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EirGenix, Inc. | 6589.TWO

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EirGenix

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EirGenix

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

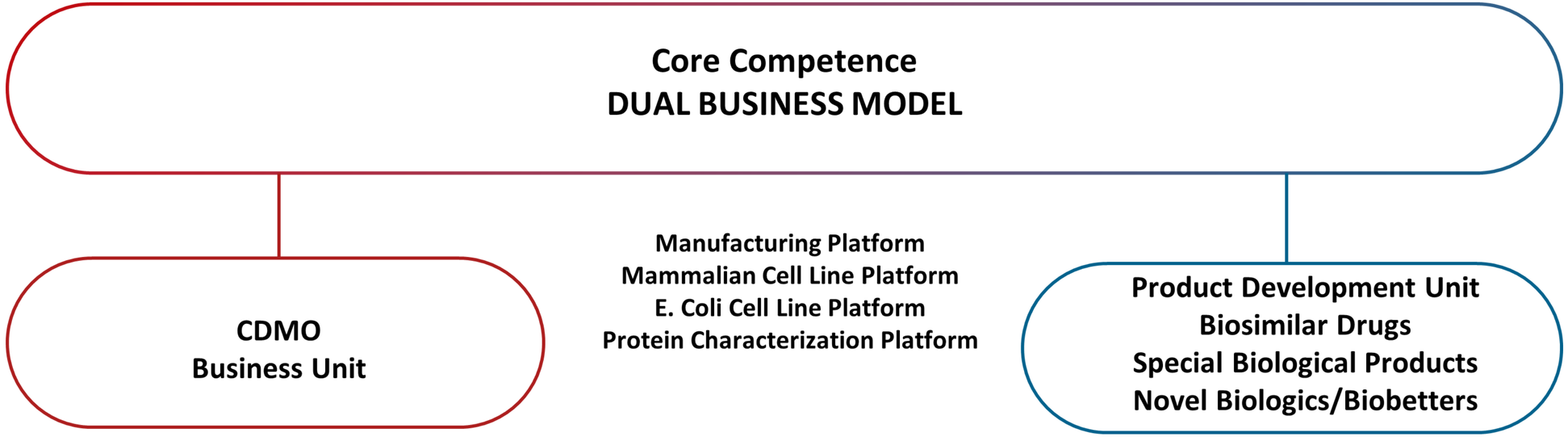
- **Founder of Foxconn, Terry Gou (Yong-Ling Capital and FTC)**
- **Government and pan-government investment funds**
- **Formosa Laboratories (4746.TW), and other initial investors**

Affirmation on business performance

- **Top 5% among TPEx-listed companies in the 8th and 9th Corporate Governance Evaluation.**

