【Press release】

ESSEX BIO-TECHNOLOGY LIMITED
億勝生物科技有限公司

(Stock code: 1061.HK)

Essex Bio-Technology Posts Sound 2023 Interim Financial Results

Revenue Up 37.1%, Profit Up 22%

Hong Kong, 16 Aug 2023

Essex Bio-Technology Ltd ("Essex" or the "Group", Stock Code: 1061.HK) today announced the interim results for the six months ended 30 June 2023 ("the period under review").

Financial Performance Returned to Pre-COVID-19 Operating Level

During the period under review, the Group achieved a consolidated revenue of approximately HK$899 million, with an increase of 37.1% as compared to the same period last year, indicating normalcy in business to the pre-COVID-19 operating level. The profit of the Group increased by 22.0% to approximately HK$170 million as compared to approximately HK$139.2 million for the same period last year.

As of 30 June 2023, the Group had cash and cash equivalents of approximately HK$506 million (31 December 2022: approximately HK$543 million). The Board is pleased to propose an interim dividend of HK$0.045 (For the six months ended 30 June 2022: HK$0.04) per ordinary share for the six months ended 30 June 2023.

Revenue Growth in Ophthalmology and Surgical Segments

The Group's revenue is primarily made up of the segments of Ophthalmology and Surgical (wound care and healing). For the six months ended 30 June 2023, the revenue of Ophthalmology increased by 41.6% to approximately HK$382 million, accounting for approximately 42.4% of the Group's revenue, while the revenue of Surgical up 34.0% to approximately HK$518 million, representing approximately 57.6% of the Group's revenue. The core products that are as current growth driver under each segment are:

1. Ophthalmology – Beifushu® series (Beifushu® eye drops, Beifushu® eye gel and Beifushu® unit-dose eye drops), Tobramycin Eye Drops, Levofloxacin Eye Drops, Sodium Hyaluronate Eye Drops and 適麗順® (Iodized Lecithin Capsules); and

2. Surgical (Wound care and healing) – Beifuji® series (Beifuji® spray, Beifuji® lyophilised powder and Beifuxin® gel), Carisolv® dental caries removal gel, 仔典醫生® (Dr. YaDian) mouth wash,伊血安顆粒 (Yi Xue An Granules) and PELNAC® collagen-based artificial dermis.

Significant Business Development Activities

The Group is committed to pragmatically investing in new products and technologies to strengthen the Group's product and research and development ("R&D") pipeline as near to mid-term growth driver in ophthalmology and long-term plan for new therapeutics in oncology. During the period under review, major investments in ophthalmic products that are currently in an advanced stage of clinical development are outlined as follows:

Re-establishing the VISTA programme after the acquisition of SkQ1's intellectual property rights

In order to provide the Group with flexibility and independence in the continuing development of the US FDA VISTA programme in the field of dry eye disease and to allow the Group to explore further the development of products for other ophthalmic indications, the Group successfully secured a patent assignment deed and a patent and know-how licence agreement relating to SkQ1 in the field of ophthalmology from Mitotech.

Following the acquisition of the intellectual property rights relating to SkQ1 on 13 October 2022, the Group's priority is to complete the transfer of chemistry, manufacturing and controls (CMC), know-how and intellectual property rights relating to SkQ1 from Mitotech. Concurrently, the Group is re-establishing the VISTA programme with regulators for mitigating any identifiable risks before continuing with the clinical trial. According to Frost & Sullivan, the estimated number of patients with moderate-to-severe dry eye disease was around 119.7 million in the PRC in 2020. It is expected that the size of the potential market of the SkQ1 product will be significant.

EB12-20145P (HLX04-O) global phase 3 clinical study makes significant progress

In 2020, the Group entered into a co-development and exclusive licence agreement with Shanghai Henlius Biotech, Inc. to co-develop a pharmaceutical product (EB12-20145P), a recombinant anti-vascular endothelial growth factor ("anti-VEGF") humanised monoclonal antibody injection for the treatment of exudative (wet) age-related macular degeneration ("wet-AMD"). As at the date of this announcement, the product has been approved to commence phase 3 clinical trials in Australia, the United States, Singapore, Russia, Serbia and European Union countries such as Hungary, Spain, Latvia, the Czech Republic and Poland. So far, the first patient has been dosed in a phase 3 clinical study for EB12-20145P for the treatment of wet-AMD in the PRC, Latvia,

Australia and the United States. Also, the phase 1/2 clinical study for EB12-20145P for the treatment of wet-AMD has shown its safety and tolerability and demonstrated preliminary efficacy.

