
CONNECTED TRANSACTIONS

OVERVIEW

Pursuant to Chapter 14A of the Listing Rules, the directors, substantial shareholders and chief executive of our Company and our subsidiaries (other than the directors, substantial shareholders and chief executive of insignificant subsidiaries), any person who was a director of our Company or our subsidiaries within 12 months preceding the Listing Date and any of their respective associates will be connected persons of our Company upon [REDACTED].

We have entered into certain agreements with Zhongmei Huadong, one of our substantial shareholders, who will become a connected person of our Company upon [REDACTED] and the transactions contemplated under such agreements will constitute continuing connected transactions of our Company under Chapter 14A of the Listing Rules upon [REDACTED]. As our Company is eligible for [REDACTED] on the Stock Exchange under Chapter 18A of the Listing Rules as a pre-revenue biotech company, the revenue ratio under Rule 14.07 of the Listing Rules would not be an appropriate measurement of the size of relevant continuing connected transactions as set out in this section. Accordingly, we have applied a percentage ratio test based on the total expenses for R&D and administrative matters of our Group as an alternative size test.

(A) CONTINUING CONNECTED TRANSACTIONS FULLY EXEMPT FROM THE REPORTING, ANNUAL REVIEW, ANNOUNCEMENT, CIRCULAR AND INDEPENDENT SHAREHOLDERS’ APPROVAL REQUIREMENTS

QX001S Framework Agreement

Principal terms

Our Company entered into a collaboration agreement and a supplemental agreement to the collaboration agreement (the “QX001S Framework Agreement”) with Zhongmei Huadong on August 14, 2020 and December 7, 2023, respectively, pursuant to which we agreed to (i) grant an exclusive right to Zhongmei Huadong to promote and commercialize QX001S in the PRC and Zhongmei Huadong shall be the MAH of QX001S in the PRC to exclusively conduct marketing activities and commercialization of QX001S; (ii) together with Zhongmei Huadong, jointly engage in the R&D of QX001S, including but not limited to its clinical trials and regulatory communication and registration; and (iii) bear the expenses of sample production and process development and optimization prior to the commercialization of QX001S. In addition, our Company and Zhongmei Huadong also agreed to engage Cellularforce to manufacture and supply all quantities of QX001S for commercial use in the PRC (the “Product Supply”), by entering into individual agreement. Except when Cellularforce is unable to meet the manufacturing demand, the parties shall not engage other manufacturers for the commercial production of QX001S. As of the Latest Practicable Date, Zhongmei Huadong and Cellularforce had entered the QX001S Production Quality Agreement and the QX001S Supply Agreement as individual agreements under the QX001S Framework Agreement based on the principles provided in the QX001S Framework Agreement. For details of the QX001S Production Quality Agreement and the QX001S Supply Agreement, see “Business—Collaboration with Zhongmei Huadong—QX001S Production Quality Agreement” and “Business—Collaboration with Zhongmei Huadong—QX001S Supply Agreement.”

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In consideration of our Company agreeing to the above arrangement, pursuant to the QX001S Framework Agreement, Zhongmei Huadong agreed to (i) make an upfront payment of RMB30.0 million (the “Upfront Payment”) to us within ten days after the execution of the QX001S Framework Agreement and a milestone payment of RMB20.0 million (the “Milestone Payment”) to us within ten days after we complete the sample production of QX001S for the Phase III clinical trial and have, upon a consultation with the CDE, obtained consent to proceed with such Phase III clinical trial; (ii) bear the expenses of clinical trials and regulatory communication and registration for QX001S during the term of the QX001S Framework Agreement; and (iii) after setting off accumulative losses attributable to the commercialization of QX001S incurred in prior years (if any), share with us the accumulative pre-tax profit (as calculated pursuant to the QX001S Framework Agreement) derived from sales of QX001S in the PRC on a 50:50 basis, provided that 50% of the markup for the manufacturing of QX001S under the Product Supply corresponding to the sales of QX001S by Zhongmei Huadong will be further deducted from our portion of the pre-tax profit receivable and attributed to Zhongmei Huadong’s portion instead (the “Profit Sharing”). Pursuant to the QX001S Framework Agreement, Zhongmei Huadong paid the Upfront Payment and the Milestone Payment to us on August 28, 2020 and July 16, 2021, respectively.

