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ESSEX BIO-TECHNOLOGY LIMITED

億勝生物科技有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 1061)

DISCLOSEABLE TRANSACTIONS IN RELATION TO AN EXCLUSIVE GLOBAL CO-DEVELOPMENT LICENSE AGREEMENT WITH SHANGHAI HENLIUS BIOTECH, INC. FOR TREATMENT OF AGE-RELATED MACULAR DEGENERATION

THE CO-DEVELOPMENT LICENSE AGREEMENT

Co-development and License

On 15 October 2020 (after trading hours), the Licensee (both are wholly-owned subsidiaries of the Company) entered into the Co-Development License Agreement with the Licensor, pursuant to which (i) the Licensee has agreed to co-fund the development of the Licensed Product; and (ii) the Licensee is granted with a license under the Licensed IP, the license of which is, subject to the terms of the Co-Development License Agreement, sub-licensable, perpetual and irrevocable, transferrable and exclusive, (a) to use and reference the Dossier for any purpose relating to the Licensed Product; and (b) for the regulatory development, manufacture and commercialisation of the Licensed Product under one or more of the Licensee's trademark(s), in the Field in the Territory.

Pursuant to the Co-Development License Agreement, the Licensee shall pay to the Licensor a signing payment, subsequent regulatory milestone payments and sharing of the Development Costs totalling up to US\$49,000,000 (equivalent to approximately HK\$379,750,000) and, where applicable, commercial sales milestone payment and/or royalties (both levied on net sales of the Licensed Product in the Territory).

The Licensed Product shall contain the Compound as an active pharmaceutical ingredient, which is intended for the treatment of exudative (wet) age-related macular degeneration (wAMD).

Sub-license and Put Option

In the event that the Licensee grants a sub-license to a third party for the commercialisation of the Licensed Product in the Territory in accordance with the terms of the Co-Development License Agreement, each of the Licensor and the Licensee will share the relevant sub-licensing revenues in accordance with the agreed percentage provided that the Licensee may, by exercise of the Put Option, reduce the Licensee Sub-licensing Percentage in consideration of the Buy Back Amount payable by the Licensor, subject to the terms of the Co-Development License Agreement.

LISTING RULES IMPLICATIONS

As the highest applicable percentage ratio (as defined in the Listing Rules) for each of (i) the transactions contemplated under the Co-Development License Agreement; and (ii) the transaction contemplated under the Put Option, exceeds 5% but is less than 25%, the entering into of the Co-Development License Agreement (including the Put Option) constitutes discloseable transactions for the Company under Chapter 14 of the Listing Rules and is accordingly subject to the notification and announcement requirements under Chapter 14 of the Listing Rules.

The Board is pleased to announce that, on 15 October 2020 (after trading hours), each of Essex Bio-Investment and Zhuhai Essex (both are wholly-owned subsidiary of the Company) entered into the Co-Development License Agreement with the Licensor.

The principal terms of the Co-Development License Agreement are as follows:

THE CO-DEVELOPMENT LICENSE AGREEMENT

Date

15 October 2020 (after trading hours)

Parties

- (i) Essex Bio-Investment (as licensee);
- (ii) Zhuhai Essex (as licensee); and
- (iii) the Licensor (as licensor).

The Licensor is a joint stock company incorporated in the PRC with limited liability, the stock of which are listed on the Stock Exchange (stock code: 2696).

To the best of the Directors' knowledge, information and belief, having made all reasonable enquiries, as at the date of this announcement, the Licensor and its ultimate beneficial owners are third parties independent of, and not connected with, the Company and its connected persons (as defined in the Listing Rules).

License and assignment

Subject to the terms of the Co-Development License Agreement, the Licensor (on its own behalf and on behalf of its affiliates) granted to the Licensee a license under the Licensed IP, the license of which is sub-licensable, perpetual and irrevocable, transferrable and exclusive:

- (a) to use and reference the Dossier for any purpose relating to the Licensed Product in the Field in the Territory; and
- (b) for the regulatory development, manufacture and commercialisation of the Licensed Product under one or more of the Licensee's trademark(s) in the Field in the Territory.

Following Licensor's submission of each Dossier to the relevant regulatory authority, the Licensor assigns (by way of present assignment of existing and future rights) any and all rights, title and interest in such Dossier to the Licensee.

