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www.eirgenix.com

EirGenix Corporate Introduction

EirGenix, Inc. | 6589.TWO

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Disclaimer

Statements made in this material include forward-looking statements, which include, without limitation, statements about the issues, plans and expectations of EirGenix. Without limiting the foregoing, statements including the words "believes", "anticipates", "plans", "expects" and similar expressions are also forward-looking statements. Forward-looking statements reflect, among other things, management's plans and objectives for future operations, current views with respect to future events and future economic performances and projections of various financial items. These forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results to differ materially from those implied by such forward-looking statements.

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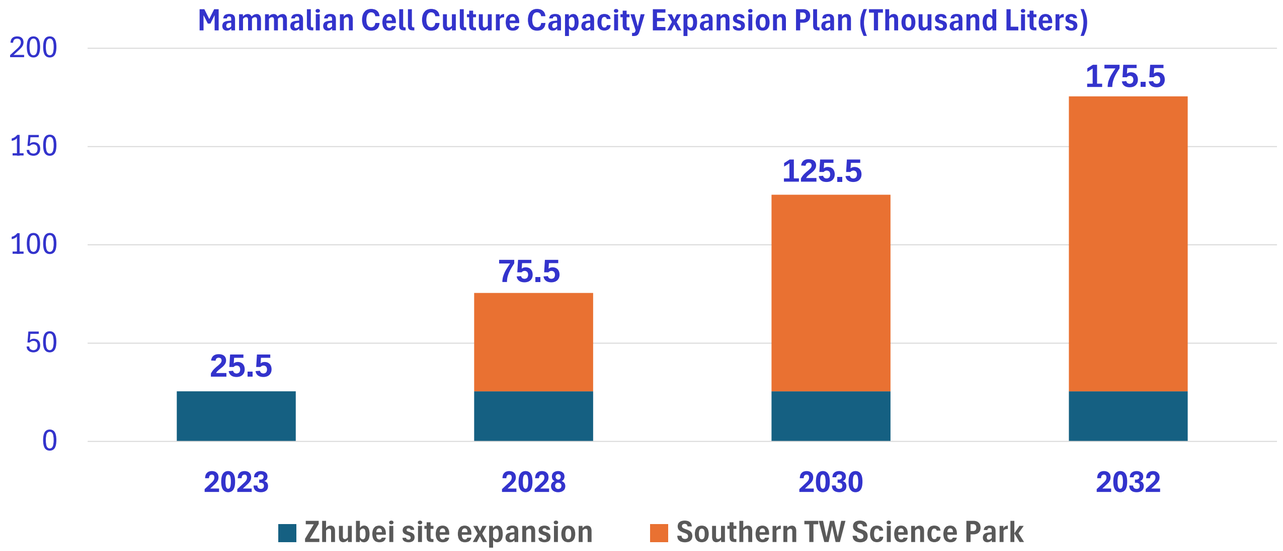
Capacity and Expansion Schedule

(Xizhi | Zhubei | Kaohsiung STSP)

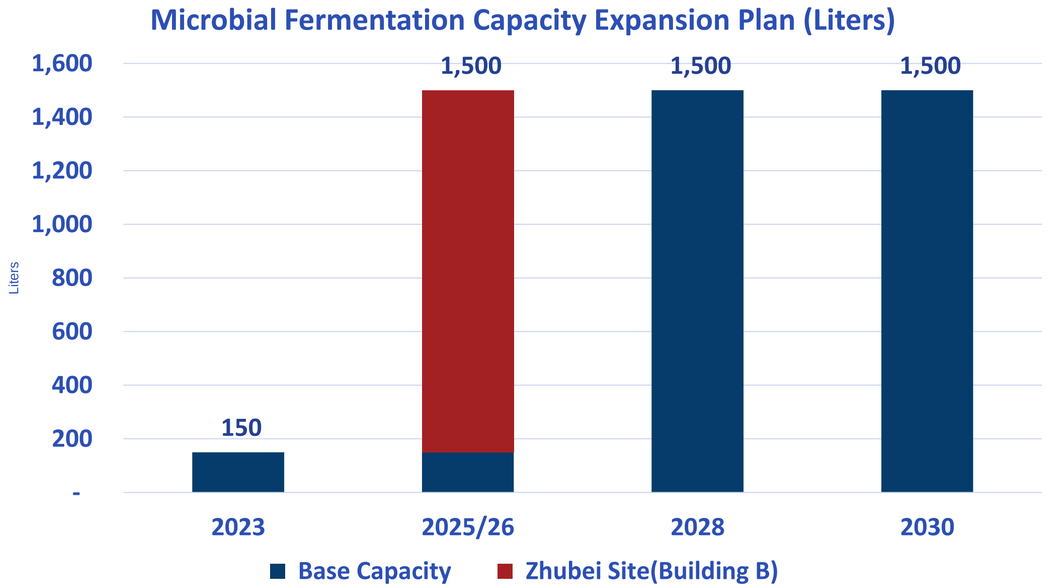
Mammalian Cell Culture Capacity – 2023 has reached 25,500 L



