Apr 2026

www.eirgenix.com

EirGenix Corporate Introduction

EirGenix, Inc. | TWSE:6589

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

- ❑ Q1 Revenue Performance
- ❑ Pipeline Updates (EG12014 and EG1206A)
- ❑ Reassessment and Redefinition of Our Business Model
- ❑ Expansion into New CDMO Opportunities
- ❑ Continued Expansion of the Biosimilar Pipeline

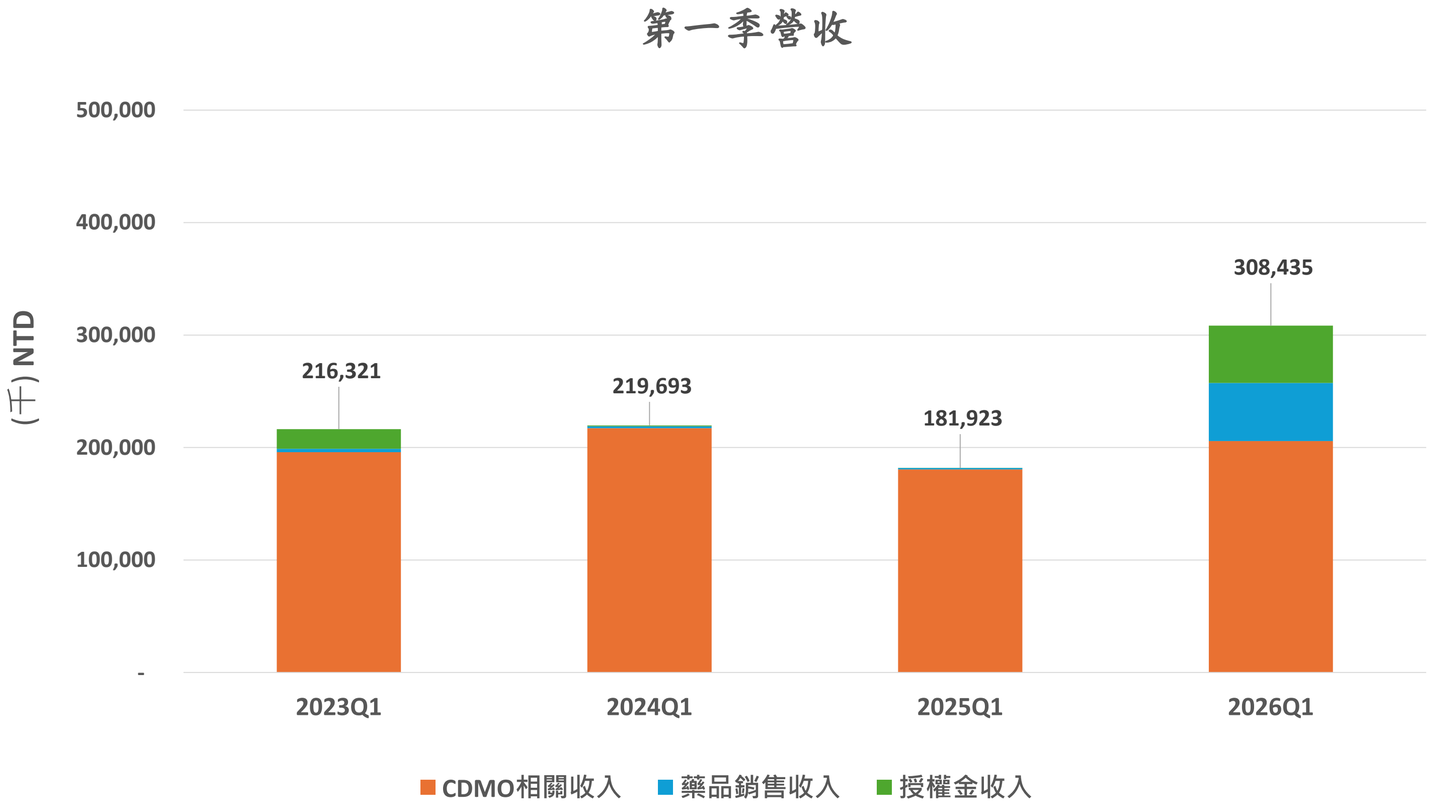
Q1 Revenue Overview and Breakdown

As of Q1 2026：

1. Revenue increased by 42.6%, 40.4%, and 69.5% year-over-year in 2023, 2024, and 2025, respectively. The main reason for the increase was the growth in pharmaceutical drug sales and licensing revenue recognition.

2. CDMO-related revenue grew by 14% year-over-year in 2025, indicating a gradually warming market and an increase in executed projects.

3. In addition to an increase in early-stage development projects (such as Enabling INDs) this year, we anticipate executing four projects preparing for BLA/NDA submissions or product launches. These stable and relatively large projects will significantly contribute to this year's revenue.