Co-development and Commercialisation

The Licensor shall be responsible for the development of the Licensed Product in the Territory and the conduction of the Clinical Trial Programme in accordance with agreed Development Costs' sharing arrangement with the Licensee. Please refer to the sub-section headed "Consideration – (II) Development Costs Sharing" for details. The Licensor shall initiate a global Clinical Trial Programme, which comprises of two Phase 3 Clinical Trials with a Phase 3 Clinical Trial in Europe, the PRC and the U.S. as stage 1 ("Study 1") and a Phase 3 Clinical Trial in the PRC as stage 2 ("Study 2").

Subject to the terms of the Co-Development License Agreement, the Licensee shall be responsible for the regulatory filings of the Licensed Product in the Territory required for obtaining and maintaining the marketing approvals for the Licensed Product in the Territory and shall use commercially reasonable efforts to commercialise the Licensed Product in the Territory by itself or through the sub-licensing arrangement.

Consideration

(I) Payments and Royalties

Pursuant to the Co-Development License Agreement, the Licensee shall, within 30 days upon receipt of the relevant invoice from the Licensor (which can be issued only after achievement of the relevant stage), pay to the Licensor:

- (i) a signing payment of US\$10,000,000 (equivalent to approximately HK\$77,500,000) or its Renminbi equivalent;
- (ii) regulatory milestone payment of US\$5,000,000 (equivalent to approximately HK\$38,750,000) or its Renminbi equivalent upon initiation of the Clinical Trial Programme as determined by the date of the first site authorised and ready to recruit patients under the agreement entered into between the Licensor and the Licensee's contract research organisation for conducting Study 1 in Europe, the PRC or the U.S.; and
- (iii) a further regulatory milestone payment of US\$10,000,000 (equivalent to approximately HK\$77,500,000) or its Renminbi equivalent upon completion of the Clinical Trial Programme as determined by the date of the report (whichever is later) of Study 1 or Study 2.

After commercialisation of the Licensed Product, the Licensee shall pay to the Licensor:

- (i) (where the Licensee commercialises the Licensed Product by itself only) commercial sales milestone payments (which shall be paid once only) of US\$3,000,000 (equivalent to approximately HK\$23,250,000), US\$15,000,000 (equivalent to approximately HK\$116,250,000) and US\$30,000,000 (equivalent to approximately HK\$232,500,000), upon the Licensee achieving the first US\$100 million cumulative net sales, the next US\$500 million cumulative net sales above the first US\$100 million and every US\$1 billion above the first US\$600 million, respectively; and
- (ii) royalty fees based on the royalty fee rates of 6% to 10% of the annual net sales of the Licensed Product depending on the level of net sales of Licensed Product in the Territory. After 10 years from the first commercial launch of the Licensed Product in any of the four regions of the United States, Europe, Japan and the PRC, the royalty rates will be adjusted subject to mutual agreement of the parties but will be at a maximum of 3%.

(II) Development Costs Sharing

Subject to the terms of the Co-Development License Agreement, the Licensee has agreed to share the Development Costs in the aggregate amount of up to US\$30,000,000 (equivalent to approximately HK\$232,500,000) with the Licensor as to 80% by the Licensee (i.e. up to US\$24,000,000 (equivalent to approximately HK\$186,000,000) (“**Essex Funding**”)) and as to 20% by the Licensor. The Essex Funding shall be payable in accordance with the funding schedule agreed with reference to the achievement of the specified milestones.

If the Development Costs exceed the agreed amount as set out in the Co-Development License Agreement, the parties will further negotiate on the cost sharing arrangement in accordance with the terms of the Co-Development License Agreement. In such case, the Company will make further announcement(s) as and when appropriate pursuant to the requirements under the Listing Rules.

The aggregate amount of the signing payment, the regulatory milestone payments and the Essex Funding totalling of up to US\$49,000,000 (equivalent to approximately HK\$379,750,000), which will be financed by internal resources and/or other means depending on the prevailing market conditions, was determined after arm’s length negotiations by the parties on normal commercial terms based on, among others, the estimated research and development costs required of the Licensed Product.

Sub-license

In the event that the Licensee grants a sub-license to a third party for the commercialisation of the Licensed Product in the Territory in accordance with the terms of the Co-Development License Agreement, each of the Licensor and the Licensee will share the relevant sub-licensing revenues as to 20% and 80% respectively, provided that the Licensee may, by exercise of the Put Option, reduce the Licensee Sub-Licensing Percentage by 10% to 20% in consideration of the Buy Back Amount payable by the Licensor in accordance with the terms of the Co-Development License Agreement.