In February 2023, the Group entered into an amendment agreement with Henlius to amend certain terms of the co-development and exclusive license agreement, which included payments for regulatory and commercial sales milestones and development costs in respect of the Anti-VEGF licensed product, details of which are in the announcement dated 22 February 2023 and the annual results announcement on 8 March 2023.

The Anti-VEGF Licensed Product can be used for treating wet-AMD, diabetic macular edema, macular edema caused by retinal vein occlusion and myopic choroidal neovascularisation. According to Frost & Sullivan, the estimated number of patients with these 4 categories of disease was around 15.8 million in the PRC in 2020. Assuming each patient applies 4 doses in the first year of treatment and 2 to 3 doses in subsequent years, it is expected that the size of the potential market of the Anti-VEGF licensed product will be significant.

Honors and Awards Obtained In 2023

Zhuhai Essex Bio-Pharmaceutical Company Limited (珠海億勝生物製藥有限公司), a wholly-owned subsidiary of the Group, has been recognised as one of the 2022 top 100 innovative companies in Zhuhai (2022 年珠海市創新百強企業創新綜合實力 100 強), and has also been recognised as one of the 2022 top 100 chemical pharmaceutical companies in the PRC (2022 年度 TOP100 中國化藥企業). The Group's Beifushu has been awarded as one of the Chinese reputable medicine brands in five consecutive years. This is a testament to the recognition by the industry for the efficacy and quality of our flagship biologic drug.

Market Development Entrenched Market Access Capability

The Group has been relentlessly investing in establishing and strengthening its market access capability. As at 30 June 2023, the Group maintains a network of 43 regional sales offices in the PRC with a total number of more than 1,200 sales and marketing representatives, covering more than 12,100 hospitals and medical providers, coupled with more than 2,100 pharmaceutical stores, which are widely located in the major cities, provinces and county cities in the PRC. Sales to lower-tier cities is supplemented by on-line platform for medical consultation and e-prescription, the on-line platform is further deployed for serving patients with chronic diseases.

The Group's expansion of its market access into Southeast Asian countries via its base in Singapore has been gaining good development traction since 2020.

Research and Development

During the period under review, the Group remains focused executing its 5-year (2021 to 2025) R&D's development plans. As at 30 June 2023, there are 16 R&D programmes in the pre-clinical to clinical stage, out of which the following 4 ophthalmology programmes are as mid-term growth drivers:

- **EB11-18136P:** SkQ1 eye drops, second phase 3 clinical trial (US FDA) (VISTA-2) topline data released on 24 February 2021
- **EB11-15120P:** Azithromycin eye drops, ongoing review by external key opinion leaders (National Medical Products Administration ("NMPA") in the PRC)
- **EB12-20145P:** Bevacizumab for wet age-related macular degeneration ("wet-AMD"), phase 3 clinical trial (US FDA, European Medicines Agency, Therapeutic Goods Administration and NMPA in the PRC)
- **EB11-21148P:** Cyclosporine eye drops, phase 2 clinical trial (NMPA in the PRC)

The Group holds a total of 73 patent certificates or authorisation letters, which include 52 invention patents (發明專利), 14 utility model patents (實用新型專利) and 7 design patents (外觀專利). The Group currently has diversified its R&D resources to multiple research sites in Zhuhai (PRC), Boston (United States), London (United Kingdom) and Singapore which support not only our pursuit of new therapeutics but also our recruitment of global talents.

Mr. Patrick Ngiam, Chairman of Essex, said, "With tenacity and strength, we are pleased to return our business performance to the pre-COVID-19 operating level. Barring any unforeseen circumstances, being resilient, relevant and growth ready, the Group is optimistic of delivering progressive results.

I would like to take this opportunity to express my sincere gratitude to all stakeholders, business associates and valued customers for the trust, support and cooperation accorded to us, and each and every member of the Group for their relentless efforts rendered in shaping the Group into being a progressive and promising pharmaceutical player."

~ End

About Essex (1061.HK)

Essex Bio-Technology Limited is a bio-pharmaceutical company that develops, manufactures and commercialises genetically engineered therapeutic b-bFGF (FGF-2), having six commercialised biologics marketed in China since 1998. Additionally, it has a portfolio of commercialised products of preservative-free unit-dose eye drops and 适丽顺®(Iodized Lecithin Capsules) etc.. The products of the Company are principally prescribed for the treatment of wounds healing and diseases in Ophthalmology and Dermatology, which are marketed and sold through approximately 12,100 hospitals and managed directly by its 43 regional sales offices in China. Leveraging on its in-house R&D platform in growth factor and antibody, the Company maintains a pipeline of projects in various clinical stages, covering a wide range of fields and indications.

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