Qyuns Therapeutics Co., Ltd.
江蘇荃信生物醫藥股份有限公司
(A joint stock company incorporated in the People's Republic of China with limited liability)
(Stock Code: 2509)

CONTINUING CONNECTED TRANSACTIONS: SUPPLEMENTAL AGREEMENTS TO THE QX001S SUPPLY AGREEMENT AND ANNUAL CAPS FOR THE QX001S FRAMEWORK AGREEMENT

Reference is made to the Prospectus dated March 12, 2024 published by the Company in relation to the QX001S Framework Agreement entered into between the Company and Zhongmei Huadong. Unless otherwise defined, terms used in this announcement shall have the same meanings as defined in the Prospectus.

ENTERING INTO THE SUPPLEMENTAL AGREEMENTS AND SETTING ANNUAL CAPS FOR THE QX001S FRAMEWORK AGREEMENT

Zhongmei Huadong entrusted Cellularforce to carry out production and processing of QX001S, and the two parties entered into the QX001S Supply Agreement on September 28, 2022 (re-entered on March 9, 2023) in relation to the entrusted processing after amicable negotiation. Based on the needs of the Company's operation and development and to fully realize the resource sharing and complementary advantages of the parties, Zhongmei Huadong and Cellularforce entered into the Supplemental Agreements on September 12, 2024 to supplement and adjust certain terms of the QX001S Supply Agreement in respect of procurement of raw, auxiliary and packaging materials, placing of orders, settlement of entrusted production costs, sampling and testing of QX001S, stability study fees and other related matters. Except for the matters expressly supplemented or revised in the Supplemental Agreements, all the other terms in the QX001S Supply Agreement continues to be effective. In order to realize the commercialization arrangement of QX001S, the Company has set the annual caps for Product Supply (as defined below) under the QX001S Framework Agreement, the QX001S Supply Agreement and the Supplemental Agreements and for Profit Sharing (as defined below) under the QX001S Framework Agreement, respectively.

REASONS FOR ENTERING INTO THE SUPPLEMENTAL AGREEMENTS AND SETTING THE ANNUAL CAPS

The Company was listed on the Stock Exchange on March 20, 2024, prior to which Zhongmei Huadong had entrusted the Group to carry out the process development and production and processing of drugs, and the two parties entered into the QX001S Framework Agreement in relation to the entrusted processing after amicable negotiation, and entered into the QX001S Production Quality Agreement on June 16, 2022 and the QX001S Supply Agreement on September 28, 2022 (re-entered on March 9, 2023) as individual agreements under the QX001S Framework Agreement, respectively. After reviewing the business development of the Company, Zhongmei Huadong and Cellularforce have entered into the Supplemental Agreements to the QX001S Supply Agreement on September 12, 2024, which further refined the specific requirements for the implementation of the entrusted production and detailed provisions on the entrusted production costs. In view of the long-term business relationship between the parties and the fact that the manufacturing and supply of products under the QX001S Supply Agreement are part of the ordinary course of business between the parties, we believe that the signing of the Supplemental Agreements is necessary to maintain the stable business development of the Company.

IMPLICATIONS UNDER CHAPTER 14A OF THE LISTING RULES

As at the date of this announcement, Zhongmei Huadong is our substantial Shareholder holding 16.17% of the issued share capital of the Company and is therefore a core connected person of the Company as defined under the Listing Rules. Accordingly, the entering into of the Supplemental Agreements to the QX001S Supply Agreement will constitute continuing connected transactions under Chapter 14A of the Listing Rules. As the highest applicable percentage ratios (other than profit margin) of the annual caps for the income from Product Supply (as defined below) and income from Profit Sharing (as defined below) payable by Zhongmei Huadong to the Company exceeds 0.1% but does not exceed 5% and the transactions are conducted on normal commercial terms, the transactions are not subject to approval by the independent Shareholders of the Company, but are subject to reporting, announcement and annual review requirements under Chapter 14A of the Listing Rules.

I. SUPPLEMENTAL AGREEMENTS

1. Background

As disclosed in the Prospectus, on August 14, 2020, the Company and Zhongmei Huadong entered into a collaboration agreement (as supplemented on December 7, 2023), namely the QX001S Framework Agreement, pursuant to which the parties agreed to conduct joint development and exclusive commercialization of QX001S for the diagnosis, prevention and treatment of human diseases, including but not limited to, psoriasis, active psoriatic arthritis, Crohn's disease and ulcerative colitis, in China. The Company granted Zhongmei Huadong joint clinical development, manufacturing and exclusive commercialization rights of QX001S in China, which shall not be sub-licensed to a third party without written approval from the Company. Pursuant to the QX001S Framework Agreement, Cellularforce shall be solely responsible for the commercial production of QX001S. The Company retains the full development and commercialization rights of QX001S outside China. 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 renewed for a term of five years unless terminated earlier in accordance with the terms of the QX001S Framework Agreement.