Based on the maximum amount of the Development Costs as currently agreed by the parties and assuming that the Licensee Sub-Licensing Percentage is to be reduced by 20%, the Buy Back Amount would be US\$10,500,000 (equivalent to approximately HK\$81,375,000).

The basis for calculating the Buy Back Amount was determined after arm’s length negotiations by the parties on normal commercial terms based on, among others, the Development Costs.

Term

The Co-Development License Agreement shall be effective from the Effective Date until it is terminated in accordance with its terms, subject always to certain provisions which will survive after termination.

REASONS FOR, AND BENEFITS OF, THE ENTERING INTO OF THE CO-DEVELOPMENT LICENSE AGREEMENT

The Group is principally engaged in the manufacturing, selling, marketing and distribution of biopharmaceutical products.

The Licensor is the holding company of a group principally engaged in (i) the research and development, production and sale of monoclonal antibody (mAb) drugs and the provision of related technical services (except for the development and application of human stem cells, genetic diagnosis and therapy technology); and (ii) the transfer of its own technology and provision of the related technology consultation services.

The Compound is currently a bevacizumab biosimilar candidate. While Bevacizumab has been approved as therapeutics for cancer treatment, it is used by doctors in off-label way for ophthalmic therapeutic application. The Licensed Product shall contain the Compound as an active pharmaceutical ingredient, which is intended for the treatment of exudative (wet) age-related macular degeneration (wAMD). The Directors are of the view that the Co-Development License Agreement presents a good opportunity for the parties to leverage on their respective strengths and resources to jointly pursue and accelerate the development of ophthalmic products for the global market.

The Directors consider that the terms of the Co-Development License Agreement are fair and reasonable and the transactions contemplated thereunder are in the interests of the Company and its shareholders as a whole.

LISTING RULES IMPLICATIONS

As the highest applicable percentage ratio (as defined in the Listing Rules) for each of (i) the transactions contemplated under the Co-Development License Agreement; and (ii) the transaction contemplated under the Put Option, exceeds 5% but is less than 25%, the entering into of the Co-Development License Agreement (including the Put Option) constitutes discloseable transactions for the Company under Chapter 14 of the Listing Rules and is accordingly subject to the notification and announcement requirements under Chapter 14 of the Listing Rules.

DEFINITIONS

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

“Board”	the board of Directors
“Buy Back Amount”	consideration (subject to the amount of the Development Costs and the percentage of the buy back) to be paid by the Licensor to the Licensee upon the exercise of the Put Option by the Licensee
“Clinical Trial Programme”	the development and the clinical trial programme of the Compound/ Licensed Product to be conducted in accordance with the terms of the Co-Development License Agreement
“Co-Development License Agreement”	the co-development and exclusive license agreement dated 15 October 2020, which has been entered into among Essex Bio-Investment, Zhuhai Essex and the Licensor
“Company”	Essex Bio-Technology Limited (億勝生物科技有限公司), a company incorporated in the Cayman Islands with limited liability, the shares of which are listed on the Stock Exchange
“Compound”	HLX04-o-wAMD, being the Licensor’s proprietary bevacizumab biosimilar
“Development Costs”	all the costs and expenses directly incurred by the Licensor in the performance of its development activities solely related to, and necessary for, the development of the Licensed Product under the Co-Development License Agreement, and in each case in respect of the Licensed Product, until marketing approval is obtained
“Director(s)”	director(s) of the Company

“Dossier”	the technical, medical and scientific submissions, applications, registrations, authorisations and approvals to and by any regulatory authority necessary for the development, regulatory development, manufacture, and/or commercialisation of the Licensed Product in the Field in the Territory, together with all related correspondence with any regulatory authority thereof and all documents referenced in the complete regulatory chronology
“Effective Date”	15 October 2020, being the date of the Co-Development License Agreement
“Essex Bio-Investment”	Essex Bio-Investment Limited, a company incorporated in the British Virgin Islands with limited liability and a wholly-owned subsidiary of the Company
“Europe”	national registers covered by the European Medicines Agency (and any successor agency or authority thereto) at the relevant time, any countries that may cease to be covered by the aforesaid agency after the Effective Date and the United Kingdom
“Field”	human ophthalmic therapeutic use and/or therapies only
“Group”	the Company and its subsidiaries
“Hong Kong”	the Hong Kong Special Administrative Region of the People’s Republic of China
“Licensed IP”	collectively, Licensor Intellectual Property and the Licensor Intellectual Property Rights, and any and all inventions and all patents and other intellectual property rights relating thereto controlled by Licensor and/or its affiliates, as more specifically set out in the Co-Development License Agreement
“Licensed Know-How”	all information that is (a) controlled by the Licensor and/or its affiliates as of the Effective Date or at any time during the term of the Co-Development License Agreement that is not generally known and not readily ascertainable by proper means; and (b) necessary for the development, regulatory development, manufacture, and/or commercialization of the Licensed Product in the Territory