營收概況及分布

The First Product/ Trastuzumab Biosimilar EG12014

(EIRGASUN® - EirGenix)

- 2023-May, received the market approval letter from Taiwan Ministry of Health and Welfare for EIRGASUN 150 mg lyophilized injection
- 2023-Oct, EIRGASUN 150 mg lyophilized injection has been approved by Taiwan National Health Insurance Administration to be enrolled in the reimbursement system.
- 2025-Oct, received the market approval letter from Taiwan Ministry of Health and Welfare for EIRGASUN 420 mg lyophilized injection
- 2026-Apr, post-approval change approved for EIRGASUN 150 mg lyophilized injection, designating Formosa as the DP (drug product) fill-finish site.
- EIRGASUN 150 mg has been adopted across Taiwan's four major medical center systems, as well as regional, district, and government-affiliated hospitals. The number of treated patients continues to grow, strengthening supply resilience for breast cancer treatment in Taiwan.

(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-Nov, received the Marketing Authorization approval letter from EC.
- 2025-Jun, after receiving two CRLs related to the originally contracted fill-finish partners, EirGenix has adjusted its manufacturing strategy, transitioning to Sandoz's fill-finish site for FDA resubmission.
- 2025-Dec, received complete response letter (CRL) from US FDA
- 2025-Sep, Sandoz received EMA approval for a change in the fill-finish site of Herwenda® 150 mg to Sandoz's facility.
- 2026-Mar, Sandoz officially launched Herwenda® 150 mg in Slovakia, with plans to expand into additional markets.
- 2026-Apr 24th, Submitted a variation application to the EMA for the 420 mg vial strength.
- EirGenix is working closely with Sandoz to proactively address FDA inspection observations and required remediation areas, including data supplementation and facility enhancements, in order to fully meet regulatory expectations. The resubmission of the application is targeted for the second half of 2026.

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Expanded Value of EG12014

- We are developing EG12043 (trastuzumab emtansine) ADC, utilizing EG12014 as the drug substance (DS) for conjugation
- EG13084 (Phesgo-like®) is a subcutaneous combination product of EG12014 and EG1206A
- Providing drug substance (DS) for new drug conjugate modalities,e.g., radiopharmaceuticals

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The Second Product/ Pertuzumab Biosimilar - EG1206A

- May 2023: 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.
- Q1 2025: Initiation of Phase III clinical studies
  - Phase III clinical trial applications approved: US, Taiwan, Georgia, Argentina, Kazakhstan, Mexico, Turkey, and Thailand.
- April 2025: Received an invitation from the US FDA to discuss whether a waiver or reduction of the Phase III clinical trial (Comparative Clinical Study) is feasible.
  - June 19, 2025 (US Time): Submitted a briefing book to FDA for seeking a Type 2a meeting concerning a Phase III clinical trial waiver.
  - May 23, 2025: Submitted a briefing book to the EMA for a consultation meeting regarding a Phase III clinical trial waiver.
- Aug 22, 2025: Received EMA SAWP feedback supporting the potential to waive or streamline Phase III clinical trials. Sep 18, 2025 Following a formal meeting with the U.S. FDA, confirmation was received that Phase III trial for EG1206A can be waived. Based on regulatory feedback from both the FDA and EMA, along with further analysis of immunogenicity data, EirGenix decided to terminate the Phase III trial for EG1206A, with no additional clinical studies required. Preparation for BLA and MAA submissions has been initiated.
- Nov 12, 2025: EirGenix entered into a global licensing agreement with Sandoz for EG1206A (excluding Taiwan, China, Japan, Korea, and certain ASEAN countries), which includes upfront and milestone payments totaling USD 152 million, as well as entitlement to double-digit royalties on future sales.
- EGirGenix/Sandoz reached the settlement with Roch and Genentech for the EG1206A launch date in the US and EU
- Completed three validation batches for both drug substance (DS) and drug product (DP) in 2025/2026.
- According to Roche's 2025 annual financial report: the global annual sales of this product still reached 2.96billion CHF.