- 2019/Q1 The first large scale mammalian commercial production in the Zhubei facility on stream
- October of 2023, the 2nd mammalian cell culture production line to complete at Zhubei facility

  (Additional 3 sets of 2x2,000L). Totaled 25,500 L
- Southern Taiwan Science Park (STSP) – 150 KL very large-scale mammalian cell culture facility. Over three stages , 50 KL each in 2028, 2030, and 2032. Total mammalian capacity to reach 175 KL by 2032.

Microbial fermentation capacity – 150 L
(2026 to reach 1,500L)



- Expansion of Zhubei facility Building “B” for microbial fermentation capacity (350 + 1,000 L) with 2 downstream purification suites;
- Total microbial fermentation capacity to reach 1,500 L by 2026
- 6/21/2023 Groundbreaking Ceremony

Current Construction Status of Zhubei Commercial Production Plant

Microbial Production Line (Building B)

- **75 L, 500 L & 1,500 L** stainless-steel fermenters in USP*Note* facility 5F
- **Two purification suites** in DSP facility 3F
- Both purification suites can handle up to **1000 gm/lot** intracellular IB protein or **250 gm/lot** soluble products with 80 lots/year capacity.

Two Mammalian Cell Production Line (Building A)

- Two mirror-image production lines in 3F and 5F
- Each production line consists of one USP suite with **2x1,000L** SUBs (capable of N-1 perfusion) and **6x2,000L** SUBs; one DSP suite with hybrid of traditional LPC and TFF systems with SUMs which can handle up to **16 Kg** of harvested Mab/lot. Each production line can run up to 60 lots/year. With 3 sets of 2x2,000L SUBs, can produce up to **500~600 Kg** Mab /Year and **Total 1,000~1,200 kg** Mab/Year.

Note:
USP: upstream process
DSP: downstream process
LPC: low pressure chromatography
TFF: tangential flow filtration
SUBs: single use bioreactor
SUMs: single use mixing system