Product Supply

The payment to be received by our Group from Zhongmei Huadong for the Product Supply pursuant to the QX001S Framework Agreement will be determined in accordance with the following formula:

Amount receivable by us = unit supply price⁽¹⁾ × amount of QX001S supplied under the Product Supply

Note:

1. The unit supply price will be determined by taking into account our actual costs expected to be incurred for manufacturing of QX001S and a cost-plus margin of 25% for such manufacturing.

Profit Sharing

The payment to be received by our Group from Zhongmei Huadong for the Profit Sharing pursuant to the QX001S Framework Agreement will be determined in accordance with the following formula:

Amount of pre-tax profit receivable by us under the Profit Sharing = (net sales revenue of QX001S by Zhongmei Huadong⁽¹⁾ – amount received and receivable by our Group under the Product Supply corresponding to the sales of QX001S by Zhongmei Huadong – marketing and sales and other operating costs of QX001S by Zhongmei Huadong – taxes and surcharges incurred by Zhongmei Huadong for the sales of QX001S⁽²⁾) × 50% – the markup for the manufacturing of QX001S under the Product Supply corresponding to the sales of QX001S by Zhongmei Huadong × 50%

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Notes:

1. Net sales revenue shall be the results of gross sales (net of value-added taxes) minus sales returns, allowances and discounts.
2. Such taxes and surcharges include but not limited to consumption tax, urban maintenance and construction tax, urban land use tax, resource tax, education surcharge, real estate tax, land use tax, vehicle and vessel tax and stamp duty (if applicable).
3. When calculating the accumulative pre-tax profit, (i) amount received and receivable by our Group under the Product Supply; (ii) marketing and sales and other operating costs of QX001S; (iii) taxes and surcharges for the sales of QX001S; and (iv) the markup for the manufacturing of QX001S under the Product Supply corresponding to the sales of QX001S by Zhongmei Huadong are listed as cost items. If the formula produces negative results, it constitutes a loss attributable to the commercialization of QX001S of the current year. The accumulative pre-tax profit to be shared by Zhongmei Huadong and us shall net off the accumulative losses attributable to the commercialization of QX001S incurred in prior years (if any).

The fees paid and payable under the QX001S Framework Agreement, including the Upfront Payment, the Milestone Payment and the amount to be received by us under the Product Supply and Profit Sharing were determined after arms’ length negotiations between our Group and Zhongmei Huadong, having taken into account various factors, including but not limited to the expenses incurred and to be incurred for the development of QX001S, expected prospects of the development and commercialization of QX001S in the PRC, rights and obligations of both parties under the QX001S Framework Agreement and the reasons and benefits of the transactions contemplated under the QX001S Framework Agreement. The QX001S Framework Agreement and the overall arrangements thereunder, including the Upfront Payment, Milestone Payment, Product Supply and Profit Sharing, as a whole, are generally in line with the market practice, as confirmed by Frost & Sullivan.

The QX001S Framework Agreement has a term of 15 years commencing from August 14, 2020 and ending on August 13, 2035, which can be automatically extended for a further term of five years unless terminated earlier in accordance with the terms of the QX001S Framework Agreement. Frost & Sullivan has confirmed that it is market practice in the pharmaceutical industry for similar collaboration agreements to be entered into for a long term, primarily due to the substantial amount of capital committed by the collaboration partners and the risks involved.

For further details of the QX001S Framework Agreement, see “Business—Collaboration with Zhongmei Huadong—QX001S Framework Agreement.” The Company will comply at all time with the applicable provisions under Chapter 14A of the Listing Rules in respect of the transactions contemplated under the QX001S Framework Agreement.