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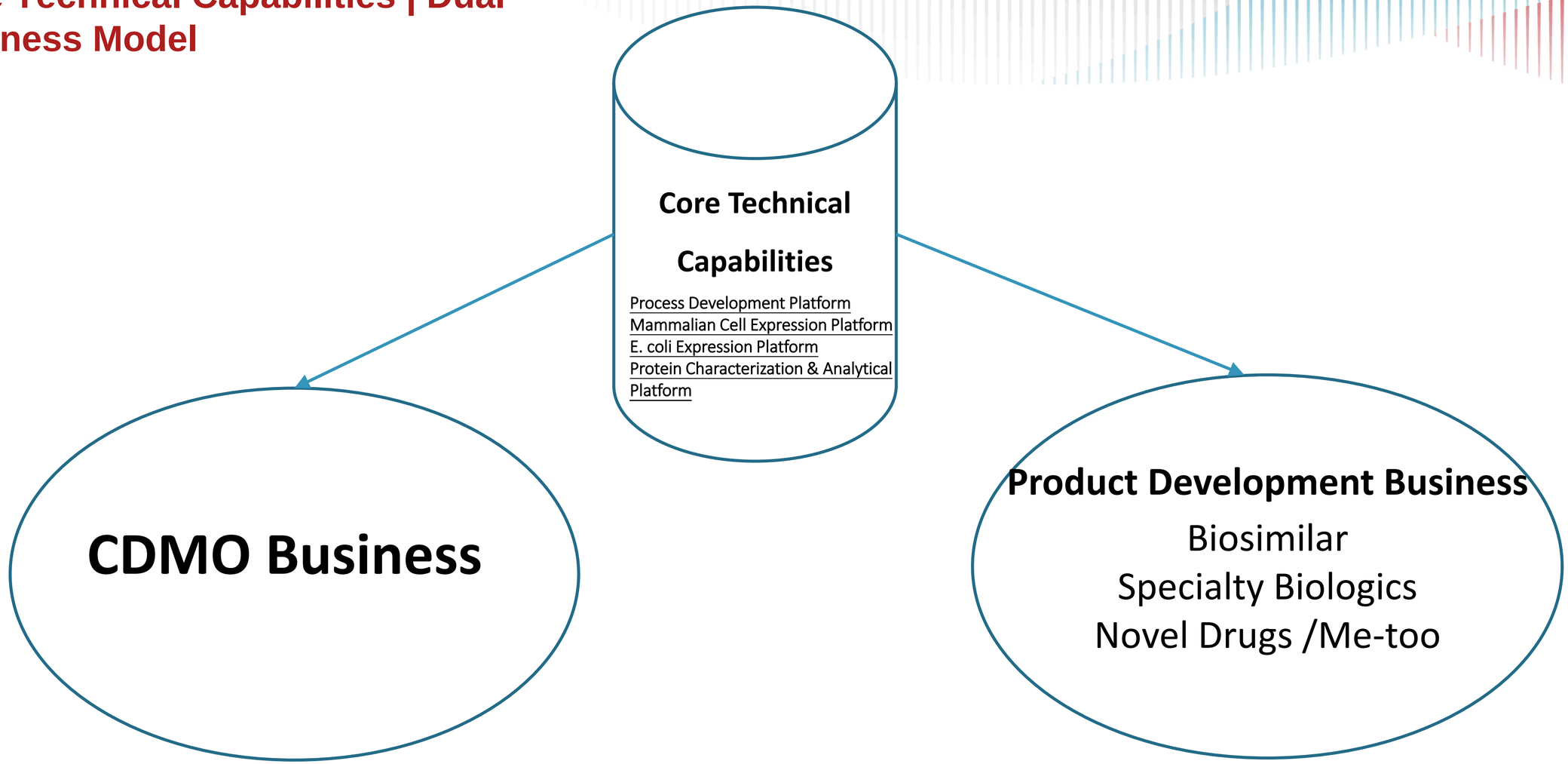
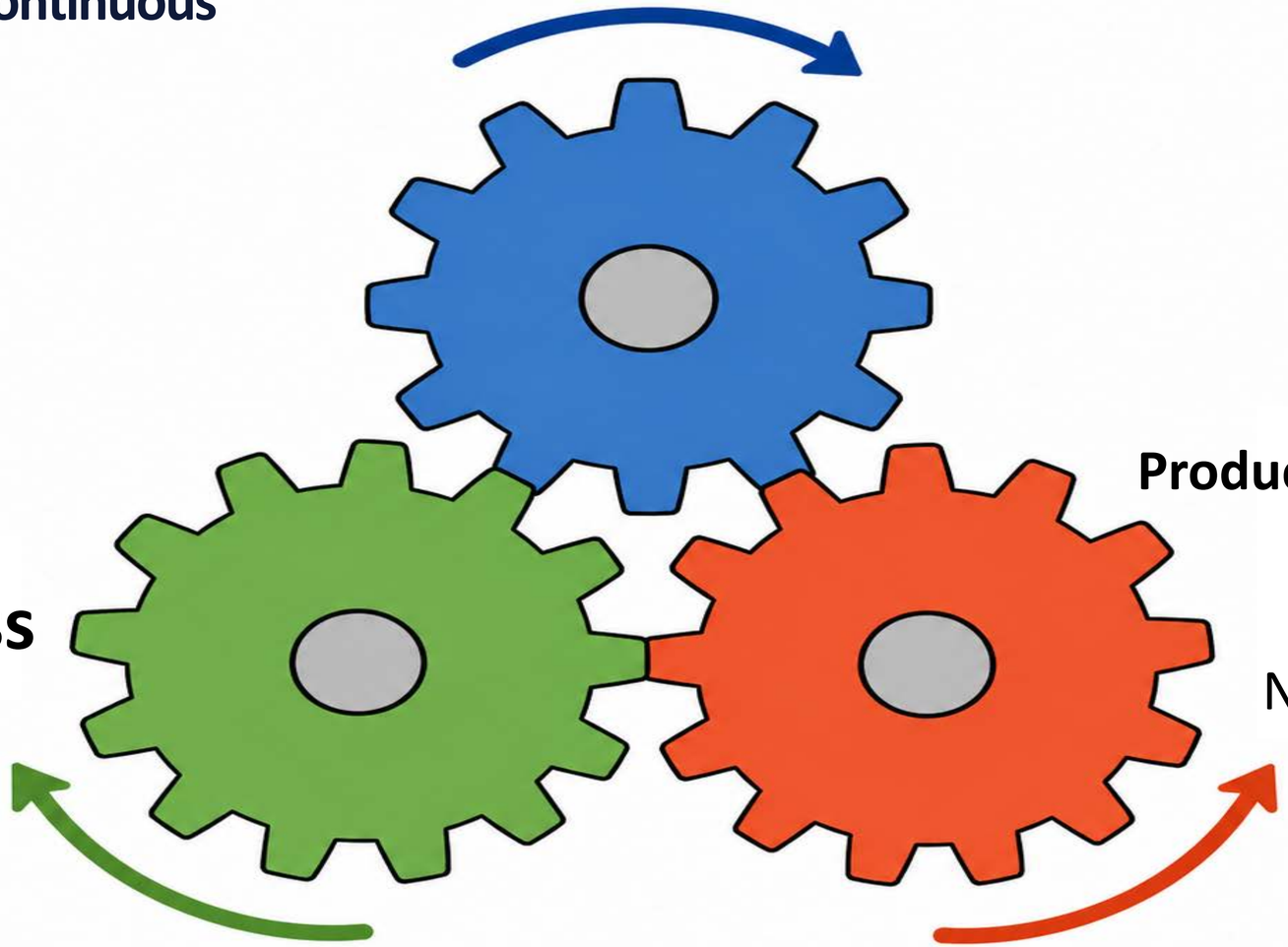
Core Technical Capabilities | Dual Business Model