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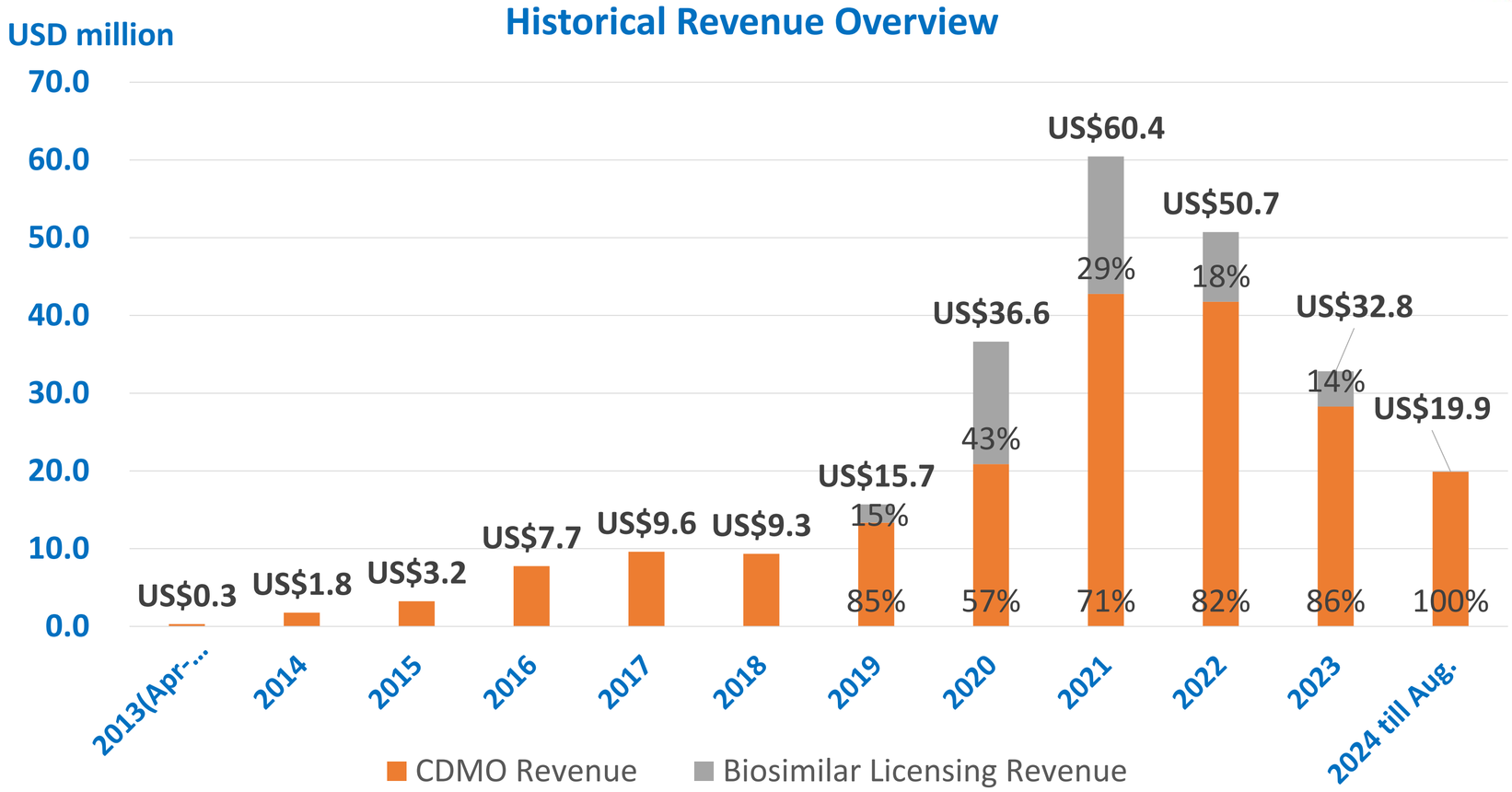
Revenue Breakdown

As of August 2024:

1. **Revenue has increased by 32.48% compared to the same period last year, in line with the expectations.**
2. **Production at the Xizhi will be intensive in the H2. Expected revenue will be steadily increasing.**