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Reasons for and benefits of the transaction

We entered into the QX001S Framework Agreement with Zhongmei Huadong for the following reasons:

- (a) the primary purpose of this collaboration is to leverage Zhongmei Huadong’s market access, nationwide sales and marketing network targeting the autoimmune and allergic disease field as well as its extensive experience in chronic disease management, which will be crucial to help achieve rapid commercialization of QX001S in the PRC. Considering that patients with autoimmune and allergic diseases are largely scattered at county-level hospitals in the PRC, we believe it would be in the best interest of our Group to find a business partner that is a large pharmaceutical company with strong R&D and commercialization capabilities nationwide to ensure the successful commercialization of QX001S in the PRC. Zhongmei Huadong is wholly owned by Huadong Medicine, a leading PRC pharmaceutical company whose shares are listed on the Shenzhen Stock Exchange (stock code: 000963). Having considered Huadong Medicine’s active role in the PRC pharmaceutical market for more than 30 years, the business of Huadong Medicine covers the whole pharmaceutical industrial chain, integrating R&D, production and sales of medicine and has established strong expert resources and sales and marketing network in the PRC, with its annual operating revenue of more than RMB37.7 billion in 2022 according to its annual report published on April 14, 2023. We believe this collaboration will enable us to leverage Zhongmei Huadong and Huadong Medicine’s market access, nationwide sales and marketing network targeting the autoimmune and allergic disease field as well as its extensive experience in chronic disease management;
- (b) the QX001S Framework Agreement allows both our Group and Zhongmei Huadong to leverage respective strength and share value of QX001S reasonably commensurate with their respective contribution in R&D and sales and marketing. Our Group expects to focus our resources on the ongoing R&D of QX001S and other drug candidates as a late clinical-stage biotech company, while Zhongmei Huadong has robust commercial network and experienced sales and marketing team for sales and distribution of QX001S in hospitals in the PRC. It is in line with industry practice and commercially beneficial for our Group and Zhongmei Huadong to enter into the QX001S Framework Agreement so that we can continue to focus on drug R&D while Zhongmei Huadong would be compensated fairly for its R&D efforts in the Phase III clinical trial and commercialization efforts in respect of QX001S. In addition, our Group will exclusively manufacture and supply QX001S to Zhongmei Huadong under the Product Supply, which allows us to utilize our in-house manufacturing capability and ensure quality control while providing such services at arm’s length. Therefore, through leveraging the respective resources and established capabilities of our Group and Zhongmei Huadong, we believe such collaboration agreement will bring commercial benefits to both our Group and Zhongmei Huadong; and

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- (c) the QX001S Framework Agreement allows both our Group and Zhongmei Huadong to share the risks and costs associated with the advancement of clinical trials and commercialization of QX001S and to leverage their respective resources and established capabilities to expeditiously establish an advantageous position in relevant markets.

Taking into consideration of the above and the evaluation procedures in place as set out below, we believe that the QX001S Framework Agreement is in the interest of our Company and our Shareholders as a whole.

Procedures in evaluation of collaboration arrangements

During the ordinary and usual course of our business, we evaluate potential collaboration opportunities from time to time. When such opportunity arises, we would normally focus on well-known companies in the pharmaceutical industry that can offer access to established distribution channels, recognized branding, an experienced sales force and longstanding connections with well-known physicians and hospitals. When selecting potential business partners, we will also consider their expertise in the relevant therapeutic area and their regulatory know-how. In parallel, prior to a decision of developing a particular product, our R&D, manufacturing, financial and business development teams perform in-house market forecasts and financial analysis for such potential products, and project competitive landscape of the products for the territory of interest. Furthermore, our business development team routinely evaluates collaboration arrangements with potential partners in respect of drug products with similar mechanism of action for deal benchmarking and for term sheet evaluation purposes.

In addition, the commercial negotiations with potential business partners are led by our chief executive officer and/or certain members of our senior management, who will independently evaluate the terms taking into account all relevant factors as we consider necessary. A decision on whether to establish collaborations with another company will be made purely based on commercial considerations and only if we consider it is in the best interest of our Company and our Shareholders to enter into such collaboration arrangement.