Advanced capabilities unlock new markets, and market demand drives continuous innovation.

Advanced Technical Capabilities



CDMO Business

Product Development Business

Biosimilar
Specialty Biologics
Novel Drugs /Me-too

Advanced Technical Capabilities

台康細胞株技術平台

1. Platform Technology

Proprietary and Robust Technology Ensuring Quality and Productivity

- **Proprietary CHO Platform** — High stability, robust growth And high productivity
- **Premium Vector Design & & Codon Optimization** — Enhanced expression and Transcription efficiency
- **Robust Clone Selection Strategy** — Muti-parameter screening for quality-driven clone selection
- **Proven Scalability** — Scalable from shake flask to GMP manufacturing

2. Capacity

Strong Capacity and Track Record Driving Efficient Development

- **~4-6** Months to Lead Clone
- **>6** Projects/year Development capacity
- **>5g/L** Titer (fed-batch) Typical performance
- **>90%** Success Rate Meet the quality attributes

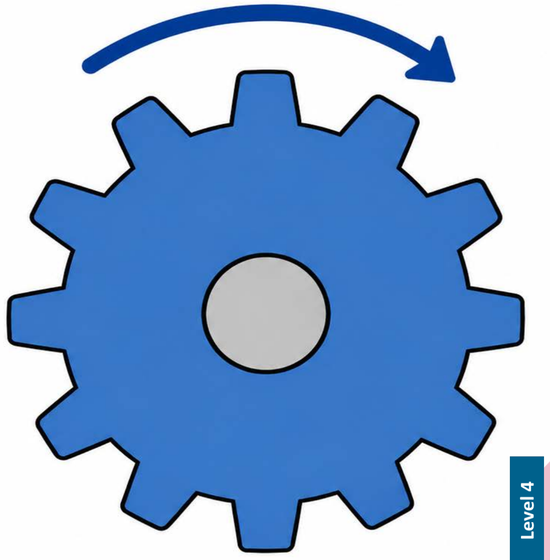
End-to-End Cell Line Development: Gene Design → Vector Construction → Cell Transfection & Screening → Lead Clone Selection → RCB / WCB Establishment

3. Differentiation & Value

Delivery Value Through Speed, Quality and Flexibility

- **Accelerate Development timeline** — Faster development timeline vs.. Industry standard
- **Consistent Product Quality** — Tight control on glycan, charge variants and other critical quality attributes
- **Flexible for Complex Modalities** — Proven experience with bispecific antibodies, ADCs and multi-specifics
- **Integrated with Downstream & CMC** — Seamless integration to ensure smooth tech transfer and scale-up
- **Proven Track Record** — Multiple IND and commercial programs advanced

Enabling rapid and reliable biologics development with consistent quality and scalable manufacturing readiness.



台康皮下注射劑型技術
HyaGenix™ rHuPH20 Technology Derived SC Product

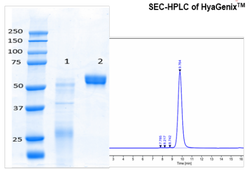
Empowering Next-Generation Subcutaneous Drug Delivery

(1)Proprietary mAb high conc. UF/DF technology
先進單株抗體濃縮及賦形劑輔助技術
-mAb concentration ≥150 mg/mL but retains its quality

(2) EG's rhuPH20 with exceptional high purity, and a lower risk of immunogenicity and allergic reactions
台康自行開發具高純度及低免疫反應的重組透明質酸酶
-Assist in increasing the penetration ability

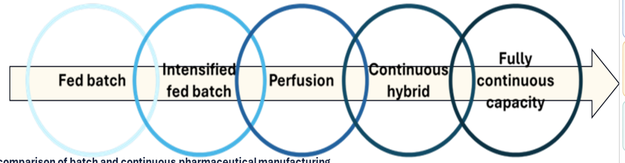
EP Hyaluronidase HyaGenix™

SEC-HPLC of HyaGenix™

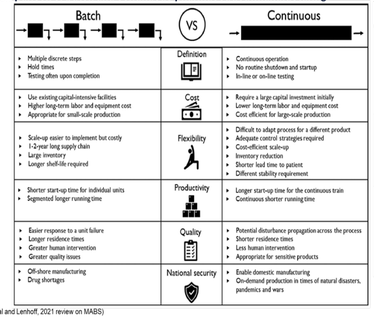


(3) Patented SC formulation design
皮下注射劑型專利配方設計
-co-formulation with rhuPH20 to achieve the desired formulation strength and pharmaceutical form

台康連續式製程技術平台
(Paradigm Shift in Biologics生產模式的進化趨勢)



A comparison of batch and continuous pharmaceutical manufacturing.



