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www.eirgenix.com

EirGenix Corporate Introduction

EirGenix, Inc. | 6589.TWO

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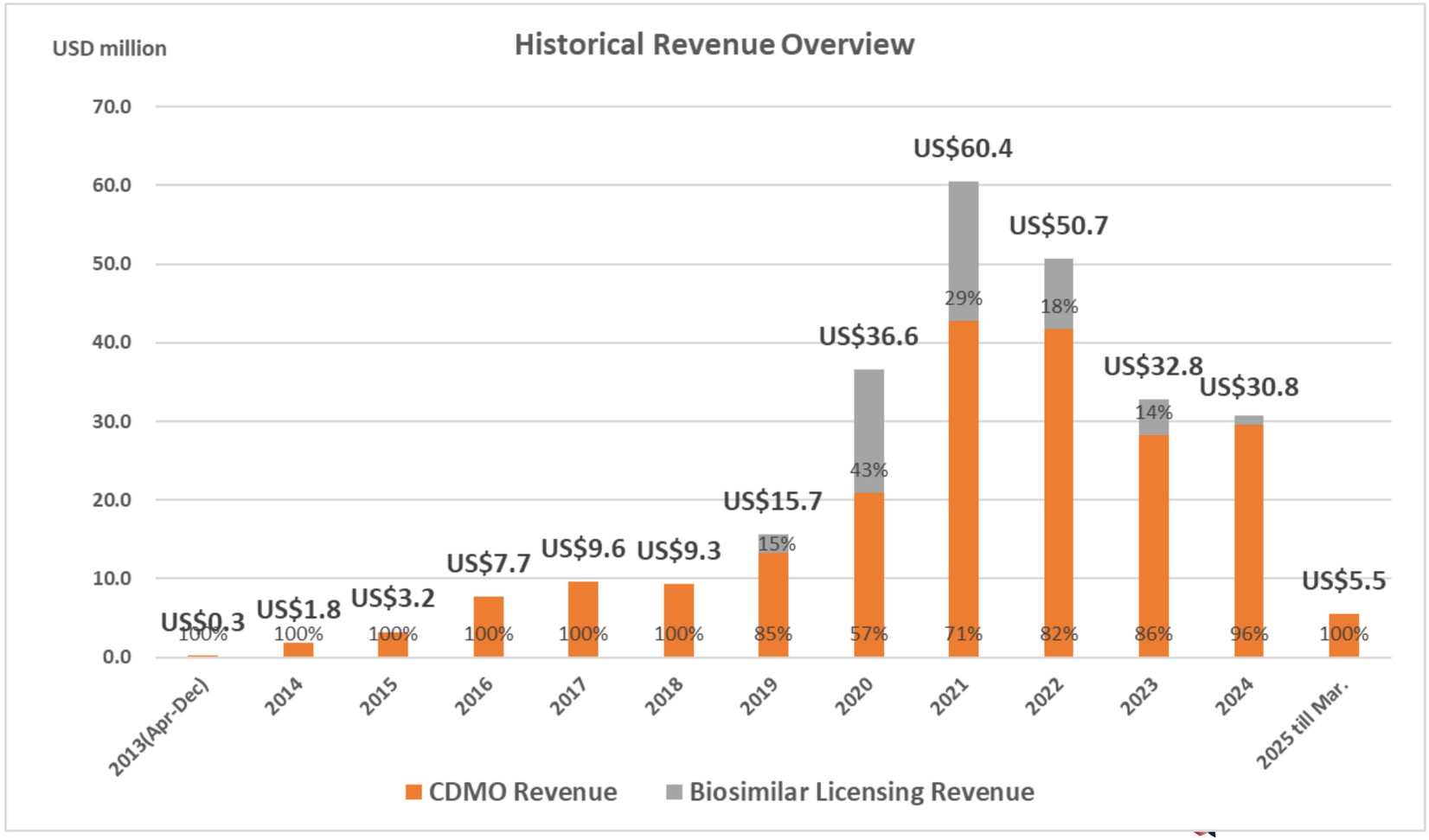
Revenue Breakdown

As of March 2025:

1. **Revenue has decreased by 17.19% compared to the same period last year, the reduced production in 1Q was mainly due to the Lunar New Year and annual maintenance.**
2. **Starting from the second quarter, production at the Xizhi plant will intensify, and the Zhubei plant is also scheduled for production.**



The Impact of the US Tariff Policy

- According to current U.S. tariff regulations, U.S. import tariffs are imposed based on the “Harmonized Tariff Schedule (HTS)” and “country of origin.” Pure CDMO services themselves—such as contract development and manufacturing—are considered “services” and are not directly subject to tariffs. However, the physical products resulting from these services may be subject to tariffs when imported into the U.S., depending on product classification and origin:

  - The declared value of goods at customs typically includes production costs, which may include CDMO service fees. However, some costs—such as licensing fees, tooling, post-sale rebates, or product used exclusively for research purposes (e.g., preclinical animal studies or human clinical trials)—can be excluded under appropriate documentation. This can be used for legal tariff reduction through so-called "tariff engineering.“
  - Current CDMO projects performed by Taiwanese firms for U.S. clients are mostly in early-phase development and have not yet reached commercial production. Therefore, we assess that Trump’s proposed “reciprocal tariffs” do not directly impact these cases.
  - The product Herwenda, licensed to Sandoz and sold in the U.S., will be the responsibility of Sandoz after final drug product (DP) manufacturing. The assessment suggests limited direct impact on Taiwan, since Sandoz is a Swiss company and the DP production is located in the EU. For now, the Trump administration has not included pharmaceutical products in the reciprocal tariff list, but if such tariffs are imposed in the future, the impact on Taiwan would depend on U.S.-EU negotiations. That said, the tax liability is borne by Sandoz, and thus the impact on EirGenix would be indirect.

The First Product/ Trastuzumab Biosimilar EG12014

(EIRGASUN® - EirGenix ; HERWENDA® - Sandoz)

- 2021-Dec Completion of submission of Biologics License Applications (BLA) to FDA and Marketing Authorization Application (MAA) to EMA；
  2022-June Submission of New Drug Application (NDA) to TFDA
- 2022/12, received complete response letter (CRL) from US FDA
- 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-May, received the market approval letter from Taiwan Ministry of Health and Welfare.
- 2023-Oct, has been approved by Taiwan National Health Insurance Administration to be enrolled in the reimbursement system.
- 2023-Nov, received the Marketing Authorization approval letter from EC.
- 2024-Jun 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.
- 2024-Jul 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.
- 2024-Oct/Nov FDA inspected the filling facility of the third party's factory and identified 7 observations.
- 2024-Dec The third party replied to the FDA of the inspection deficiencies identified during inspection.
- 2024-Dec Received complete response letter (CRL) from US FDA
- 2025-Jan EirGenix has officially submitted NDA for the biosimilar drug EIRGASUN of 420 mg lyophilized powder for intravenous administration to the TFDA.
- 2025-Mar Feedback from the FDA Type I meeting indicated that the overall strategy for conducting an analytical comparability assessment between the development batch and the commercial product is considered reasonable.
- Eirgasun 150 mg has been listed in 4 medical center systems and other regional hospitals and area hospitals.
  The accumulated number of treated patients is continuously increased that can strengthen supply resilience of breast cancer drug in Taiwan.

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Countermeasures after receiving CRL for EG12014 BLA application

- **First: Revenue remains unaffected**
  - There will be no significant impact on future revenue

- **Second: Licensure status unaffected**
  - The licensure status of Taiwan and EU is not affected (no impact).

- **Third: Marketing large and small strengths**
  - The original sales strategy of Sandoz was to simultaneously launch 150 mg and 420 mg strengths into the market to meet different needs in Europe and the United States.

- The license agreement with Sandoz was revised to transfer the drug product manufacturing process to Sandoz in 2023. Currently, Sandoz has completed all the validation batches.
- Sandoz will complete post-approval changes applications, and gradually launch 150 mg and 420 mg products in order to achieve both products on the market (420 mg captures 2/3 of the European market)
- Sandoz remains in close contact with the US FDA and EirGenix to reach a resolution in a timely manner. In the US market, 420 mg strength is in high demand, Sandoz and EirGenix are working together to get 150 mg and 420 mg products approved by FDA and launch them into the U.S. market together as planned.

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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 2Q of 2025.
- Plan to complete three drug substance and drug product validation batches in 2025/2026
- Target for market launch in 2027/2028 (aim for the first two biosimilar drug with global launch).
- Completed the application for Phase III clinical study in US and Taiwan.
- Submitted the application for Phase III clinical study in Argentina, Georgia and Georgia.
- According to Roche's 2024 annual financial report: the global annual sales of this product still reached 3.61billion CHF.