Further details of the QX001S Framework Agreement and the QX001S Supply Agreement are disclosed in the Prospectus.

Based on the principles provided in the QX001S Framework Agreement, Zhongmei Huadong and Cellularforce entered into the QX001S Supply Agreement in respect of entrusted processing for the first time on September 28, 2022 and re-entered on March 9, 2023, as an individual agreement under the QX001S Framework Agreement after amicable negotiation. Under the QX001S Supply Agreement, as the MAH of QX001S, Zhongmei Huadong may place production orders of QX001S with Cellularforce after Zhongmei Huadong completes the onsite assessment and verification of Cellularforce's manufacturing facility and obtains approval for the Product Supply as required by the relevant regulatory authorities. Cellularforce shall provide certain designated manufacturing facility, quality control lab and storage center for the Product Supply to Zhongmei Huadong as specified in the QX001S Supply Agreement. Zhongmei Huadong shall be responsible for the commercialization of final products, and Cellularforce shall ensure that the Product Supply is in compliance with GMP requirements and other regulatory requirements. Zhongmei Huadong is entitled to examine the production and inspection process of Cellularforce from time to time and request Cellularforce to immediately terminate production or take remedial or rectification measures in the event of Cellularforce's breach or violation of the QX001S Supply Agreement, GMP requirements or operation procedures. The term of the QX001S Supply Agreement is one year from the first batch of commercial production and may be renewed automatically for another year if the parties agree.

The Board announced that based on the needs of the Company's operation and development and to fully realize the resource sharing and complementary advantages of the parties, Zhongmei Huadong and Cellularforce entered into the Supplemental Agreements after amicable negotiation on September 12, 2024 to supplement and adjust certain terms of the QX001S Supply Agreement in respect of procurement of raw, auxiliary and packaging materials, placing of orders, settlement of entrusted production costs, sampling and testing of QX001S, stability study fees and other related matters.

2. Principal Terms of the Supplemental Agreements

Except for the matters expressly supplemented or revised in the Supplemental Agreements, all the other terms in the QX001S Supply Agreement continues to be effective. If the Supplemental Agreements are inconsistent with the provisions of the original entrusted production agreement, the Supplemental Agreements shall prevail. Those not provided for in the Supplemental Agreements shall continue to be implemented pursuant to the provisions of the original entrusted production agreement.

The key amendments under the Supplemental Agreements are summarized below:

a) Production orders under the implementation of entrusted production

Newly added: Zhongmei Huadong shall place each order based on 2,000L per batch for drug substance and tens of thousands of vials per batch for formulation (specification: 45mg (0.5ml)/prefilled syringe) as well as the number of batches needed.

b) Provision of raw, auxiliary and packaging materials under the implementation of entrusted production

Revised: Zhongmei Huadong shall be responsible for the selection of suppliers of drug substance, auxiliary materials, and packaging materials for commercial batches of entrusted drugs, and Cellularforce shall be responsible for the procurement of suppliers of drug substance, auxiliary materials, and packaging materials for commercial batches of entrusted drugs. (Note: the requirements for Cellularforce's scope of work and the time for completion of testing have been deleted).

c) Calculation methods for entrusted production costs

Newly added: Drug substance and formulation shall be settled separately, and material cost and processing cost shall be separated. In particular, material costs for both drug substance and formulation shall be settled on an actual basis, with an additional 1% of the material cost as material scrap loss, and an additional 10% of the material cost as material inspection and warehousing costs. The processing fee for drug substance shall be settled at a fixed amount per batch, with the amount of the processing fee for drug substance = the number of batches of drug substance * the amount of processing fee per batch. The processing fee for formulation shall be settled at a fixed amount per vial, with the amount of the processing fee for formulation = the actual number of finished products delivered in a single batch of formulation * fixed price per vial of formulation.

