Tax Consultant compared the gross profit margin of the Retained Lepu Medical Group with those of comparable third party distributors extracted from OSIRIS, a public data pool provided by Bureau van Dijk and commonly used by the tax bureaus in China. After a series of independent screening and comparison, the Tax Consultant concluded that the gross profit margin fell within the inter-quartile range of the gross profit of the comparable distributors. In addition, our own gross profit margin in the transactions with the Retained Lepu Medical Group has been comparable with that in an ordinary sales transaction with independent third parties. Referencing to the conclusion of the Tax Consultant, the Directors are of the view that the Group’s sales to the Retained Lepu Medical Group have been in compliance with the relevant transfer pricing laws and regulations in the PRC during the Track Record Period and the potential tax payable in relation to such sales was based on arm’s length standard and that the amount is adequate.

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Annual caps

The proposed annual caps in respect of the transactions contemplated under the Sale of Products Framework Agreement are RMB14.3 million, RMB17.9 million and RMB20.4 million for the three years ending December 31, 2022, 2023 and 2024, respectively.

Basis of caps

The above proposed annual caps are determined with reference to the following factors: (1) the historical transaction amounts paid by the Retained Lepu Medical Group to our Group, (2) the estimated demand for the products to be distributed by the Retained Lepu Medical Group due to the growth of our own sales and distribution capabilities in overseas markets; and (3) the expected maximum selling prices of the relevant products for the three years ending December 31, 2024.

Implications under the Listing Rules

Since the highest of all applicable percentage ratios in respect of the Sale of Products Framework Agreement will be 5% or more, the Sale of Products Framework Agreement will be subject to the reporting, annual review, announcement and independent shareholders' approval requirements under Chapter 14A of the Listing Rules. [We have applied for, and the Stock Exchange has granted, waivers from these requirements as described below.]

2. Entrusted Products Related Framework Agreement

Description of the agreement

As part of the Reorganization and with a view to solidifying the Group's position as the sole platform under Lepu Medical Group focusing on interventional medical devices primarily targeting structural heart diseases, the interventional heart valve business was injected into Shanghai Shape Memory alloy by Lepu Medical in January 2021. Among the product candidates involved in such injection, the key research and development work of certain heart valve product candidates (i.e., the Entrusted Products) were initially conducted under the name of Lepu Medical. As at the Latest Practicable Date, due to the Entrusted Products Regulatory Restrictions, it was not feasible for us to directly take over and continue with the subsequent research and development procedures of the Entrusted Products that are expected to take place during the initial term of the Entrusted Products Related Framework Agreement, including conducting the clinical trials (notwithstanding the fact that Shanghai Shape Memory Alloy became the legal owner of all intellectual properties related to the Entrusted Products). Therefore it is only reasonable for Lepu Medical to continue the Relevant Activities for the Entrusted Products. In particular, for the R&D process of the Entrusted Products, Lepu Medical will continue to conduct the activities that are necessary to be carried out by Lepu Medical as a registration applicant under the PRC laws, including procuring the raw materials and producing the sample products used in the subsequent clinical trials, and communicating with the governmental authorities involved therein. Further, once TAVR system and TMVCRS

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become commercialized, which is expected to take place in 2024, Lepu Medical will carry out the manufacturing of TAVR system and TMVCRS which falls within the Catalogue of Medical Devices Prohibited from Entrusted Production as prescribed by the NMPA. We have built in the Entrustment Arrangements in the asset transfer agreement and an intellectual property transfer agreement as an attachment thereto with Lepu Medical in January 2021, as further elaborated in “Business — Our Products — Heart Valve Product Candidates — Entrusted Products.”

With a view to restating the Entrustment Arrangements as a continuing connected transaction under the Listing Rules, on [●] 2022, our Company entered into a framework agreement with Lepu Medical (the “Entrusted Products Related Framework Agreement”), pursuant to which our Group agreed to engage the Retained Lepu Medical Group to conduct the Relevant Activities legally according to the directions of our Group. We will reimburse Lepu Medical of its costs and fees actually incurred for the R&D and registration related activities associated with the Entrusted Products. Our finance department will (a) scrutinize the underlying supporting documents submitted by Lepu Medical as proof of payment, e.g., contracts and invoices; (b) follow the Group’s internal cost control measures which require, among others, every payment request from Lepu Medical being submitted to the finance department for verification and to Chen Juan (陳娟), our executive Director, chairman of the Board of Directors and general manager, for approval; and (c) compare the amount of fees paid by Lepu Medical against market prevailing prices on a regular basis to determine whether the payments are in line with the value of the relevant services. See also “— Internal Control Measures for Non-Exempt Continuing Connected Transactions” in this section for more details of the internal review procedures we have adopted to ensure the fairness and reasonableness of the pricing. Upon commercialization of the Entrusted Products which may take place as early as 2024, we may purchase the TAVR system and TMVCRS to be manufactured by Lepu Medical for sales and distribution onwards as authorized by Lepu Medical irrevocably and exclusively pursuant to the asset transfer agreement. Should any product liabilities associated with the Entrusted Products arise, Lepu Medical shall be liable for such liabilities by operation of law due to the fact that it is the registrant of the Entrusted Products and will be entitled to claim compensations from our Group to the extent that such liabilities are not caused by Lepu Medical’s fault. The transaction amount pertaining to our purchase of the Entrusted Products (which will constitute connected transactions between the Retained Lepu Medical Group and us) will increase accordingly. We will continue to comply with the requirements under Chapter 14A of the Listing Rules for such purchase of the Entrusted Products. When and if the applicable laws entitle our Group to conduct the Relevant Activities, the Retained Lepu Medical Group shall immediately engage and authorize our Group to do so. For further details of the Entrustment Arrangements, see “Business — Our Products — Heart Valve Product Candidates — Entrusted Products.”