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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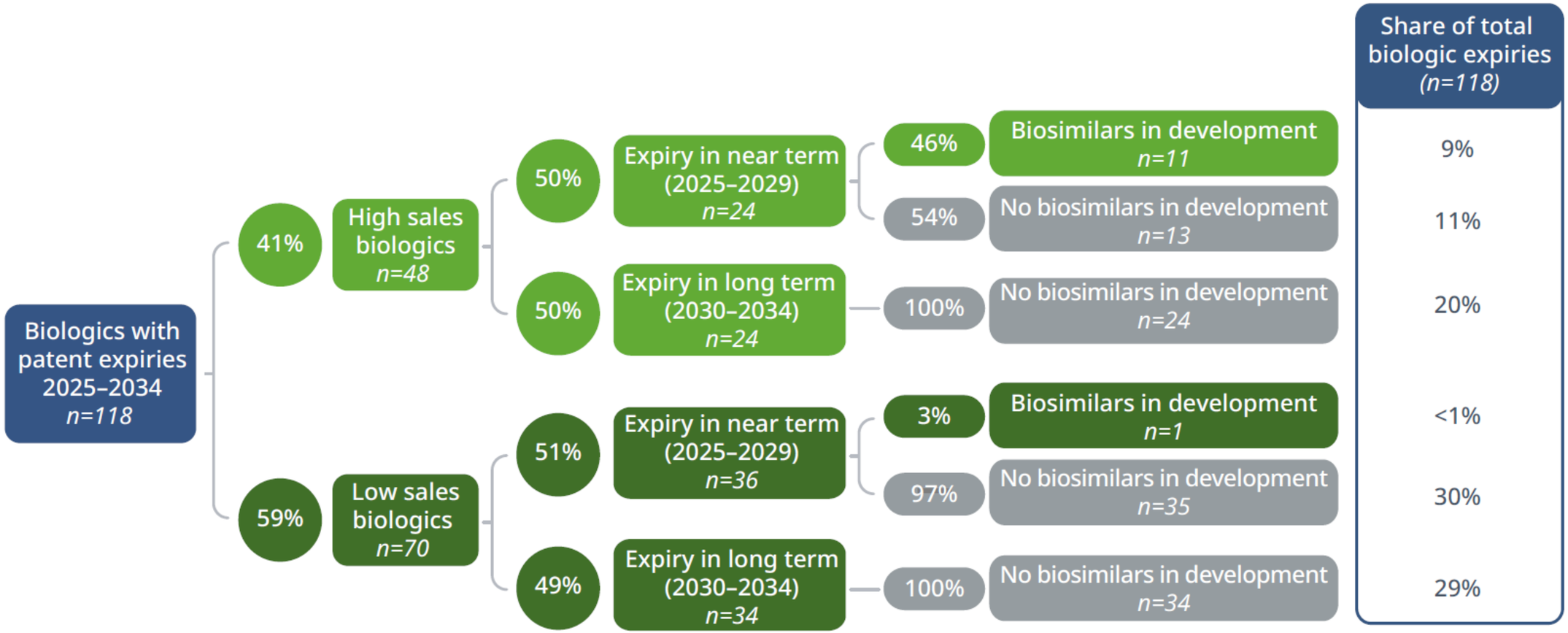
BIOLOGICS WITH PATENT EXPIRIES 2025-2034 HAVE BIOSIMILAR IN DEVELOPMENT



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

US FDA May Be Shifting Its Thinking On Biosimilar Trials

05 Mar 2025
• By Dave Wallace

Two recent disclosures from Xbrane Biopharma and Formycon demonstrate the evolving US Food and Drug Administration thinking about the need for Phase III trials to support biosimilar filings

The US Food and Drug Administration is increasingly open to approving biosimilar filings without full Phase III clinical trial data.

Two recent company disclosures revealed agency scientific advice indicating applications could be approved without the usual suite of supporting trials.

Phase III trials are not a formal necessity for biosimilar approval. The FDA evaluates each proposed biosimilar individually and advises manufacturers on the scope and extent of testing necessary to show biosimilarity.

Supporting data to demonstrate biosimilarity can include analytical studies as well as clinical trials, but the FDA reserves “discretion to determine that an element is unnecessary in a proposed biosimilar application.”

An end-to-end solution for biosimilars—from reverse-engineering-based product development, process validation, and CMC regulatory services to commercial-scale manufacturing—will become a new direction for CDMO business development.

- A full Phase III clinical trial typically accounts for **60% to 70% of the total cost** of developing a biosimilar. If this phase can be simplified or eliminated, the cost of developing biosimilars could be significantly reduced, enabling companies to pursue biosimilars for **lower-revenue biologics** (those with annual sales of less than **$1 billion**)
- More companies are entering biosimilar development and commercialization. However, globally, **only a few CDMOs** possess comprehensive capabilities across **reverse engineering, CMC regulatory services, and commercial-scale manufacturing**
- **Enhance cell line development capabilities** – focusing on **speed and high expression performance**
- **EirGenix** will further **restructure and allocate internal human resources** to align with the strategic direction of expanding its **CDMO service business**. This means that **we will not only develop our own biosimilars**, but also **assist other companies** in developing their biosimilar candidates **on a fee-for-service basis**

Biosimilar Promotion Policy in Taiwan

Reforming NHI Pharmaceutical Pricing Policies to Strengthen Drug Supply Resilience

The NHIA stated that the draft amendments to the NHI Drug Fee Schedule and certain provisions of the Drug Price Adjustment Regulations aim to foster the future development of the pharmaceutical industry, offering significant benefits.

- the NHIA encourages the timely introduction of biosimilars into the market to expand prescription drug options. For domestically manufactured biosimilars developed to enter the market after the expiration of a brand-name drug's patent, the first two to obtain drug licenses within five years of the patent's expiry will be eligible for pricing equivalent to, at most, that of the original brand-name drug.
- Domestically manufactured drugs will receive preferential pricing to ensure a stable drug supply. This includes drugs made with locally produced active pharmaceutical ingredients that the NHI pricing will obtain a 10% premium.
- To ensure a stable supply and reasonable pricing of pharmaceuticals, products may be exempt from annual pricing adjustments if all three of the following criteria are met: the product is listed as an essential drug by the competent authority, domestically manufactured alternatives exist within the same category, and no more than three items exist in the same classification within that category.

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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