Term of the QX001S Framework Agreement

Rule 14A.52 of the Listing Rules provides that the period for the agreement of a continuing connected transaction must not exceed three years except in special circumstances where the nature of the transaction requires a longer period. Our Directors are of the view that the nature of the collaboration under the QX001S Framework Agreement requires a longer period commencing from August 14, 2020 to August 13, 2035 (the “Initial Term”), which can be automatically extended for a further term of five years unless terminated earlier in accordance with the terms the QX001S Framework Agreement, on the following grounds:

- (i) the nature of the collaboration requires a longer period. The QX001S Framework Agreement is a strategic collaboration between our Group and Zhongmei Huadong with respect to the joint development and exclusive commercialization of QX001S in the PRC, which allows our Group and Zhongmei Huadong to (a) share the risks

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and costs associated with the R&D and marketing and sales of QX001S following the market practice and share the value of QX001S reasonably commensurate with their respective contributions in R&D and sales and marketing of QX001S; and (b) leverage their respective resources and established capabilities to expeditiously establish an advantageous position in relevant market, both of which are long term in nature. According to Frost & Sullivan, it is market practice in the pharmaceutical industry for similar collaboration agreements to be entered into for a long term, primarily due to the substantial amount of capital and contributions committed by the collaboration partners and the risks involved;

- (ii) a contractual arrangement of long term is necessary and critical to the development of our business and to ensure stable revenue and cash flows from the future commercialization of QX001S. Our primary purpose of this collaboration is to leverage Zhongmei Huadong’s market accessibility, nationwide sales and marketing network targeting the autoimmune and allergic disease field as well as its extensive experience in chronic disease management, which will be crucial to help achieve rapid commercialization of QX001S in the PRC and accordingly, Zhongmei Huadong will be the MAH of QX001S in the PRC to exclusively conduct marketing activities and commercialization of QX001S. If the QX001S Framework Agreement is determined at a short term, our Company may face the unnecessary and substantial risks of failing to renew such agreement upon expiry of a relatively short term and losing its competitive advantages. Imposing an arbitrary three-year term of the QX001S Framework Agreement will also be contrary to the business intention of the parties to have a long term collaboration and the commercial objective of such strategic collaboration to allow both parties to leverage respective strength and share value of QX001S reasonably commensurate with their respective contribution in R&D and sales and marketing;
- (iii) such long-term collaboration is in the interest of our Company and our Shareholders as a whole; and
- (iv) immediately before the expiry of the Initial Term, our Company will re-comply with the provisions of Chapter 14A of the Listing Rules applicable to such transactions, including seeking independent shareholders’ approval where the case may so require.

The Sole Sponsor is of the view that, taking into consideration (i) the reasons for entering into the QX001S Framework Agreement as set out above; (ii) the market practice in the pharmaceutical industry for similar collaboration agreement and the confirmation from Frost & Sullivan as set out above; and (iii) the fact that the relevant arrangements were negotiated on an arm’s length basis and in accordance with the procedures in evaluation of collaboration arrangements of our Group as set forth above, it is reasonable for QX001S Framework Agreement to be entered into for a term of 15 years commencing from August 14, 2020 and ending on August 13, 2035, which can be extended for a further term of five years unless terminated earlier in accordance with the terms the QX001S Framework Agreement, and it is normal business practice for agreements of this type to be of such duration.

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Historical transaction amounts

As QX001S has not yet been approved for commercialization by the relevant authorities in the PRC, there was no historical amount received by our Group from Zhongmei Huadong in relation to the Product Supply and Profit Sharing during the Track Record Period.

Annual caps

There will be no transaction amount under the QX001S Framework Agreement from the [REDACTED] to the commercialization of QX001S in the PRC.

Immediately before the commercialization of QX001S in the PRC, our Company will, based on specific circumstances at that time, set monetary annual caps for the purpose of Rule 14A.53 of the Listing Rules and will re-comply with the provisions of Chapter 14A of the Listing Rules applicable to such transactions, including seeking independent shareholders’ approval where the case may so require.

