June 2024

www.eirgenix.com

# EirGenix Corporate Introduction

## EirGenix, Inc. | 6589.TWO


EirGenix

# 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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# EirGenix's Profile

## Established Dec. 21, 2012

- 2013-March, Completed acquisition of DCB's Biopharmaceutical Pilot Facility
- 2019-June, IPO on Taiwan Stock Exchange (TPEx Board: 6589.TWO )

財團法人生物技術開發中心
Development Center for Biotechnology

## Back up by very strong and stable investors include

- Founder of Foxconn, Terry Gou (Yong-Ling Capital and FTC)
- Government and pan-government investment funds
- Formosa Laboratories (4746.TW), and other initial investors

## Affirmation on business performance

- Consistently ranked in the top 5% in corporate governance evaluations for three consecutive sessions (8th, 9th, and 10th sessions)
- Ranked among the top 10% in corporate governance evaluations in the non-financial electronics category with a market capitalization exceeding NT$10 billion for listed companies.

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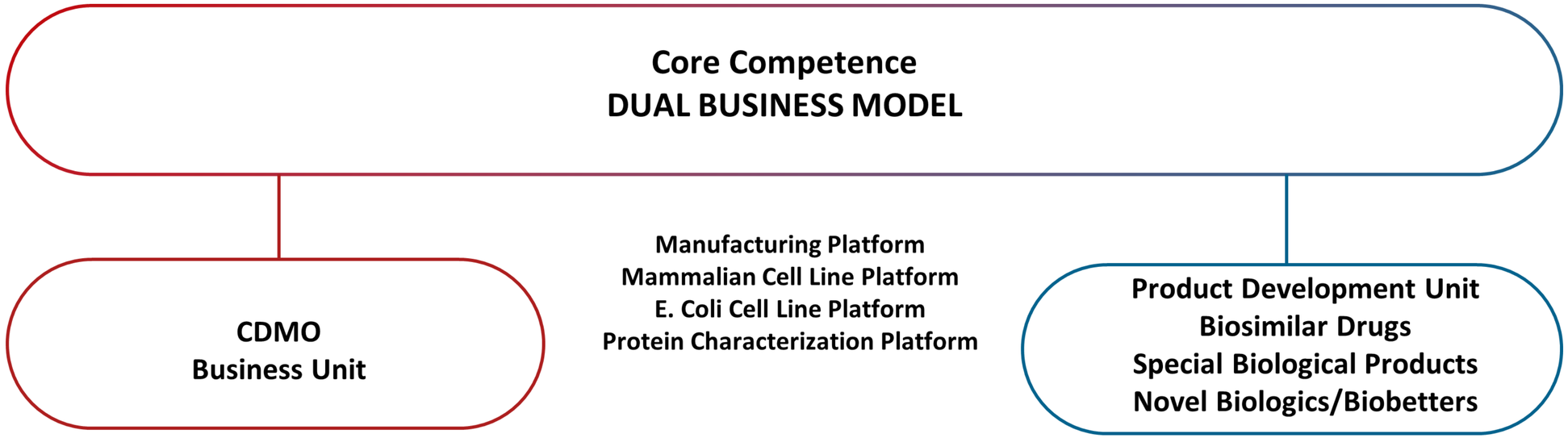
# Company Profile




*EirGenix is the largest CDMO service provider in Taiwan, both by* ***manufacture capacity*** *and* ***annual revenue.***

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# Company Profile

## Office, Facilities & Business Partners


In search of M&A opportunities in United States & Europe to expand CDMO global footprints