We may enter into individual agreements separately with the Retained Lepu Medical Group with respect to different transactions which provide for specific terms and conditions including target, price, payment and other terms in accordance with the Entrusted Products Related Framework Agreement and applicable laws. The term of the Entrusted Products Related Framework Agreement shall commence from the [REDACTED] and expire on December 31, 2024, subject to renewal upon mutual consent of both parties.

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Reasons for and benefits of entering into the transaction

Historically the type inspections and animal tests of the Entrusted Products were conducted under the name of Lepu Medical. As at the Latest Practicable Date, due to the Entrusted Products Regulatory Restrictions, it was not feasible for us to directly take over and continue with the Relevant Activities including conducting the clinical trials. Entrusting the Retained Lepu Medical Group with the subsequent R&D, registration and manufacturing of the Entrusted Products is crucial to the realization of their commercialization and subsequent monetization. As further elaborated in “Business — Our Products — Heart Valve Product Candidates — Entrusted Products”, the Entrustment Arrangements under this transaction, which are integral to the injection of interventional heart valve business from Lepu Medical to our Group, strategically complemented our existing product portfolio and placed us as the only provider in China with a product portfolio covering all three major fields of application in the interventional medical device market targeting structural heart diseases, according to the F&S Report.

Pricing policies

We will pay to the Retained Lepu Medical Group the costs, comprising raw material, labor and equipments consumption, and fees to be incurred during the R&D and registration process. Upon the commercialization of TAVR system and TMVCRS, we will purchase the TAVR system and TMVCRS manufactured by Lepu Medical at price to be determined by the actual costs and expenses for manufacturing the TAVR system and TMVCRS (including costs of raw materials, labor power, depreciation of equipment and consumption of manufacturing utilities involved) plus reasonable profits. When deciding the profit margin, we will take into consideration (i) the nature of services provided by Lepu Medical; and (ii) the expected duration and complexity of techniques involved in the manufacturing process.

Historical transaction amounts

For the three years ended December 31, 2019, 2020, 2021 and the six months ended June 30, 2022, the aggregate transaction amount was nil, nil, approximately RMB28.7 million and RMB16.1 million, respectively.

Annual caps

The proposed annual caps in respect of the transactions contemplated under the Entrusted Products Related Framework Agreement are RMB28.0 million, RMB18.0 million and RMB11.0 million for the three years ending December 31, 2022, 2023 and 2024 respectively. The expected decrease in the proposed annual caps is mainly based on the estimated research and development stage to be conducted in the three years ending December 31, 2024. Among all the steps, clinical trials are expected to incur relatively highest amount of fees and expenses. As an increasing number of projects are expected to complete clinical trial stage in 2022 and 2023, the associated fees and expenses are expected to decrease correspondingly. Out of the proposed annual cap for 2024, the R&D and registration related fees of the Entrusted Products and the payment for purchase of TAVR system and TMVCRS is expected to be RMB6.0 million and RMB5.0 million, respectively.

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Basis of caps

The above proposed annual caps are determined with reference to the estimated progress of research to be made by the Retained Lepu Medical Group for the three years ending December 31, 2024, the estimated purchase volume of TAVR system and TMVCRS by us from Lepu Medical during the year of 2024 and the corresponding estimated costs, comprising those for labor, raw materials and payments made to third parties, to be incurred in conducting research and development, registering and manufacturing involved therein of the Entrusted Products by the Retained Lepu Medical Group plus the estimated profit to be charged by Lepu Medical associated with the VATR system and TMVCRS.

Implications under the Listing Rules

Since the highest of all applicable percentage ratios in respect of the Entrusted Products Related Framework Agreement will be 5% or more, the Entrusted Products Related Framework Agreement will be subject to the reporting, annual review, announcement and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules. [We have applied for, and the Stock Exchange has granted, waivers from these requirements as described below.]

