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东曜药业

TOT BIOPHARM International Company Limited

東曜藥業股份有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1875)

**CONTINUING CONNECTED TRANSACTIONS
IN RELATION TO
TECHNICAL SERVICE AGREEMENT AND
BUSINESS DEVELOPMENT SERVICE AGREEMENT**

INTRODUCTION

The Board is pleased to announce that on 22 December 2021, TOT Suzhou and Lumosa entered into (i) the Technical Service Agreement, pursuant to which TOT Suzhou will provide certain Technical Services to Lumosa; and (ii) the Business Development Service Agreement, pursuant to which Lumosa will provide certain Business Development Services to TOT Suzhou. The Agreements pertain to TAA013, a self-developed antibody drug conjugate (ADC) candidate of the Group for the treatment of HER2+ advanced breast cancer, which is currently undergoing Phase III clinical trials.

THE TECHNICAL SERVICE AGREEMENT

Date

22 December 2021

Parties

- (a) TOT Suzhou as the service provider
- (b) Lumosa as the client

Scope of Services

Pursuant to the Technical Service Agreement, TOT Suzhou shall provide certain Technical Services to Lumosa in respect of comparative bridging studies on the biosimilarity between TAA013 and Kadcyła (a brand-name drug owned by Roche) as required under European Union regulations, which mainly include:

- (a) conducting of experiments relating to comparative studies and forced degradation studies on TAA013 and Kadcyła; and
- (b) translation of documents relating to technical processes as well as non-clinical studies and Phase I and Phase III clinical trials conducted in the PRC for TAA013.

The Technical Service Agreement will be effective for a period of one year upon signing or until the completion by TOT Suzhou of the aforesaid studies, whichever is later, but in any event not longer than three years. Such studies are currently expected to be completed in 2022.

Service Fees Payable by Lumosa

The service fees payable by Lumosa to TOT Suzhou under the Technical Service Agreement are currently expected to be RMB2,385,800.

It is expected that the payment of service fees under the Technical Service Agreement will be made in several installments, of which (i) the first installment of RMB818,080 is expected to be payable shortly after signing (either in December 2021 or in early 2022); and (ii) the remaining installments totaling RMB1,567,720 are expected to be payable during 2022 in accordance with the progress of the relevant research project.

Basis of Determination of Service Fees

The above service fees were determined by TOT Suzhou and Lumosa after arm's length negotiations primarily with reference to (i) the scope, contents and requirements of technical services involved; and (ii) prices of similar technical services provided by the Group to independent third party clients.

Proposed Annual Caps

The proposed annual caps for the transaction amount under the Technical Service Agreement during its effective period are as follows:

	For the year ending 31 December	
	2021	2022
Proposed annual cap	RMB818,080	RMB2,600,000

The above annual caps were determined primarily with reference to the following factors:

- (a) the inclusion of the first installment of the service fees in the annual caps for both 2021 and 2022 because of the uncertainty as to the exact timing of payment; and
- (b) the inclusion of the entirety of the service fees potentially receivable plus a buffer for possible additional fees for services beyond the originally agreed work scope in the annual cap for 2022.

THE BUSINESS DEVELOPMENT SERVICE AGREEMENT

Date

22 December 2021

Parties

- (a) Lumosa as the service provider
- (b) TOT Suzhou as the client

Scope of Services

Pursuant to the Business Development Service Agreement, Lumosa shall provide certain Business Development Services to TOT Suzhou in areas outside of mainland China, Hong Kong, Macau and Taiwan and the scope of services shall cover (without limitation) the following aspects with regards to TAA013:

- (a) strategic planning of authorized distribution or sales;
- (b) introduction of potential customers;
- (c) assisting in the enhancement of promotion contents;
- (d) assisting in the construction of a due diligence database on customers;
- (e) consultation with regulatory authorities in relevant jurisdictions, including the European Medicines Agency; and
- (f) contract negotiation.

The Business Development Service Agreement is non-exclusive and will be effective for a period of one year upon signing.

Service Fees Payable by TOT Suzhou

Pursuant to the Business Development Service Agreement, with regards to any form of proceeds received from any third party in any mode as a result of any Business Development Services provided by Lumosa, including but not limited to any signing fees, milestone fees, sales right fees, distributorship revenues and payments for goods (the “**Business Proceeds**”), the service fees payable by TOT Suzhou to Lumosa shall be equal to the sum of the following:

- (a) approximately USD700,000, being preliminary research and development fees which include the application fee and consultation fee in connection with the registration with the European Medicines Agency, the fee for comparative biosimilarity studies and the fee for freedom-to-operate (FTO) analysis (the “**Preliminary Fees**”); and
- (b) a percentage of the net Business Proceeds after deducting the Preliminary Fees, being:
 - (i) if the Business Proceeds are more than USD10,000,000 but less than or equal to USD15,000,000, an amount that equals 6% of the net Business Proceeds after deducting the Preliminary Fees;
 - (ii) if the Business Proceeds are more than USD15,000,000 but less than or equal to USD30,000,000, an amount that equals 7% of the net Business Proceeds after deducting the Preliminary Fees; or
 - (iii) if the Business Proceeds are more than USD30,000,000 or involve transactions beyond the scope permitted by laws and regulations applicable to TOT Suzhou or by relevant authorities, an amount to be separately negotiated between Lumosa and TOT Suzhou.