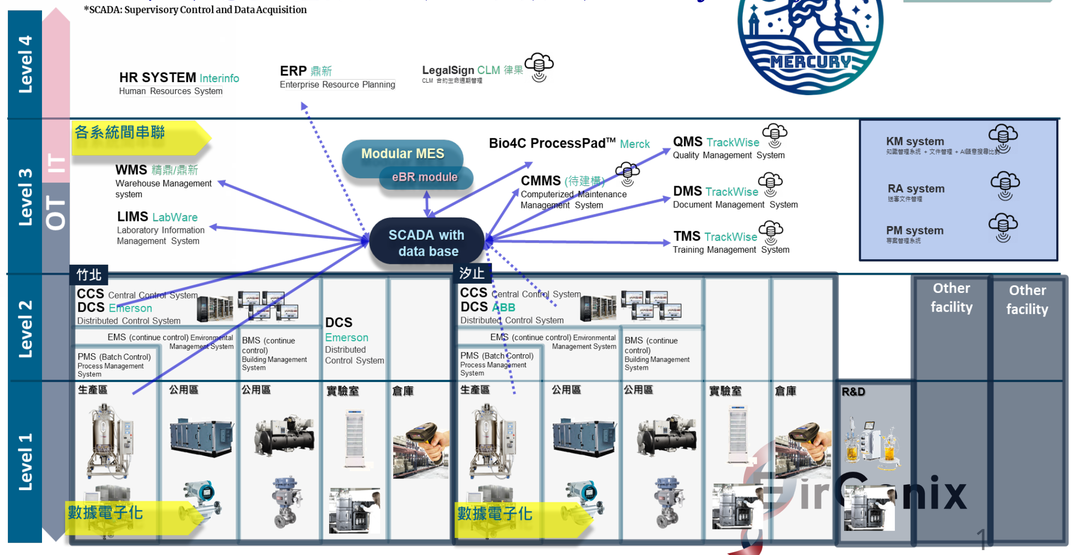
	From	To
Lower Cost	Titer: 1-5 g/L	Titer: 5-10 g/L
	Cost: < USD $150	Cost: < USD $50
	Large infrastructure footprint	Smaller, low initial investment, Less CAPEX
Time (Higher Probability of Success, time to market)	Fixed capacity	Flexible capacity
	Scale-up	No scale-up
	Long construction time	Short construction period
High Quality	Screening for the best protein	Designing the protein fit for target via AI
	High level of manual technician	High level of automation, reduce manpower
	Cells long-term in culture media	Fresh out of cells

(Khanal and Lenhoff, 2021 review on MABS)

台康智慧生產數位解決方案 (Mercury Project)

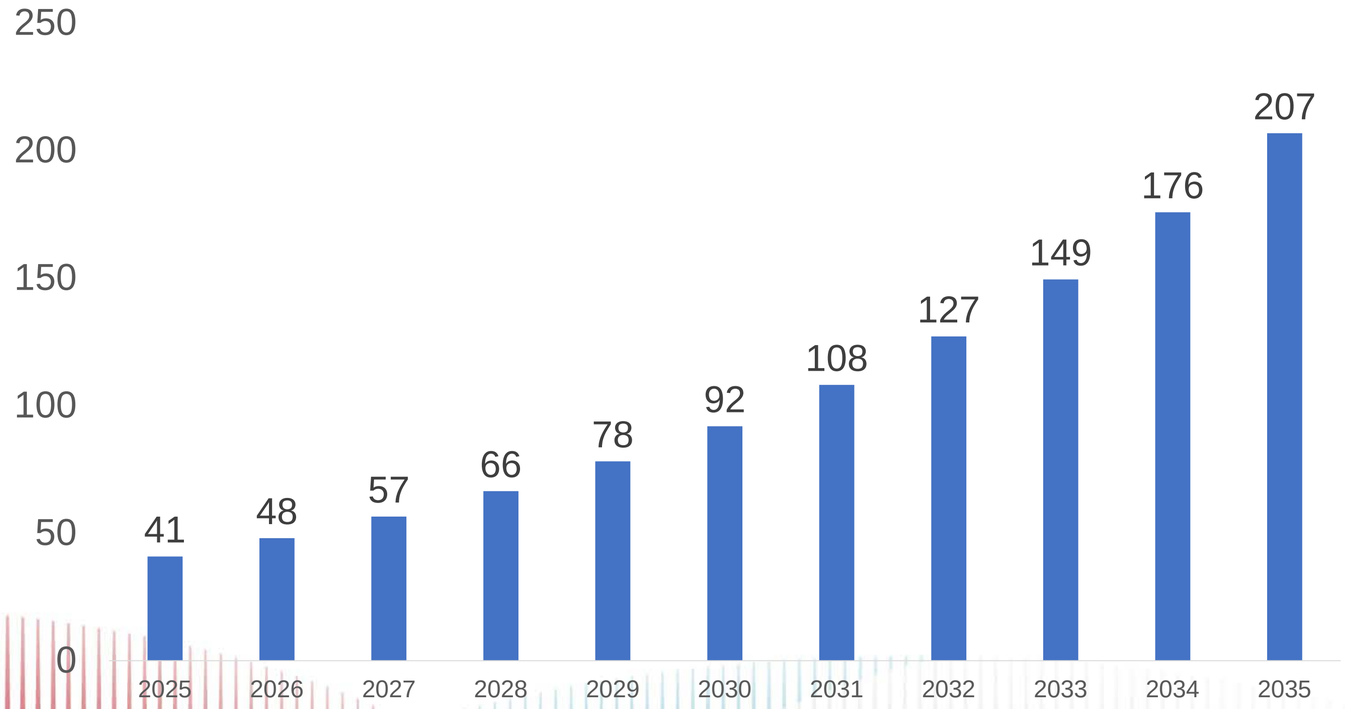
Digitization
Digitalization
Digital transformation