“Licensed Product”	a pharmaceutical product in any form that contains at least the Compound as an active ingredient and that may also contain other active ingredients and/or inactive ingredients and/or adjuvants
“Licensee”	collectively, Essex Bio-Investment and Zhuhai Essex
“Licensee Sub-Licensing Percentage”	percentage of the sub-licensing revenue to be received by the Licensee
“Licensor”	Shanghai Henlius Biotech, Inc. (上海復宏漢霖生物技術股份有限公司), a company incorporated in the PRC, being the Licensor under the Co-Development License Agreement
“Licensor Intellectual Property”	(i) the Compound; (ii) the Licensed Product; (iii) the Licensed Know-How; (iv) any and all inventions as so specified in the Co-Development License Agreement; (v) any and all intellectual property created, conceived, invented, generated, and/or made on or after the Effective Date, during the term of the Co-Development License Agreement by, or on behalf of, the Licensor (and/or any of its affiliates) relating to, or in connection with, the foregoing; and (vi) any and all improvements to any of the foregoing
“Licensor Intellectual Property Rights”	any and all intellectual property rights controlled by the Licensor and/or its affiliates on or after the Effective Date which cover or arise from the Licensor Intellectual Property
“Listing Rules”	the Rules Governing the Listing of Securities on the Stock Exchange
“Phase 3 Clinical Trial”	with respect to the Licensed Product, a controlled (or a portion thereof) clinical trial, in humans of the efficacy and safety of a pharmaceutical product, which study is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a manner sufficient to file a drug approval application as described in the relevant Code of Federal Regulations of the United States and the foreign equivalent thereof
“PRC”	solely for the purpose of the Co-Development License Agreement and this announcement, the People’s Republic of China (excluding the Hong Kong Special Administrative Region, the Macao Special Administrative Region and Taiwan)

“Put Option”	subject to the satisfaction of the conditions that (i) Phase 3 Clinical Trial of the Licensed Product has been completed; and (ii) the Licensee has not granted or agreed to grant any sublicense in any country in the Territory, Licensee’s right to reduce the percentage of its share of the sub-licensing revenues under the Co-Development License Agreement by a percentage which is between 10% to 20% and thereby the percentage of the Licensor’s share of such sub-licensing revenues will be increased accordingly
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“Territory”	all over the world
“U.S.” or “United States”	the United States of America
“Zhuhai Essex”	珠海億勝生物製藥有限公司(Zhuhai Essex Bio-Pharmaceutical Company Limited*), a company incorporated in the PRC and an indirect wholly-owned subsidiary of the Company
“HK\$”	Hong Kong dollars, the lawful currency of Hong Kong
“US\$”	U.S. dollars, the lawful currency of the U.S.
“%”	per cent.

On behalf of the Board
Essex Bio-Technology Limited
Ngiam Mia Je Patrick
Chairman

Hong Kong, 15 October 2020

In this announcement, for the purpose of illustration only, amounts quoted in US\$ have been converted into HK\$ at the rate of US\$1.00 to HK\$7.75. Such exchange rate has been used, where applicable, for the purpose of illustration only and does not constitute a representation that any amounts were or may have been exchanged at this or any other rates or at all.

Executive directors of the Company as at the date of this announcement are Mr. Ngiam Mia Je Patrick, Mr. Fang Haizhou, Mr. Ngiam Hian Leng Malcolm and Ms. Yau Lai Man. Independent non-executive directors of the Company as at the date of this announcement are Mr. Fung Chi Ying, Mr. Mauffrey Benoit Jean Marie and Ms. Yeow Mee Mooi.

* For identification purpose only