EirGenix

Company Profile



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

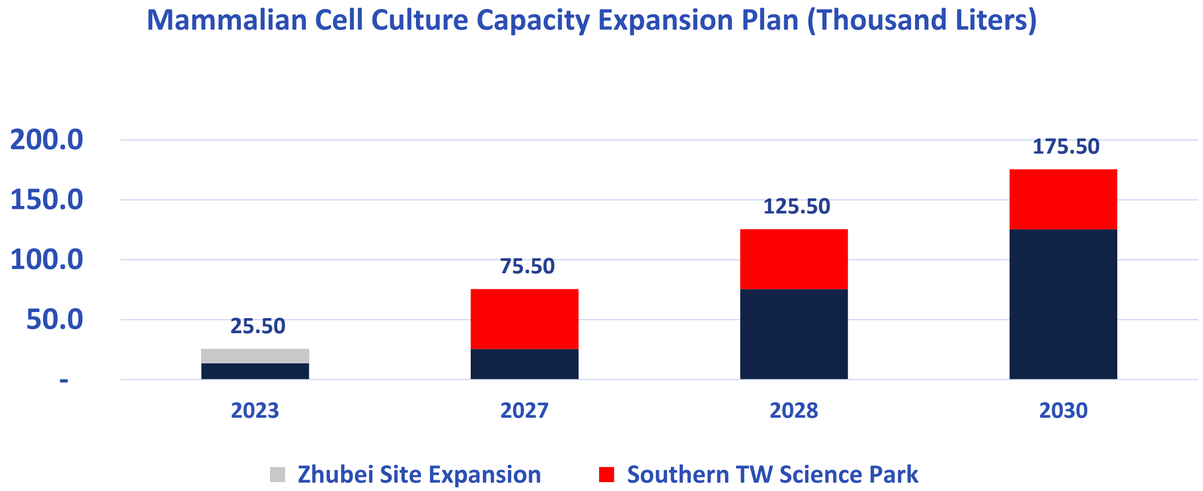
Company Profile

Office, Facilities & Business Partners

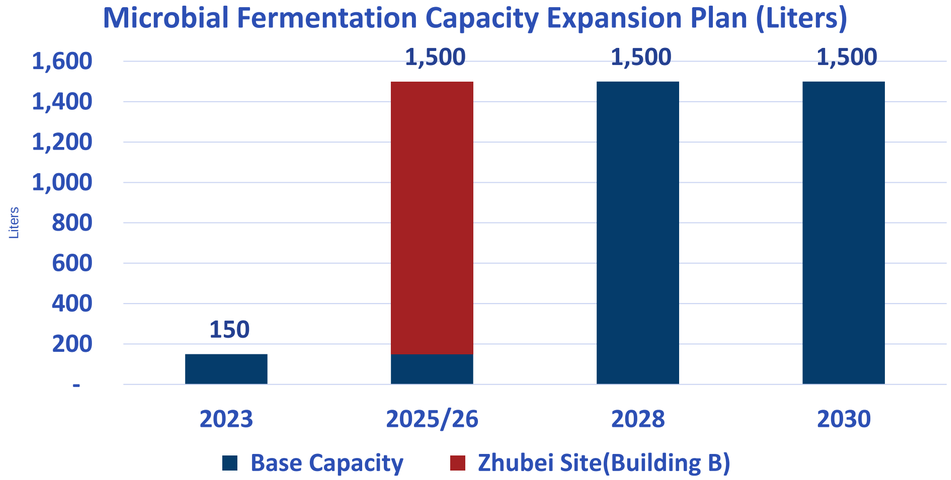
Capacity and Expansion Schedule

(Xizhi | Zhubei | Kaohsiung STSP)

Mammalian Cell Culture Capacity 13,500 L
(2023 to reach 25,500 L)



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



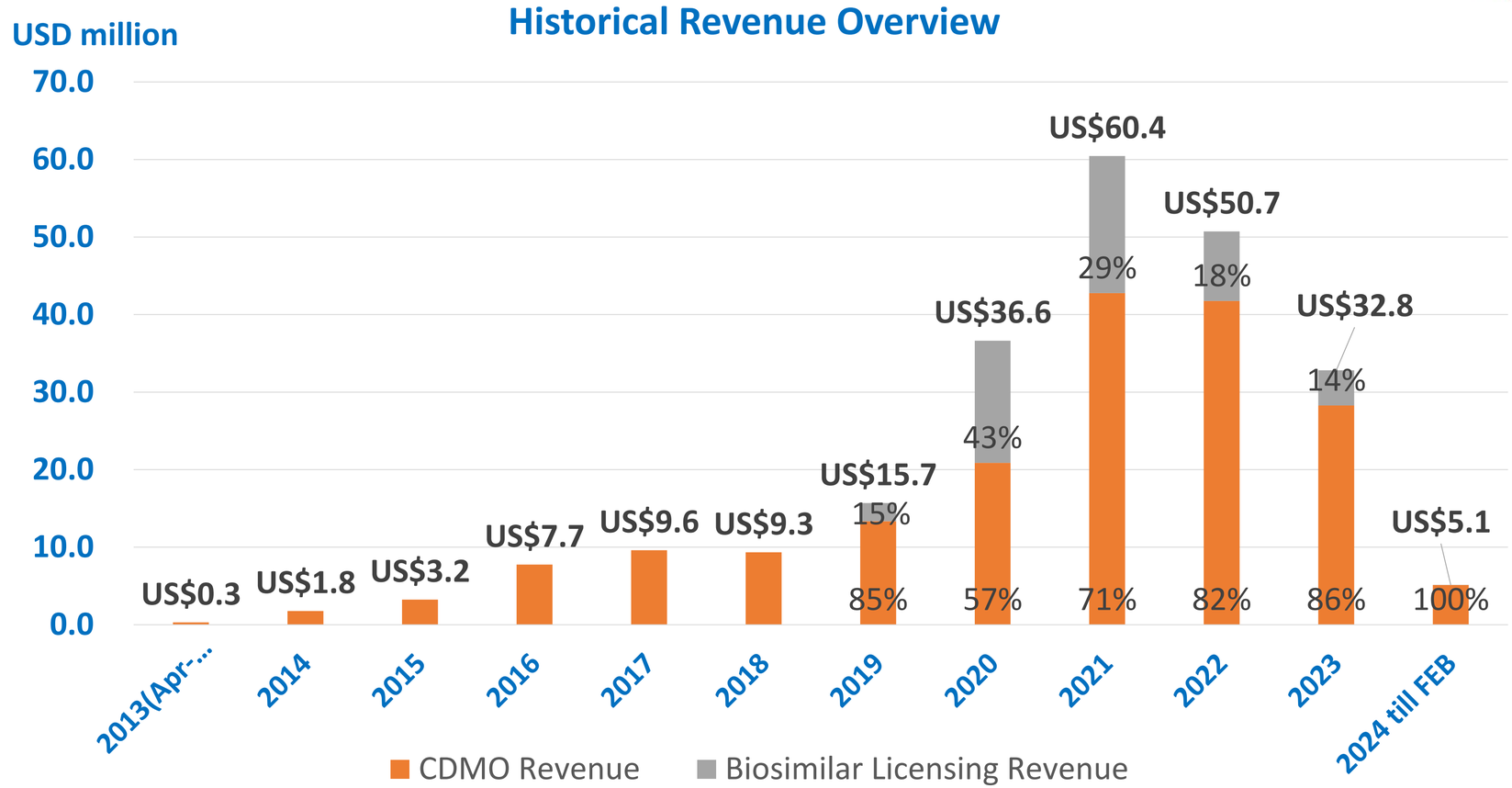
- **2019/Q1 The first large scale mammalian commercial production in the Zhubei facility on stream**
- **October of 2023, the 2nd mammalian cell culture production line to complete at Zhubei facility**