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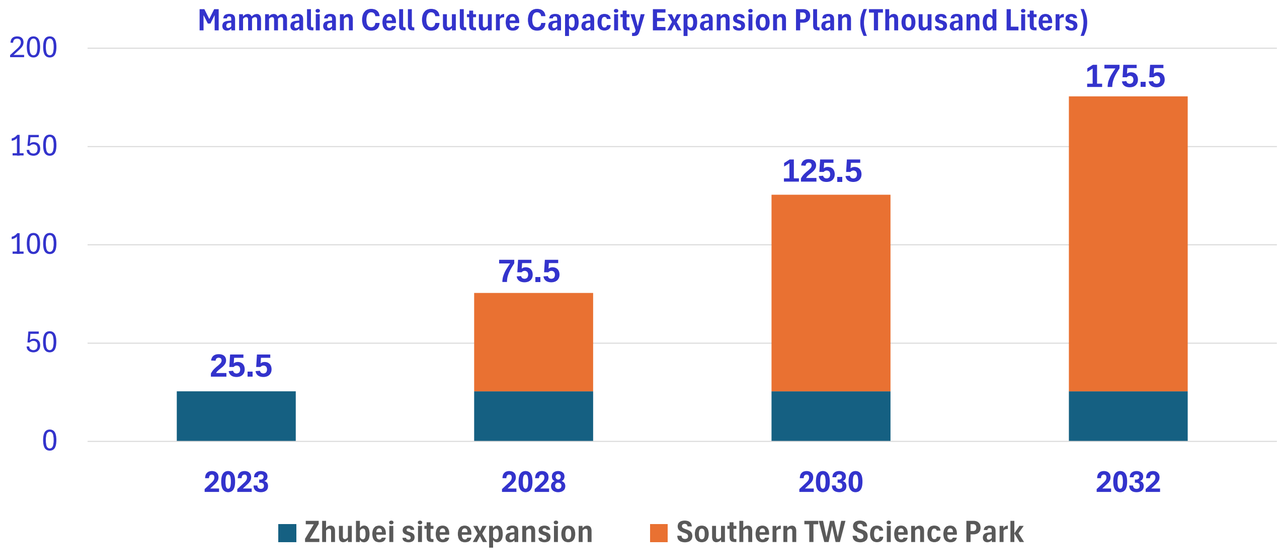
# Capacity and Expansion Schedule

**(Xizhi | Zhubei | Kaohsiung STSP)**

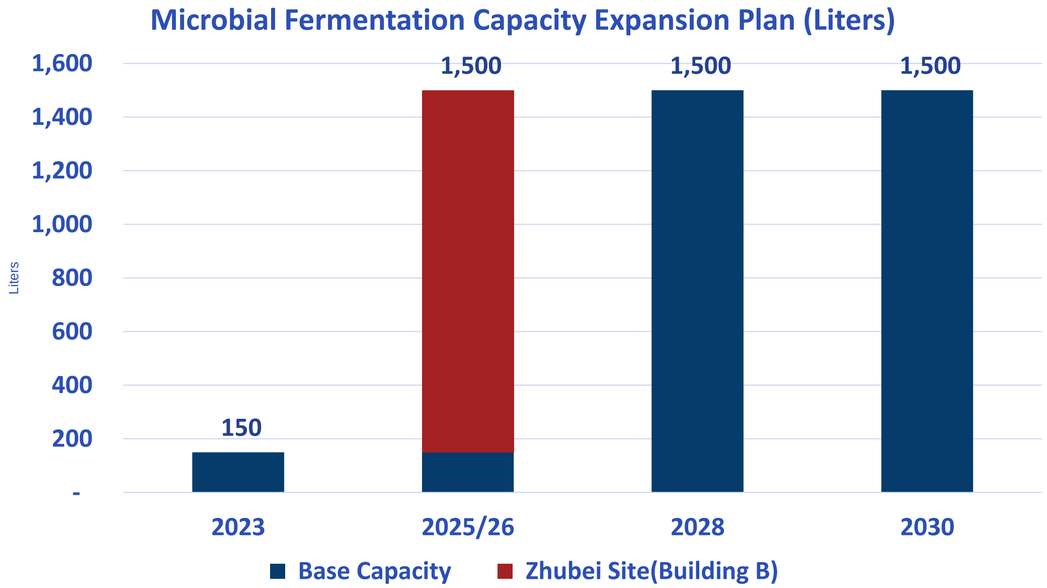
**Mammalian Cell Culture Capacity – 2023 has reached 25,500 L**