Listing Rules implications

As there will be no transaction amount under the QX001S Framework Agreement from the [REDACTED] to the commercialization of QX001S in the PRC, the transactions contemplated under the QX001S Framework Agreement for the corresponding period will be within the *de minimis* threshold provided under Rule 14A.76 of the Listing Rules and will, upon the [REDACTED], be fully exempt from the reporting, annual review, announcement, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

(B) CONTINUING CONNECTED TRANSACTIONS SUBJECT TO THE REPORTING, ANNUAL REVIEW AND ANNOUNCEMENT REQUIREMENTS BUT EXEMPT FROM THE CIRCULAR AND INDEPENDENT SHAREHOLDERS’ APPROVAL REQUIREMENTS

CDMO Services Framework Agreement

Principal terms

On January 16, 2024, Cellularforce, our CMC-focused subsidiary, entered into a CDMO services framework agreement (the “CDMO Services Framework Agreement”) with Zhongmei Huadong, pursuant to which Zhongmei Huadong and/or its subsidiaries (“Zhongmei Huadong Group”) may from time to time commission Cellularforce to provide CDMO services for their drug substance and drug products and in return Zhongmei Huadong Group shall agree to pay service fees to Cellularforce for such CDMO services. The CDMO Services Framework Agreement has a term commencing from the [REDACTED] to December 31, 2025, which may be renewed for a further term not exceeding three years from time to time, as the parties may mutually agree, subject to compliance with the requirements under Chapter 14A of the Listing Rules and all other applicable laws and regulations. Relevant members of both parties will enter into separate CDMO services agreements setting out the specific terms and conditions based on the principles provided in the CDMO Services Framework Agreement.

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The service fees chargeable by Cellularforce will be determined after arm’s length negotiations between Cellularforce and Zhongmei Huadong Group on a cost-plus basis, with the cost-plus margin ranging from approximately 5% to 30% of our cost depending on the nature, scope and complexity of services to be provided, the expected cost and expenses for provision of the required services.

Reasons for and benefits of the transaction

The provisions of CDMO services under the CDMO Services Framework Agreement are in the ordinary and usual course of business of our Group and on normal commercial terms. The transactions under the CDMO Services Framework Agreement can enhance the utilization of our in-house, commercial-scale biologic drug manufacturing capability, fulfill our business needs and diversify our source of revenue, which in turn can also support our R&D activities. Taking into consideration of the above and the corporate governance procedures in place as set out below, we believe that the transactions contemplated under the CDMO Services Framework Agreement are in the interest of our Company and our Shareholders as a whole.

Procedures in determination of price and terms of the transaction

In determining the price and terms of the transactions contemplated under the CDMO Services Framework Agreement, we follow our internal procedures which are applicable to all clients engaging Cellularforce for similar services. Such internal procedures cover the execution of confidentiality agreements with potential clients, discussions with potential clients to understand service needs and demands, preparation of work proposal and fee quote, arm’s length negotiations with clients on the terms of transactions, preparation and internal review of written agreements and execution of the same.

In addition to the above business procedures, we have promulgated the guidelines for establishing pricing for different kinds of services applicable for all clients and the business development department of Cellularforce shall conduct market analysis on specific service and making pricing proposal to our senior management after considering a number of factors as they consider necessary, including but not limited to service cost, profit margin, market pricing, capacity utilization and marketing perception. The business development department of Cellularforce shall review the reasonableness of pricing of relevant services on regular basis and ensure that the terms for the transactions under the CDMO Services Framework Agreement will not be more favorable than terms available to Independent Third Parties, and report to our senior management, if necessary, for their approval for any adjustment. Our independent non-executive Directors will also conduct annual review on the transactions under the CDMO Services Framework Agreement 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 CDMO Services Framework Agreement.

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Historical transaction amounts

As Cellularforce commenced the provision of CDMO services to Zhongmei Huadong Group in February 2023, there was only an upfront payment of approximately RMB2 million received by Cellularforce from Zhongmei Huadong Group under the CDMO Services Framework Agreement during the Track Record Period.

Annual caps

Our Directors estimate that the maximum amount of service fees payable by Zhongmei Huadong Group to Cellularforce under the CDMO Services Framework Agreement for each of the two years ending December 31, 2025 will not exceed RMB10.0 million and RMB12.0 million, respectively.