d) Settlement method for entrusted production costs

Newly added: The material costs related to drug substance and formulation shall be prepaid by Zhongmei Huadong to Cellularforce in advance. The processing fee for drug substance and formulation shall be paid by Zhongmei Huadong to Cellularforce in the next month after the shipment of the completed batches. The cost of the three-year stability study shall be paid by Zhongmei Huadong to Cellularforce upon delivery of the first batch of drug substance each year.

e) Sampling and testing of QX001S

Newly added: Zhongmei Huadong's sampling and testing of QX001S requires renting of Cellularforce's laboratory premises, materials, reagents and equipment. Cellularforce will charge specific fees based on the actual sampling procedures conducted, which will be invoiced once a year, with a bill of costs to be issued to Zhongmei Huadong for confirmation in advance.

f) Scope of entrusted production of drugs

Revised: Zhongmei Huadong has entrusted Cellularforce with the production and processing of QX001S injection (45mg (0.5ml)/prefilled syringe) and QX001S injection (IV) (130mg (26 ml)/vial) (Note: the description of vial of the QX001S injection has been refined).

II. ANNUAL CAPS FOR THE CONTINUING CONNECTED TRANSACTIONS UNDER THE QX001S FRAMEWORK AGREEMENT

Pursuant to the QX001S Framework Agreement, the QX001S Supply Agreement and the Supplemental Agreements, the Group and Zhongmei Huadong will conduct the following continuing connected transactions after commercialization of QX001S expected to be in the fourth quarter of 2024:

(i) Product Supply

During the term of the QX001S Framework Agreement, the Group will exclusively manufacture and supply QX001S to Zhongmei Huadong in the PRC (the "**Product Supply**") and be responsible for relevant quality control. Except when Cellularforce is unable to meet the manufacturing demand, Zhongmei Huadong cannot engage other manufacturers. Cellularforce shall supply QX001S to Zhongmei Huadong at a unit supply price which 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 (the "**Markup**"), and on a priority basis.

Matters related to Product Supply have covered the renting of Cellularforce's laboratory premises, materials, reagents and equipment for sampling and testing of QX001S by Zhongmei Huadong, as well as the need to carry out a three-year long-term stability study on no less than one batch of QX001S drug substance and injections each year as required by Zhongmei Huadong to continuously monitor the stability of the products in order to comply with the relevant GMP requirements.

(ii) Profit Sharing

The parties agree that the accumulative pre-tax profit generated from sales of QX001S in China (as calculated pursuant to the QX001S Framework Agreement), after setting off the accumulative losses attributable to the commercialization of QX001S incurred in prior years (if any), shall be shared by the two parties on a 50:50 basis, provided that 50% of the Markup for the manufacturing of QX001S will be further deducted from our portion of the pre-tax profit receivable and attributed to Zhongmei Huadong's portion instead (the "**Profit Sharing**").

The Board further announced that based on the arrangements under the Supplemental Agreements, the annual caps for the continuing connected transactions under the QX001S Framework Agreement are as follows:

	2024	**2025**
	(RMB'000)	
Product Supply (payment to be received by the Group from Zhongmei Huadong under the QX001S Framework Agreement, the QX001S Supply Agreement and the Supplemental Agreements)	10,000	15,000
Profit Sharing (payment to be received by the Group from Zhongmei Huadong under the QX001S Framework Agreement)	5,000	38,000

III. REASONS FOR ENTERING INTO THE SUPPLEMENTAL AGREEMENTS AND SETTING THE ANNUAL CAPS

The Company was listed on the Stock Exchange on March 20, 2024, prior to which Zhongmei Huadong had entrusted the Group to carry out the process development and production and processing of drugs, and the two parties entered into the QX001S Framework Agreement in relation to the entrusted processing after amicable negotiation, and entered into the QX001S Production Quality Agreement on June 16, 2022 and the QX001S Supply Agreement on September 28, 2022 (re-entered on March 9, 2023) as individual agreements under the QX001S Framework Agreement, respectively. Zhongmei Huadong is wholly owned by Huadong Medicine, a leading PRC pharmaceutical company with over 30 years of experience covering the whole pharmaceutical industrial chain and strong research and development and commercialization capabilities at a national level. Cellularforce, an indirect non-wholly owned subsidiary of the Company, is actively expanding its entrusted production business in China and overseas. We believe that the continued cooperation between the two parties in matters relating to entrusted processing will fully realize the resource sharing and complementary advantages of both parties.

