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www.eirgenix.com

EirGenix Corporate Introduction

EirGenix, Inc. | 6589.TWO

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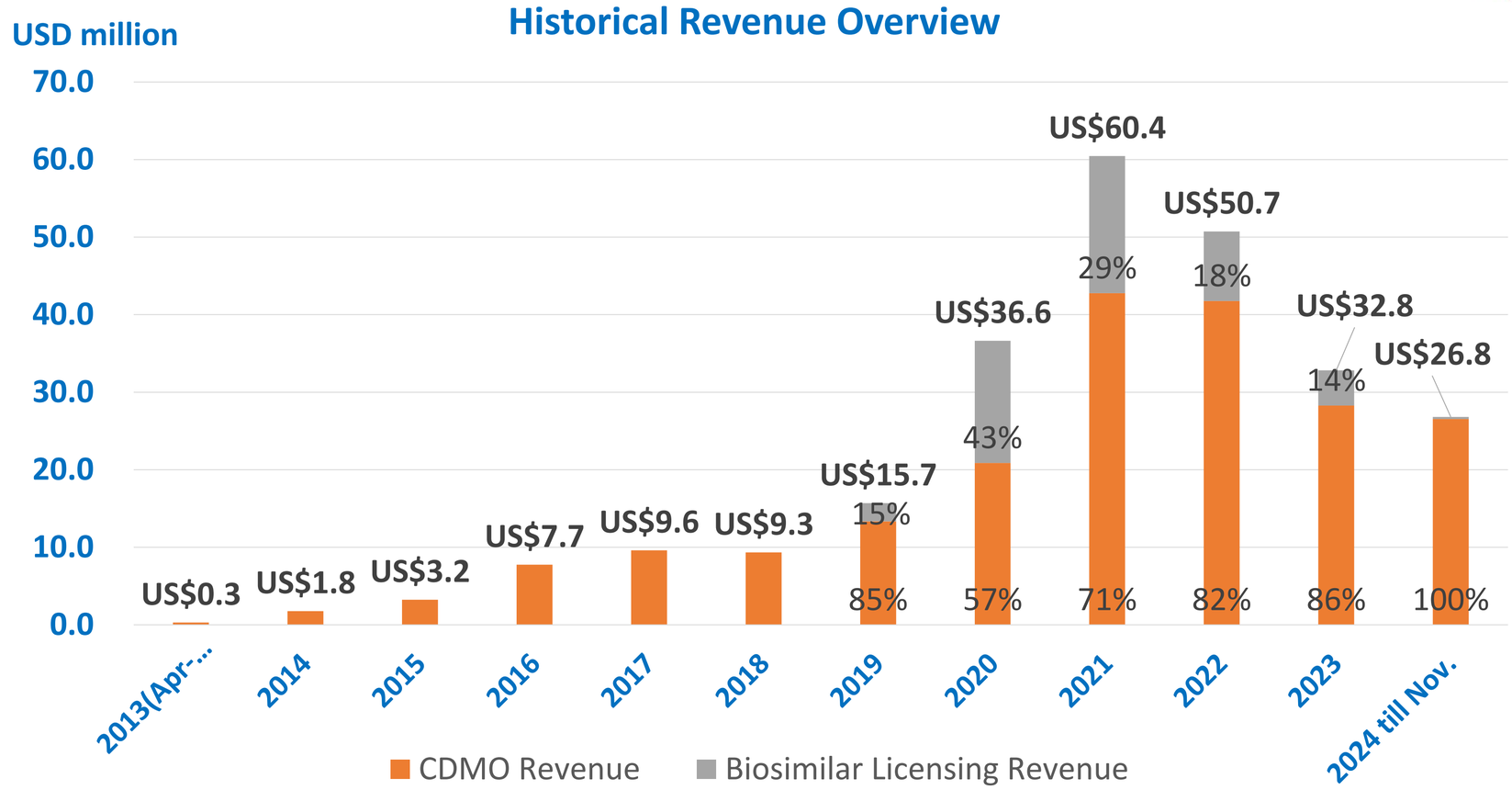
Revenue Breakdown

As of November 2024:

1. **Revenue decreased by 5.01% compared to the same period last year, primarily due to achieving the sixth milestone payment for the licensing of the biosimilar EG12014 in the same period last year.**
2. **CDMO revenue increased by over 10% compared to the same period last year.**
3. **Production at the Xizhi will be intensive in the H2. Expected revenue will be steadily increasing.**



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

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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 1Q/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).
- 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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End of the Presentation

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