  (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 2027, 2029, and 2031. Total mammalian capacity to reach 175 KL by 2030.**

- **Expansion of Zhubei facility Building "B" for microbial fermentation capacity (350 + 1,000 L) with 2-3 downstream purification suites;**
- **Total microbial fermentation capacity to reach 1,500 L by 20226**
- **6/21/2023 Groundbreaking Ceremony**

Revenue Breakdown

- Last year, due to (1) cancellations of orders for COVID-19 vaccine production and (2) delays in development projects by some manufacturers due to financial reasons, revenue declined in the first three quarters of 2023. However, in the fourth quarter, operations returned to normal scheduling.
- It is estimated that the utilization rate of production lines at the Xizhi factory this year will increase compared to last year, especially for the microbiology plant, which is expected to reach over 80% utilization. It is projected that the Xizhi production lines will produce more than 20 batches throughout the year.
- The 5th floor production line in Zhubei completed its verification in the fourth quarter of last year and immediately commenced production. This year, negotiations are underway with large-scale production clients, and it is expected that production plans utilizing 2,000 L plus capacities for these clients will gradually increase.



Products in Development

Pipeline Overview

Biosimilars

Her 2 Family

- EG12014
- EG1206A
- EG12043 (TSY0110)

New Formulations & Drug Delivery for Biosimilars

Her 2 Family SC route

- EG13074
- EG13084

Specialty Biologics

Key biologics used for EG mfg platforms and B2B reagent sales

- EG74032 — CRM 197
- EG74091 — HRV 3C

Me-too/Novel (NCE)

- BDC-1001
- Bolt Biotheraptics Immune Stimulating Antibody Conjugate (ISAC) - collaboration

- 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.**

EirGenix expect to launch a new drug product **each or every other year** after 2026, hence the large-scale commercial production capability (Kaohsiung - Southern TW Science Park site) becomes very critical.

Quick Overview of Products in Development

Pipeline Progress

Product Code	Drug Class	Indication	Target	PROGRESS				Partner
				Pre-Clinical	Phase I	Phase II/III	MAA/BLA	
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.
EG13074 TRZ (SC formulation)	Monoclonal Antibody	Cancer	HER2	→				
EG13084 TRZ+PTZ (SC formulation)	Monoclonal Antibody	Cancer	HER2	→				
EG1211X IO	Monoclonal Antibody	Cancer	PD-L1	→				
EG1216X Hemato-oncology	Monoclonal Antibody	Cancer	CD38	→				
Specialty Biologics								
EG74032 CRM197 Carrier Protein	Carrier Protein for Vaccine Conjugates	N/A	Infectious/ cancer					
EG74093 HRV 3C	HRV3C Enzyme	Clevage Enzyme	His-Tag					

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, we expected to receive the approval from EMA in the 4Q of this year.
- 2023-Nov, received the Marketing Authorization approval letter from EC.
- We had a meeting with FDA in June to discuss the resubmission after we received the CRL on December 14, 2022. Basically, most of the remediations done by our fill/finish subcontractor met the requirements, however, FDA requested us to complete three reverification batches before the resubmission. We have completed three reverification batches run and working with Sandoz to finalize the document for submission. It is expected that the approval from FDA will be in the 4Q of 2024.

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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.**
- **Schedule to have a FPI for the Phase III clinical study in the 4Q of 2024.**
- **Targeting for market launch in 2027 (aim for the first two biosimilar drug with global launch).**

Manufacturing And 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.
- We completed the EMA SAWP and FDA consultation meetings for IND filing and phase 1 clinical designs.
- We plan to initiate the Phase 1 clinical trial in 2024.

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

Q & A

EirGenix