After reviewing the business development of the Company, Zhongmei Huadong and Cellularforce have entered into the Supplemental Agreements, which further refined the specific requirements for the implementation of the entrusted production and detailed provisions on the entrusted production costs. In view of the long-term business relationship between the parties and the fact that the manufacturing and supply of products under the QX001S Supply Agreement are part of the ordinary course of business between the parties, we believe that the signing of the Supplemental Agreements are necessary to implementation of the entrusted production and maintain the stable business development of the Company.

In order to realize the commercialization arrangement of QX001S, the Company has set the annual caps for Product Supply and Profit Sharing, respectively. In determining the annual caps for Product Supply, the Directors have taken into account: (i) the production costs (including raw material costs, energy costs and labor costs, etc.) expected to be incurred by Cellularforce in the supply of the QX001S products, with the Product Supply in 2024 taking into account the inventory requirements of Zhongmei Huadong for sales in 2025; (ii) the sample testing categories, testing frequency and estimated workload of sample testing; and (iii) the workload and consumption of reagents and consumables arising from the three-year long-term stability study on no less than one batch of QX001S drug substance and injections each year as required. In determining the annual caps for Profit Sharing, the Directors have taken into account: (i) the expected amount of the QX001S products to be sold during the period from 2024 to 2025 and the estimated unit price of such products under the Supplemental Agreements; (ii) the sales capability and distribution channels of Zhongmei Huadong; (iii) the selling and administrative expenses incurred based on (ii); and (iv) the profit before tax expected to be generated by Zhongmei Huadong from the sales of the QX001S products after deducting the relevant costs.

IV. CONFIRMATION BY THE BOARD

The Board has considered the resolutions in relation to the Supplemental Agreements and the annual caps for the QX001S Framework Agreement. Mr. Yu Xi, a non-executive Director, is the general manager of investment department at Huadong Medicine, the parent company of Zhongmei Huadong. Since he may have conflicts of interest and for good corporate governance practice, Mr. Yu Xi has abstained from voting on the Board resolutions approving the Supplemental Agreements and the annual caps for the QX001S Framework Agreement. Save as aforesaid, none of the Directors has any material interest in the Supplemental Agreements and none of the Directors is required to abstain from voting on the relevant Board resolutions.

The Board (including the independent non-executive Directors) considers that the terms of the Supplemental Agreements and the annual caps are (i) fair and reasonable; (ii) on normal commercial terms or better in the ordinary and usual course of business of the Group; and (iii) in the interests of the Company and its Shareholders as a whole.

V. IMPLICATIONS UNDER CHAPTER 14A OF THE LISTING RULES

As at the date of this announcement, Zhongmei Huadong is our substantial Shareholder holding 16.17% of the issued share capital of the Company and is therefore a connected person of the Company as defined under the Listing Rules. Accordingly, the entering into of the Supplemental Agreements constitutes a continuing connected transaction under Chapter 14A of the Listing Rules.

As the highest applicable percentage ratios (other than profit margin) of the annual caps for the income from Product Supply and income from Profit Sharing payable by Zhongmei Huadong to the Company exceeds 0.1% but does not exceed 5% and the transactions are conducted on normal commercial terms, the transactions are not subject to approval by the independent Shareholders of the Company, but are subject to reporting, announcement and annual review requirements under Chapter 14A of the Listing Rules.

VI. INFORMATION OF THE PARTIES

Zhongmei Huadong

Zhongmei Huadong is a company established in the PRC, and a substantial shareholder of the Company, a wholly-owned subsidiary of Huadong Medicine. Zhongmei Huadong principally engaged in the development, manufacturing and sales of pharmaceutical products. Zhongmei Huadong is our commercialization partner for joint development and exclusive commercialization of QX001S, one of the Company's key products in China since August 2020.

Cellularforce

Jiangsu Cellularforce Biopharma Co., Ltd. (江蘇賽孚士生物技術有限公司), a company established in the PRC with limited liability on August 2, 2018 and an indirect non-wholly owned subsidiary of the Company which is owned as to 66% by Saifu Juli and 34% by Taizhou Huacheng Medical Investment Group Co., Ltd. (泰州華誠醫學投資集團有限公司) ("**Taizhou Huacheng**"). Taizhou Huacheng is a company established in the PRC controlled by Taizhou Medicine City Holding Group Co., Ltd. (泰州醫藥城控股集團有限公司), a company wholly owned by the Management Committee of Taizhou Medical New and High-tech Industrial Development Zone (泰州醫藥高新技術產業開發區管理委員會), which is an administrative agency of Jiangsu Provincial Committee of the Communist Party of China (中國共產黨江蘇省委員會) and Jiangsu Provincial People's Government (江蘇省人民政府).