It is expected that the payment of service fees under the Business Development Service Agreement will be made during 2022.

Basis of Determination of Service Fees

The above service fees were determined by TOT Suzhou and Lumosa after arm’s length negotiations primarily with reference to the current fee rates of similar business development services (i) provided by Lumosa and its affiliates to other clients; and (ii) provided by independent third party service providers to the Group.

Proposed Annual Caps

The proposed annual caps for the transaction amount under the Business Development Service Agreement during its effective period are as follows:

	For the year ending 31 December	
	2021	2022
Proposed annual cap	RMB0	RMB19,000,000

The above annual caps were determined primarily with reference to the following factors:

- (a) that no service fee is expected to be payable during 2021;
- (b) the expected Business Proceeds potentially receivable by the Group during 2022 (up to USD30,000,000) as a result of the Business Development Services provided by Lumosa; and
- (c) a buffer for exchange rate fluctuations between USD and RMB.

REASONS FOR AND BENEFITS OF ENTERING INTO THE AGREEMENTS

TAA013 is a self-developed antibody drug conjugate (ADC) candidate of the Group for the treatment of HER2+ advanced breast cancer, which is currently undergoing Phase III clinical trials. The Technical Service Agreement was entered into with the aim of conducting comparative studies on the biosimilarity between TAA013 and Kadcyla (a brand-name drug owned by Roche) and procuring Lumosa's proactive performance of its obligations under the Business Development Service Agreement. The primary purpose of the Business Development Service Agreement is to leverage the overseas market experience and resources of Lumosa and its affiliates in assisting the Group's pursuit of better commercial opportunities, thereby promoting the overseas commercialization progress of TAA013 and providing an effective, safe and affordable high-quality drug to global cancer patients. Please refer to pages 187 and 212 to 215 of the Prospectus for technical details of TAA013.

The Directors (including the independent non-executive Directors) consider that the Agreements and the transactions contemplated thereunder are entered into on normal commercial terms, that the Agreements are entered into in the ordinary and usual course of business of the Group, and that the terms of the Agreements are fair and reasonable and are in the interest of the Company and its shareholders as a whole.

To the best of the knowledge, information and belief of the Directors having made all reasonable enquiries, none of the Directors has a material interest in the Agreements.

INFORMATION ON THE PARTIES

TOT Suzhou

TOT Suzhou is a limited liability company incorporated in the PRC and is a wholly-owned subsidiary of the Company. The Company is an investment holding company incorporated in Hong Kong with limited liability, whose shares are listed on the Stock Exchange (stock code: 1875). The Group is principally engaged in research and development, manufacturing, and marketing of oncology drugs in the PRC.

Lumosa

Lumosa is a clinical-stage biopharmaceutical company in Taiwan, dedicated to the development of new drugs in the fields of neurological disorders, inflammatory diseases and others. Its main products being researched and developed include an opioid analgesic and an innovative drug for the treatment of acute ischemic stroke. Its shares are listed on the Taipei Exchange (stock code: 6535).

Based on public information, as at 30 September 2021, Centerlab (together with its non-wholly-owned subsidiary BioEngine Capital) held approximately 33.59% of the total issued share capital of Lumosa.

CONFIRMATION IN RELATION TO CENTERLAB AND MR. LIN, JUNG-CHIN

As disclosed on pages 282 to 283 of the Prospectus, as part of the measures adopted by the Company to address any potential competition and conflict of interest between the Company on one hand and Centerlab and its chairman Mr. Lin, Jung-Chin on the other hand, the Company has undertaken to the Stock Exchange to include the following statement in this announcement.

The Company confirms that, as at the date of this announcement, (i) none of Mr. Lin, Jung-Chin or any of his associates and relatives as defined in Rules 14A.12 and 14A.21(1)(a) of the Listing Rules respectively (the “**Relevant Persons**”) had discussed or voted on any matters relating to the entering into of the Agreements between TOT Suzhou and Lumosa (the “**Relevant Matters**”) at any relevant meeting of the board of directors of Centerlab; and (ii) where the Relevant Matters involved the approval or deliberation by the board of directors or the investment committee of Centerlab, none of Mr. Lin, Jung-Chin or any of the Relevant Persons was a member of the investment committee of Centerlab at the material time.