*SCADA: Supervisory Control and Data Acquisition



Global Biosimilars Market Opportunity

Global Biosimilar Market Forecast (2025–2035, USD Billion)



Source: https://www.towardshealthcare.com/insights/biosimilars-market

17.6%

CAGR 2026–2035

Sustained double-digit growth decade

$48Bn

Market in 2026

Crossing threshold driven by oncology

$207Bn

Market by 2035

Up from ~$41Bn in 2025 (5× growth)

Asia-Pacific is the fastest-growing region, fuelled by expanding healthcare budgets, patent expirations and increasing regulatory capacity.

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Sustainability of Biosimilar Development

- **High development cost for biosimilar:**
  - Average it cost around $150 – 300 million USD to develop a biosimilar product.
  - Any biologics with a revenue prior to LoE less than $1 billion USD, very few of these products have biosimilar product in development.
- **Financial P&L burden on the biosimilar developer**
  - Limiting the development speed of biosimilar product
  - Limiting the number of biosimilar products to be developed simutaneously
- **Pricing and Reimbursement Challenges:**
  - Biosimilars are priced lower but may not receive sufficient reimbursement. (pricing erosion)
  - Payer hesitancy in covering biosimilars over biologics.
- **Recommendations:**
  - **Capitalize certain part of R&D expenses:** to improve the P&L in the income statement.
  - **Competitive Pricing Models:** Implement tiered pricing to enhance affordability.
  - **Payer Engagement:** Work with insurance providers on value-based reimbursement models.