- 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)**

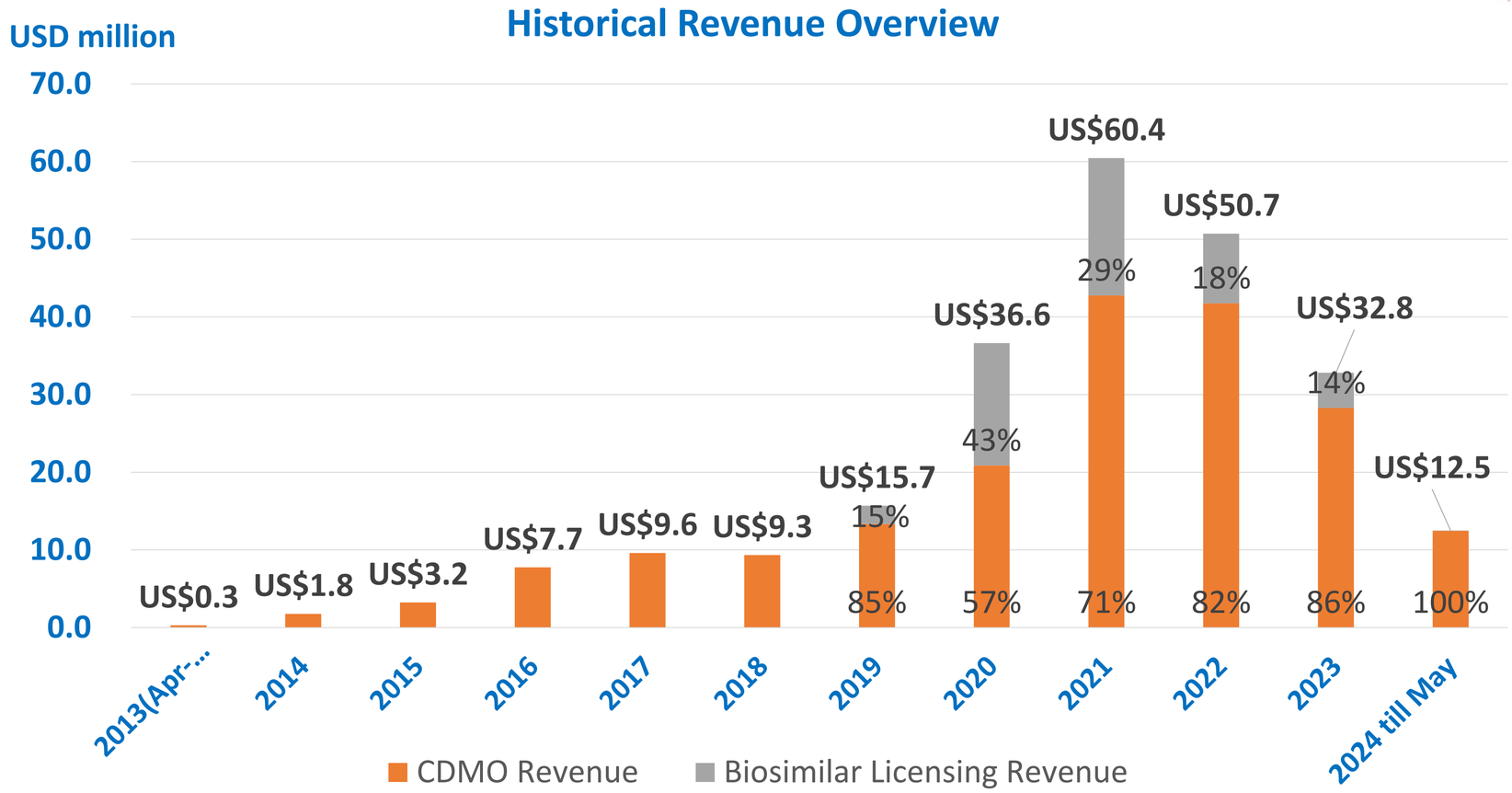



- Expansion of Zhubei facility Building “B” for microbial fermentation capacity (350 + 1,000 L) with 2 downstream purification suites;
- Total microbial fermentation capacity to reach 1,500 L by 2026
- 6/21/2023 Groundbreaking Ceremony

# Revenue Breakdown

**As of May 2024:**

1. **Revenue has increased by 34% 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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# Products in Development

## Pipeline Overview

### Biosimilars

Her 2 Family

- EG12014
- EG1206A
- EG12043 (TSY0110)

### New Formulations & Drug Delivery for Biosimilars

Her 2 SC

- EG7412X
- EG13084

### Specialty Biologics

Key biologics used for EG mfg platforms and B2B reagent sales

- EG74032 — CRM 197
- EG74091 — HRV 3C

- EG1211X
- EG1216X
- EGxxxxx
- EGxxxxx

New List to be:

1) **In-house developed**, or
2) **In-licensed**, or
3) **Potential IO biosimilars development alliance**

** Drug development alliance to reduce the high development cost & risks, also shorten market launch time.

# Quick Overview of Products in Development

## Pipeline Progress

| Product Code | Drug Class | Indication | Target | PROGRESS | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Pre-Clinical | Phase I | Phase II/III | MAA/BLA | Partner |
| **EG12014*** **(EIRGASUN®/HERWENDA®)** Trastuzumab Biosimilar | Monoclonal Antibody | Cancer | HER2 | → | → | → | → | SANDOZ |
| **EG1206A** Pertuzumab Biosimilar | Monoclonal Antibody | Cancer | HER2 | → | → | → | | Currently Confidential |
| **EG12043 (TSY0110)** Antibody Drug Conjugate | Antibody Drug Conjugate | Cancer | HER2 | → | → | | | FORMOSA PHARMACEUTICALS, INC. |
| **EG13084** TRZ+PTZ (SC formulation) | Monoclonal Antibody | Cancer | HER2 | → | | | | |
| **EG1211X** IO | Monoclonal Antibody | Cancer | PD-L1 | → | | | | |
| **EG1216X** Hemato-oncology | Monoclonal Antibody | Cancer | CD38 | → | | | | |
| **EG7412X** Recombinant Protein | Enzyme | N/A | Not disclose | → | | | | |
| **Specialty Biologics** | | | | | | | | |
| **EG74032** CRM197 Carrier Protein | Carrier Protein for Vaccine Conjugates | N/A | Infectious/ cancer | B to B | | | | |
| **EG74093** HRV 3C | HRV3C Enzyme | Clevage Enzyme | His-Tag | B to B | | | | |



***EG12014 has received approval letter from EC and TFDA as well as obtained the Taiwan Health Insurance Agency's benefit qualification**

# 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 Slovakia 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 4Q of 2024.
- 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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# EG12014/ EG1206A Marketing Plan for ASEAN, Japan & China

- Through existing partnership, networking, conferences, and target market analysis , EirGenix has been discussing and negotiating with multiple potential partners.
- For ASEAN countries and Korea, EirGenix is in late-stage discussions on business terms with MS company for EG12014 and EG1206A.
- EirGenix is having initial business discussions with a few partners on EG12014, EG1206A and other biosimilars for Japan and China markets.

# Co-Development Partner Project :
# Kadcyla Biosimilar - EG12043 (TSY-0110)

- 2022-Mar, EirGenix and Formosa Pharmaceuticals establish a co-development alliance to develop EG12043 / TSY-0110 (Ado-Trastuzumab Emtansine Biosimilar) for HER2-Positive Breast Cancer. EG12043 (TSY-0110) is a biosimilar of Antibody-Drug Conjugate (ADC), ado-trastuzumab emtansine (Kadcyla®).
- EG12043 (TSY-0110) aims to be the first-launched biosimilar of Kadcyla.
- Completed the EMA SAWP and FDA consultation meetings for IND filing and phase 1 clinical designs.
- Plan to submit the IND application in 2024.
- According to Roche's 2023 annual financial report, the global annual sales of this product reached 1.97 billion CHF, with an annual growth rate of 4%.
- According to the 2024 Research and Markets report, the global ADC (Anti-Drug Conjugate) market will be approximately US$8.8 billion in 2023 and is expected to reach US$10.7 billion in 2024. It will even reach US$24.8 billion by 2028 with a compound annual growth rate of 23.4%.

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# Product Development and Technology Platform

- **Actively developing a subcutaneous injection platform.**
- **Additional new compounds to begin development, under the Immuno-Oncology Biosimilar Development Alliance.**
- **EirGenix is actively optimizing the existing plasmid DNA technology platform for use for production of viral vectors.**

***Plasmid DNA is a circular DNA molecule commonly used as a vector in genetic engineering research, and can be used in gene expression, protein production, gene therapy, and vaccine development. As the demand for pDNA as a vector increases with the development of gene therapy and vaccine research, the global gene therapy market is expected to grow from around $8 billion in 2021 to approximately $19 billion in 2026, according to market research firms. In addition, as the biopharmaceutical market continues to expand, the application of pDNA in the production of biologics will also be further expanded, leading to increased market demand.**



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# 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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