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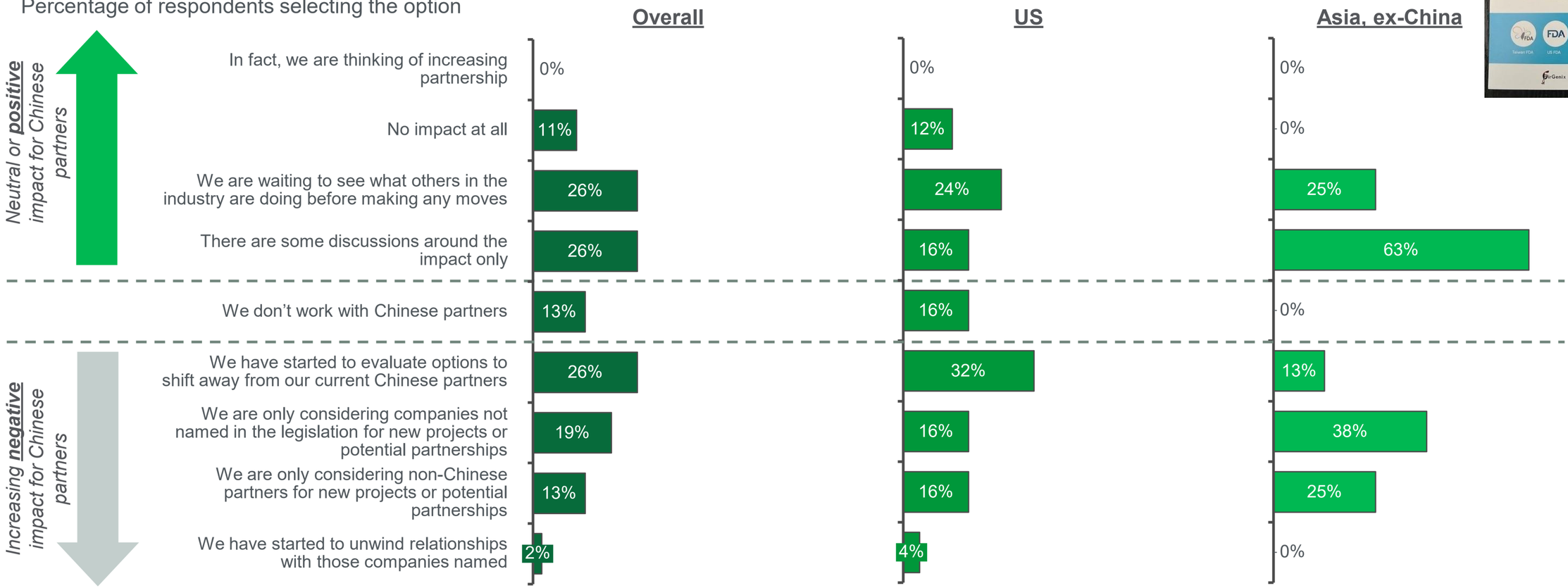
The Impact of the US Biosafety Act on CDMO Business

BIOSECURE Act impact on current operations*

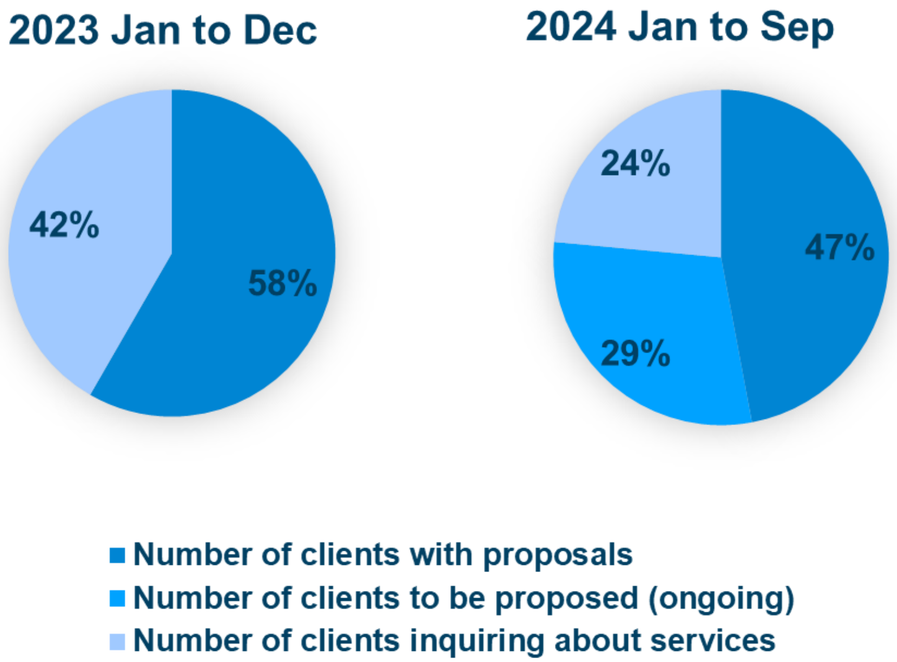
Percentage of respondents selecting the option



*Survey question: Has the BIOSECURE Act impacted your company's current operations? Select those which apply (Multi-select)
Source: L.E.K. 2024 Global Survey on Impact of US BIOSECURE Act

Growth of Potential Customers in the United States in 2024

New Client Growth 41.7%



Proposal Value Growth 108.1%

The First Product/ Trastuzumab Biosimilar EG12014

(EIRGASUN® - EirGenix ; HERWENDA® - Sandoz)