VII. DEFINITIONS

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

"Board"	the board of Directors of the Company
"Business Day"	any day other than (a) a Saturday or a Sunday or (b) a day on which commercial banking institutions are authorized or required by applicable laws to be closed in China
"Company"	Qyuns Therapeutics Co., Ltd. (江蘇荃信生物醫藥股份有限公司) (stock code: 2509) (formerly known as Qyuns Therapeutics Co., Ltd. (江蘇荃信生物醫藥有限公司)), a company established in the PRC with limited liability on June 16, 2015 which was converted into a joint stock company with limited liability on September 30, 2021
"Cellularforce"	Jiangsu Cellularforce Biopharma Co., Ltd. (江蘇賽孚士生物技術有限公司), a company established in the PRC with limited liability on August 2, 2018 and an indirect non-wholly owned subsidiary of our Company which is owned as to 66% by Saifu Juli and 34% by Taizhou Huacheng
"Director(s)"	the director(s) of the Company
"connected person(s)"	has the meanings ascribed to them under the Listing Rules (as modified by the Stock Exchange from time to time)
"Global Offering"	the global offering of 12,046,400 H Shares as described in the Prospectus
"GMP"	good manufacturing practice, regulations and procedures that provide for proper design, monitoring, and control of manufacturing processes and facilities
"Group"	the Company and its subsidiaries
"H Share(s)"	shares of our Company for which an application has been made for listing and permission to trade on the Stock Exchange
"Hong Kong"	the Hong Kong Special Administrative Region of the PRC
"Huadong Medicine"	Huadong Medicine Co., Ltd. (華東醫藥股份有限公司), a pharmaceutical company whose shares are listed on the Shenzhen Stock Exchange (stock code: 000963.SZ)

"Listing"	the listing of our H Shares on the Main Board
"Listing Rules"	the Rules Governing the Listing of Securities on the Stock Exchange
"MAH"	marketing authorization holder
"Main Board"	the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operated in parallel with GEM of the Stock Exchange
"PRC" or "China"	the People's Republic of China and for the purpose of this announcement, excluding Hong Kong, the Macau Special Administrative Region and Taiwan
"Prospectus"	the prospectus published by the Company on March 12, 2024 in connection with the Global Offering and Listing
"QX001S Framework Agreement"	the collaboration agreement and the supplemental agreement to the collaboration agreement entered into between the Company and Zhongmei Huadong on August 14, 2020 and December 7, 2023, respectively
"QX001S Supply Agreement"	the Ustekinumab Entrusted Production Agreement first entered into between Zhongmei Huadong and Cellularforce on September 28, 2022 and re-entered into on March 9, 2023 to update the name of the production line only with all other contents remaining the same
"RMB"	Renminbi, the lawful currency of the PRC
"Share(s)"	ordinary share(s) with par value RMB1.00 each in the share capital of the Company
"Saifu Juli"	Taizhou Saifu Juli Biomedical Co., Ltd. (泰州市賽孚聚力生物醫藥有限公司), a company established in the PRC with limited liability on July 6, 2018 and a direct wholly owned subsidiary of our Company
"Shareholder(s)"	holder(s) of our Share(s)
"Stock Exchange"	The Stock Exchange of Hong Kong Limited

"Supplemental Agreements"	including the supplemental agreement to the QX001S Supply Agreement, the first supplemental agreement to the QX001S Supply Agreement and the second supplemental agreement to the QX001S Supply Agreement, all of which were entered into between Zhongmei Huadong and Cellularforce on September 12, 2024
"Zhongmei Huadong"	Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (杭州中美華東製藥有限公司), a company established in the PRC with limited liability on December 31, 1992 and a substantial shareholder of the Company, a wholly-owned subsidiary of Huadong Medicine
"%"	per cent

By order of the Board
Qyuns Therapeutics Co., Ltd.
Mr. Qiu Jiwan
Chairman of the Board and Executive Director

Hong Kong, September 12, 2024

As at the date of this announcement, the board of directors of the Company comprises Mr. Qiu Jiwan as chairman and executive director, Mr. Wu Yiliang and Mr. Lin Weidong as executive directors, Mr. Yu Xi, Mr. Wu Zhiqiang and Dr. Xue Mingyu as non-executive directors, and Dr. Zou Zhongmei, Dr. Ling Jianqun and Mr. Fung Che Wai, Anthony as independent non-executive directors.