LISTING RULES IMPLICATIONS

As at the date of this announcement, Lumosa is an associate of Centerlab (which, together with its associate BioEngine Technology, is the controlling shareholder of the Company), and is hence a connected person of the Company pursuant to Rules 14A.07(1) and 14A.07(4) of the Listing Rules. Therefore, the transactions contemplated under the Agreements constitute continuing connected transactions of the Company.

Pursuant to Rule 14A.80 of the Listing Rules, on the basis that the revenue ratio under Rule 14.07(3) of the Listing Rules would produce an anomalous result in measuring the size of the transactions contemplated under the Business Development Service Agreement, the Company has applied to the Stock Exchange for, and the Stock Exchange has agreed to the Company, disregarding the revenue ratio in respect of the Business Development Service Agreement.

As the highest applicable percentage ratio (under the meaning of Rules 14.04(9), 14A.77 and 14A.78 of the Listing Rules) in respect of the Business Development Service Agreement is less than 5%, and that in respect of the Technical Service Agreement is less than 25% with the total consideration less than HK\$10,000,000, the Agreements are exempt from the circular (including independent financial advice) and shareholders’ approval requirements pursuant to Rule 14A.76(2), but are nonetheless subject to the reporting, announcement and annual review requirements under Chapter 14A of the Listing Rules.

DEFINITIONS

In this announcement, unless the context otherwise requires, the following expressions shall have the following meanings:

“Agreements”	the Technical Service Agreement and the Business Development Service Agreement
“BioEngine Capital”	BioEngine Capital Inc. (玉晟生技投資股份有限公司), a company incorporated in Taiwan with limited liability on 13 August 2014, which is a non-wholly-owned subsidiary of Centerlab
“BioEngine Technology”	BioEngine Technology Development Inc. (玉晟管理顧問股份有限公司), a company incorporated in Taiwan with limited liability on 27 September 2007, which is an associate of Centerlab
“Board”	the board of Directors of the Company
“Business Development Service Agreement”	the business development service agreement dated 22 December 2021 entered into between TOT Suzhou as the client and Lumosa as the service provider
“Business Development Services”	the business development services to be provided by Lumosa to TOT Suzhou pursuant to the Business Development Service Agreement
“Centerlab”	Center Laboratories Inc. (晟德大藥廠股份有限公司), a company incorporated in Taiwan with limited liability on 4 November 1959 whose shares are listed on the Taipei Exchange (stock code: 4123), which (together with BioEngine Technology) is the controlling shareholder of the Company
“Company”	TOT BIOPHARM International Company Limited (東曜藥業股份有限公司) (formerly known as TOT BIOPHARM International Company Limited (東源國際醫藥股份有限公司)), a company incorporated in Hong Kong with limited liability on 4 December 2009 whose shares are listed on the Stock Exchange (stock code: 1875)
“Director(s)”	the director(s) of the Company
“Group”	the Company and its subsidiaries
“HK\$”	Hong Kong dollar(s), the lawful currency of Hong Kong

“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
“Lumosa”	Lumosa Therapeutics Co., Ltd. (順天醫藥生技股份有限公司), a company incorporated in Taiwan with limited liability on 13 November 2000 whose shares are listed on the Taipei Exchange (stock code: 6535), which is an associate of Centerlab
“PRC”	the People’s Republic of China, excluding, for the purpose of this announcement, Hong Kong, Macau and Taiwan regions
“Prospectus”	the prospectus dated 29 October 2019 published by the Company
“RMB”	Renminbi, the lawful currency of the PRC
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“Taipei Exchange”	Taipei Exchange (證券櫃檯買賣中心) in Taiwan
“Technical Service Agreement”	the technical service agreement dated 22 December 2021 entered into between TOT Suzhou as the service provider and Lumosa as the client
“Technical Services”	the technical services to be provided by TOT Suzhou to Lumosa pursuant to the Technical Service Agreement
“TOT Suzhou”	TOT BIOPHARM Co., Ltd. (東曜藥業有限公司), a company incorporated in the PRC with limited liability on 5 July 2010 and is a wholly-owned subsidiary of the Company
“USD”	United States dollar(s), the lawful currency of the United States of America

By order of the Board
TOT BIOPHARM International Company Limited
Dr. Liu, Jun
Chief Executive Officer and Executive Director

Hong Kong, 22 December 2021

As at the date of this announcement, the executive Directors of the Company are Dr. Liu, Jun and Ms. Yeh-Huang, Chun-Ying; the non-executive Directors of the Company are Mr. Fu, Shan, Dr. Kung, Frank Fang-Chien, Mr. Kang, Pei and Mr. Qiu, Yu Min; and the independent non-executive Directors of the Company are Ms. Hu, Lan, Dr. Sun, Lijun Richard and Mr. Chang, Hong-Jen.