In arriving at the above annual caps, our Directors have considered: (i) the volume, work order and estimated schedule of CDMO services we expect to provide to Zhongmei Huadong Group for the two years ending December 31, 2025. Based on the current status of the project under the existing contract, it is anticipated that all major milestones under such project will be completed in 2023 save for the stability study of drug substance, and approximately RMB11.0 million of the transaction amount of such project will be recorded in 2023. The stability study of drug substance under such project carries a study period of five years with the remaining transaction amount to be recorded in 2027; (ii) the projected transaction amount of our CDMO services from other new projects under the CDMO Services Framework Agreement as a result of our plan to develop external CDMO services through our manufacturing facility in Taizhou and the demand for such services from Zhongmei Huadong Group for the clinical development of their pipeline drug candidates. It is anticipated that Cellularforce may, in each year, be engaged in one new project with similar size and completion schedule that save for its stability study which will be a five-year study, each project is expected to be completed within twelve months from its commencement; and (iii) the expected year-on-year increase in related fees charged by Cellularforce due to the estimated increase in operational costs of approximately 5% to 10% (including labor costs, material costs and administrative costs) for the provision of CDMO services.

Listing Rules implications

As each of the applicable percentage ratios (other than the profits ratio) in respect of the annual caps under the CDMO Services Framework Agreement is expected to be more than 0.1% but less than 5% on an annual basis, the transactions contemplated under the CDMO Services Framework Agreement constitute continuing connected transactions for our Company which will, upon [REDACTED], be subject to the reporting, annual review and announcement requirements but exempt from the circular and independent shareholders' approval requirements under Chapter 14A of the Listing Rules.

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WAIVER APPLICATION FOR NON-EXEMPT CONTINUING CONNECTED TRANSACTIONS

By virtue of Rule 14A.76(2) of the Listing Rules, the transactions contemplated under the CDMO Services Framework Agreement will constitute non-exempt continuing connected transactions subject to the reporting, annual review and announcement requirements but exempt from the circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

As the above non-exempt continuing connected transactions are expected to continue on a recurring, continuing basis and will extend over a period of time after [REDACTED], our Directors consider that compliance with the above announcement, circular and independent shareholders’ approval requirements would be impractical, unduly burdensome and would impose unnecessary administrative costs on our Company. Accordingly, pursuant to Rule 14A.105 of the Listing Rules, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver exempting us from strict compliance with the announcement requirement under Chapter 14A of the Listing Rules in respect of the continuing connected transactions as disclosed in “—(B) Continuing Connected Transactions Subject to the Reporting, Annual Review and Announcement Requirements but exempt from the Circular and Independent Shareholders’ Approval Requirements” in this section, on the condition that the Company will re-comply with the provisions of Chapter 14A of the Listing Rules applicable to such transactions upon the expiry of the term of the CDMO Services Framework Agreement.

In addition, we confirm that our Company will comply at all time with the other applicable provisions under Chapter 14 and Chapter 14A of the Listing Rules in respect of the notifiable and non-exempt continuing connected transactions. In the event of any future amendments to the Listing Rules imposing more stringent requirements than those applicable as of the Latest Practicable Date on the continuing connected transaction referred to in this document, our Company will take immediate steps to ensure compliance with such new requirements within a reasonable time.

CONFIRMATION FROM THE DIRECTORS

Our Directors, including the independent non-executive Directors, are of the view that the non-exempt continuing connected transactions as set out above have been and will be entered into: (i) in the ordinary and usual course of business of our Group; (ii) on normal commercial terms or better and in accordance with the respective terms that are fair and reasonable and in the interest of our Company and our Shareholders as a whole; and (iii) the proposed annual caps for the non-exempt continuing connected transactions described in this section are fair and reasonable and in the interest of our Company and our Shareholders as a whole.

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CONFIRMATION FROM THE SOLE SPONSOR

The Sole Sponsor has reviewed the relevant information prepared and provided by our Company in relation to the continuing connected transactions described in this section. Based on the above, the Sole Sponsor is of the view that the non-exempt continuing connected transactions have been entered into: (i) in the ordinary and usual course of business of our Group; (ii) on normal commercial terms or better and in accordance with the respective terms that are fair and reasonable and in the interests of our Company and our Shareholders as a whole; and (iii) the proposed annual caps for the non-exempt continuing connected transactions described in this section are fair and reasonable and in the interests of our Company and our Shareholders as a whole.