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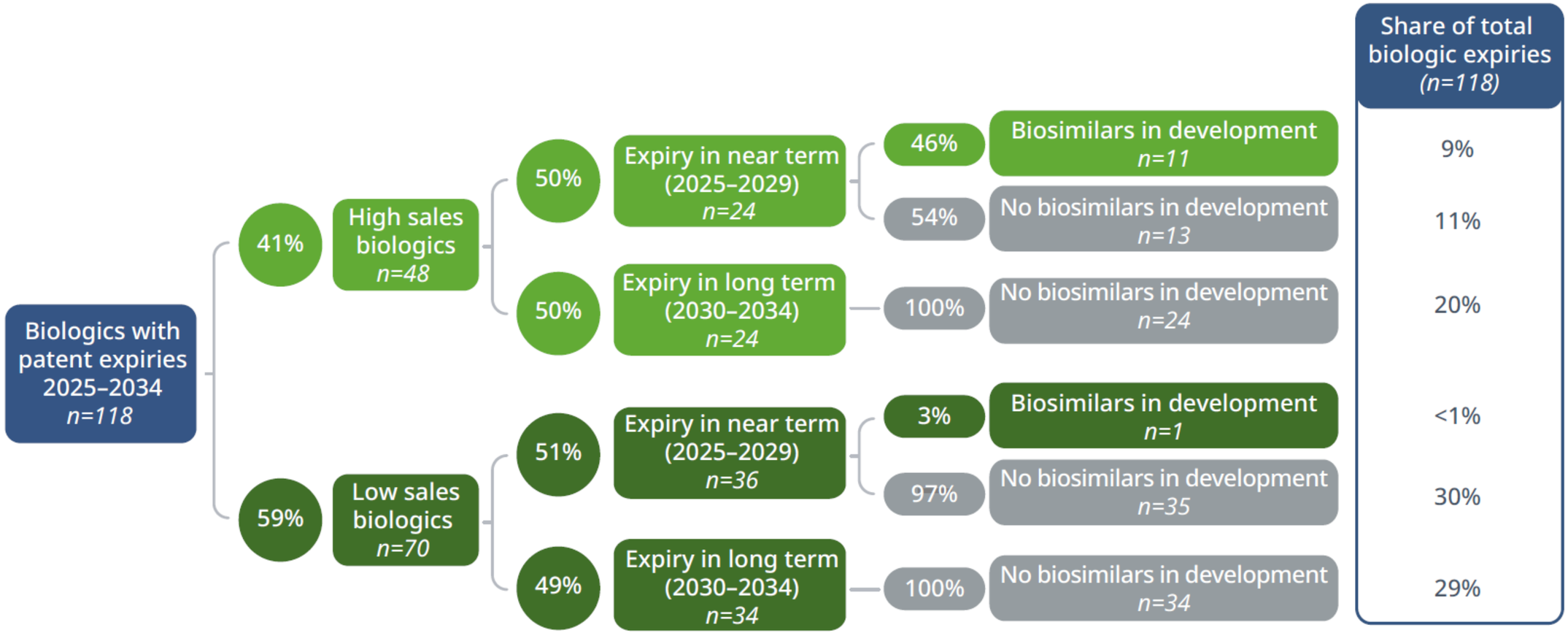
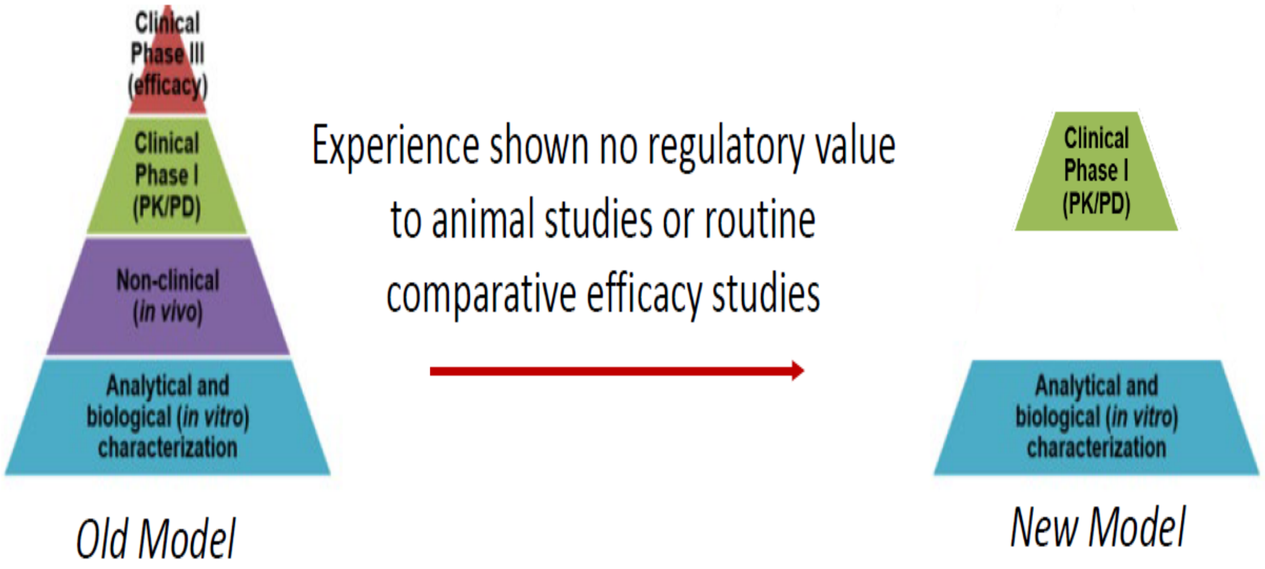
Biosimilar Development Landscape for Biologics Losing Patent Protection (2025–2034)



Source: IQVIA Ark Patent Intelligence, IQVIA Forecast Link, Jun 2024; IQVIA Global Biosimilars Database, Sep 2024; IQVIA Institute, Dec 2024.

Regulatory Trends Toward Streamlined Biosimilar Development



Graphics adapted from

IGBA
INTERNATIONAL GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

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Global Regulatory Alignment	FDA, EMA, MHRA, and Health Canada support reduced reliance on Phase III trials
Shift to Data-Centric Development	Analytical, PK, and immunogenicity data are becoming the primary basis for evaluation
Accelerated Development Pathway	Shorter timelines, lower costs, and reduced development risk

Source: Global data + EirGenix analysis

Pipelines

Product Code	Drug Class	Indication	PROGRESS				Partner
			Pre-Clinical	Clinical Phases	MAA/BLA	Approvals	
EG12014* **(EIRGASUN®/HERWENDA®)** Trastuzumab Biosimilar	Monoclonal Antibody	Cancer					SANDOZ
EG1206A Pertuzumab Biosimilar	Monoclonal Antibody	Cancer					SANDOZ JP market Confidential
EG13084 TRZ+PTZ (SC formulation)	Monoclonal Antibody	Cancer					
EG12043 (TSY110) Antibody Drug Conjugate	Antibody Drug Conjugate	Cancer					FORMOSA PHARMACEUTICALS, INC. US/EU Markets Confidential
EG12112 IO	Monoclonal Antibody	Cancer					
EG12164 /EG12184 Hemato-oncology IV/SC	Monoclonal Antibody	Cancer					
EG12170 Antibody Drug Conjugate	Antibody Drug Conjugate	Cancer					FORMOSA PHARMACEUTICALS, INC.
EG121XX Antibody Drug Conjugate	Antibody Drug Conjugate	Cancer					
Specialty Biologics							
EG74032 CRM197 Carrier Protein	Carrier Protein for Vaccine Conj.	N/A	B to B				
EG7412F Recombinant rhPH20	Enzyme	N/A	B to B				