APPLICATION FOR WAIVER

The transaction described under the subsection headed “Partially-exempt Continuing Connected Transaction” above constitute our continuing connected transaction under the Listing Rules. The transactions under the Clinical Trial Service Framework Agreement will be subject to the announcement, reporting and annual review requirements under Chapter 14A of the Listing Rules but will be exempted from the circular and independent shareholders’ approval requirement under Chapter 14A of the Listing Rules.

The transactions described under the subsection headed “Non-exempt Continuing Connected Transactions” above constitute our continuing connected transactions under the Listing Rules. The transactions under the Sale of Products Framework Agreement and the Entrusted Products Related Framework Agreement will be subject to the reporting, annual review, announcement, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

As such partially-exempt and non-exempt continuing connected transactions are expected to be carried out on a continuing basis and to extend over a period of time, and their material terms have been disclosed in this document, the Directors are of the view that strict compliance with the aforesaid reporting, annual review, announcement, circular and independent shareholders’ approval requirements under the Listing Rules would be impracticable and unduly burdensome and would impose unnecessary administrative costs upon our Company.

CONNECTED TRANSACTIONS

In respect of these continuing connected transactions, pursuant to Rule 14A.105 of the Listing Rules, we have applied for, and the Stock Exchange [has granted], a waiver exempting us from strict compliance with (i) the announcement requirement under the Listing Rules in respect of the transactions under the Clinical Trial Service Framework Agreement; and (ii) the announcement, circular and independent shareholders' approval requirements under the Listing Rules in respect of the transactions under the Sale of Products Framework Agreement and the Entrusted Products Related Framework Agreement, subject to the condition that the aggregate values of the continuing connected transactions for each financial year not exceeding the relevant amounts set forth in the respective annual caps (as stated above). We will comply with the applicable requirements under the Listing Rules, and will immediately inform the Stock Exchange if there are any changes to the non-exempt continuing connected transaction.

INTERNAL CONTROL MEASURES FOR NON-EXEMPT CONTINUING CONNECTED TRANSACTIONS

For expense-based non-exempt continuing connected transactions, we have established the following internal review procedures to ensure that the pricing under the non-exempt continuing connected transactions is fair and reasonable:

- (i) If a comparable market price is available, we shall compare the proposed price/service fee against market price to ensure that the proposed price/service fee will not be higher than that for similar part/goods/nature of service provided by independent third-party providers;
- (ii) Before selecting a part/service provider, our procurement department shall obtain quotations from certain independent third-party providers. The factors to be considered by us in conducting internal assessments shall include fee, quality, efficiency of part/service, and value added to us; and
- (iii) If no comparable market price is available, our procurement department shall conduct arm's length negotiation with the relevant connected person to determine the terms in line with the relevant pricing policies based on the value of the relevant part/service and the actual costs and expenses incurred.

We have also established the following internal review procedures to ensure that the pricing under our non-exempt continuing connected transactions is fair and reasonable:

- (i) The financial management department is responsible for preparing the accounting records, accounting, reporting, and statistical analysis of the continuing connected transactions, and for submitting the same to the Board of Directors for filing on a regular basis. The financial management department will also regularly collect and monitor the transaction amount of continuing connected transactions to ensure timely assessment on whether the annual caps are, or are expected to be, exceeded;

CONNECTED TRANSACTIONS

- (ii) The finance department will be responsible for identifying connected persons and the connected transactions, and submitting lists of the same to the Board of Directors for filing on a regular and timely basis;
- (iii) The Audit Committee shall conduct periodic examination of the overall situation of the continuing connected transactions, and report the review opinions to the Board of Directors;
- (iv) Our independent non-executive Directors will also conduct annual review on the non-exempt continuing connected transactions to ensure that such transactions have been entered into on normal commercial terms, are fair and reasonable, and conducted according to the terms of the relevant framework agreement; and
- (v) The auditor of our Company shall issue a letter to the Board of Directors to express opinions on the continuing connected transactions of the Group on an annual basis. The Company shall allow its auditor to review and check the relevant accounts to facilitate them to express opinions.

CONFIRMATION BY THE DIRECTORS

The Directors (including independent non-executive Directors) are of the view that the partially-exempt and non-exempt continuing connected transactions have been and will continue to be carried out in our ordinary and usual course of business of the Company and on normal commercial terms or better that are fair and reasonable and in the interests of the Company and our Shareholders as a whole, and that the proposed annual caps for the partially-exempt and non-exempt continuing connected transactions are fair and reasonable and in the interests of the Company and our Shareholders as a whole.

CONFIRMATION BY THE SOLE SPONSOR

The Sole Sponsor considers that the partially-exempt and non-exempt continuing connected transactions have been and will be carried out in the ordinary and usual course of business of the Company and on normal commercial terms or better that are fair and reasonable and in the interests of the Company and the Shareholders as a whole, and that the proposed annual caps of the partially-exempt and non-exempt continuing connected transactions are fair and reasonable and in the interests of the Company and the Shareholders as a whole.