- 2023-Jan, EirGenix received US FDA’s Establishment Inspection Report (EIR), indicating Zhubei cGMP manufacturing facility has passed the FDA’s Pre-License Inspection (PLI).
- 2023-Apr, received the approval letter from TFDA that the API Trastuzumab has obtained the license and the DMF number.
- 2023-May, received the market approval letter from Taiwan Ministry of Health and Welfare.
- 2023-Sept, has been approved by Taiwan National Health Insurance Administration to be enrolled in the reimbursement system.
- 2023-Sept, received a positive CHMP opinion.
- 2023-Nov, received the Marketing Authorization approval letter from EC.
- Sandoz AG, licensing partner of EirGenix, Inc., has re-submitted the biosimilar drug EG12014 (Trastuzumab Biosimilar) 150 mg powder BLA to the US FDA in June 2024 and aim to receive approval in Dec 2024.
- EirGenix has completed three 420mg validation batches at Formosa Laboratories Injection Plant and is planning to submit 420mg package to TFDA and expecting to receive approval in 2025.
- Sandoz AG, licensing partner of EirGenix, Inc., will complete three 420mg validation batches this year at their Slovenia LJ facility, and submit 420mg package to FDA/EMA in 2025 and expecting to launch in 2026.
- According to Roche's annual report, the global sales of Herceptin totaled 1.63 billion CHF in 2023
- The global sales of trastuzumab biosimilar drugs have reached US$4.27 billion in 2023.

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The Second Product/ Pertuzumab Biosimilar - EG1206A

- The Phase 1 study of EG1206A (biosimilar of pertuzumab) has successfully demonstrated the pharmacokinetic bioequivalence of EG1206A with either Roche's Perjeta® either manufactured in the US or EU.
- At the same time, global licensing negotiation is actively on going.
- Have conducted two scientific advisory meetings with EMA and one Type II meeting with FDA prior to initiation of Phase III
- Schedule to have a FPI for the Phase III clinical study in the 1Q of 2025.
- Plan to complete three drug substance and drug product validation batches in 2025
- Target for market launch in 2027/2028 (aim for the first two biosimilar drug with global launch).
- According to Roche's 2023 annual financial report: the global annual sales of this product still reached 3.77 billion CHF, with an annual growth rate of 1%.

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Biosimilar Promotion Policy in Taiwan

1. Pilot program to encourage the use of biosimilar (2024.7.1 effective)

Plan a three-year incentive pilot program to increase the use and prescription of biosimilar in medical institutions.

Aim to increase the proportion of NHI reimbursed orders to 30% within 3 years (2023 7.38%；Trastuzumab 9.8%)

Prescription Incentives

- When prescribing the Biosimilar within the plan (EirGasun is included in the plan), 150 points will be paid each order by NHIA. This fee should be used to promote the related health care use of biosimilar.
- The feedback points for the hospital's drug fee balance are included in the target management point correction of the annual self-management plan can be 100% rewarded. The feedback plan is adapted reflected to individual conditions of each NHI district.

2. Preferential pricing and drug price adjustments for Taiwan Manufactured Drugs (In Plan)

Encourage biosimilar application which original manufacturers exceeding the patent within five years

- For the first two biosimilars manufactured in Taiwan, the NHIA price will be adjusted from 85% to 100% of drug price of reference drug.

Provide preferential drug prices for Taiwan manufactured drugs to stabilize drug supply

- For Taiwan manufactured drugs that use Taiwan manufactured APIs, an extra 10% will be added to the NHIA drug price (this also applies to drugs that have been reimbursed by NHIA)
- The NHIA of price after markup shall not be higher than drug price of originator, and the product with markup price items shall ensure stable supply.

Capital Investment and M&A

- After investing in Forward BioT Venture Capital in 2022, EirGenix has seen a significant opportunities in the relevant technology platform and CDMO business, also providing considerable support to the domestic biotechnology industry. In the near future, EirGenix will actively expand investment in the biotech industry and seek for cooperation with professional investment partners to further utilize its capital.

- EirGenix is also actively screening overseas M&A projects with the goal to expand our client base and networks, with target companies located in the United States and Europe.

End of the Presentation

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