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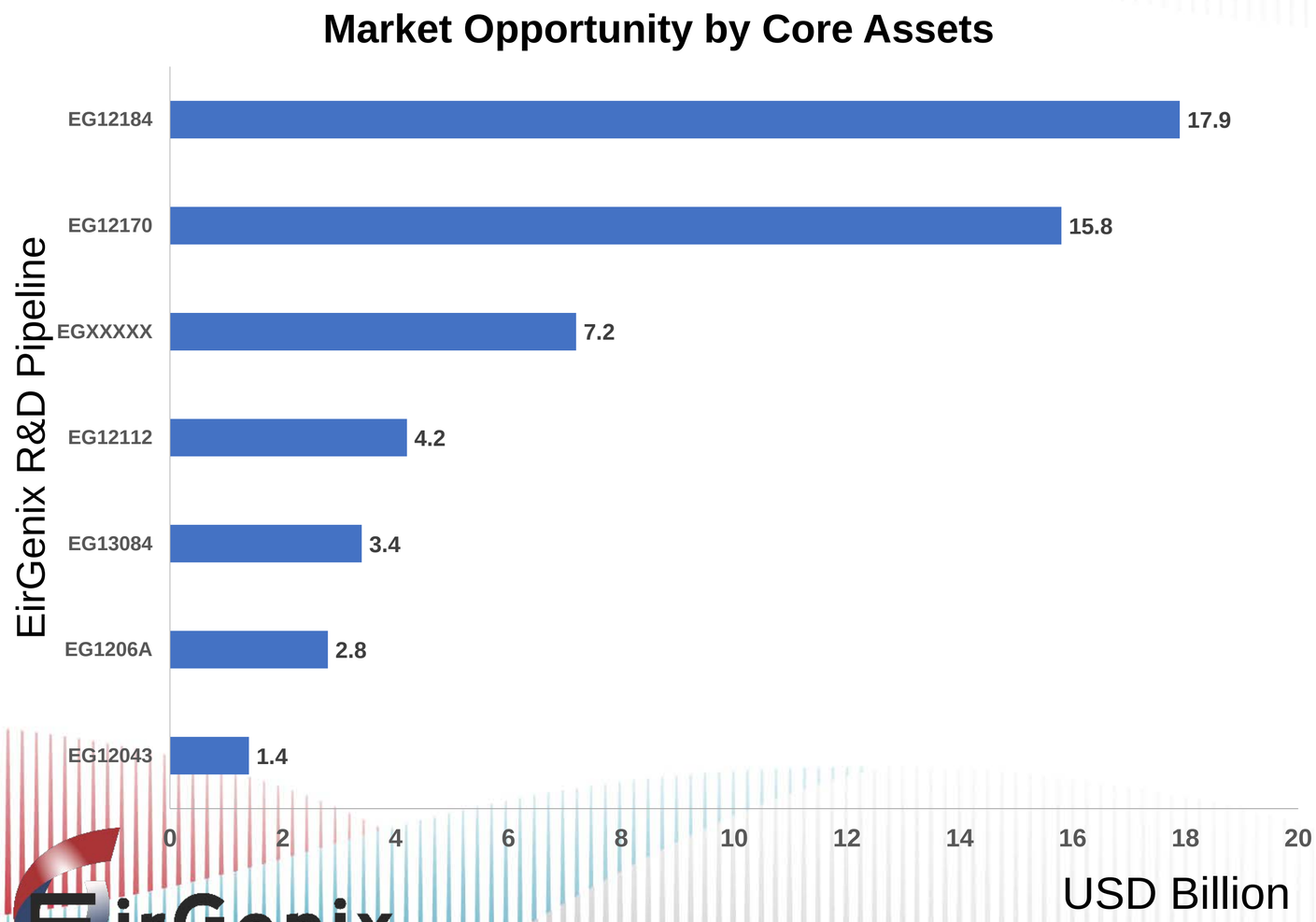
Diversified Pipeline Targeting ~$50B Originator Market Opportunity



~$50B Market Opportunity — Combined originator sales by 2030

3 ADC Biosimilars — Early entry into high-value US and EU markets

First-Mover Advantage — Few biosimilar competitors in key assets

Source: Global data + EirGenix analysis

A new direction for CDMO business development from the integrated approach for product development, process validation, CMC-regulatory services, and commercial mass production of biosimilars.

- A full Phase III clinical trial typically accounts for 60% to 70% of the total cost of biosimilar development. Simplifying or eliminating Phase III trials would significantly reduce the cost of developing biosimilars, allowing biosimilar players to focus on developing more low-volume (< $1 billion) biologics.
- More manufacturers are entering the development and marketing of biosimilars, but currently there are only a handful of CDMOs worldwide with complete reverse engineering, CMC-regulatory services, and commercial mass production capabilities.
- Enhanced cell line engineering and process development capabilities for speed and high performance
- Reshaping internal resource allocation for CDMO business development strategy, meaning we will not only develop our own biosimilars, but also assist other partners in developing their desired biosimilars based on fee for service or various collaboration models, and provide the most efficient commercial production capacity.

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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. Currently, there are two potential M&A targets in the different negotiation stage.

End of the Presentation

EirGenix