# **UBS Taiwan Corporate Day**

EirGenix, Inc. 6589.TWO

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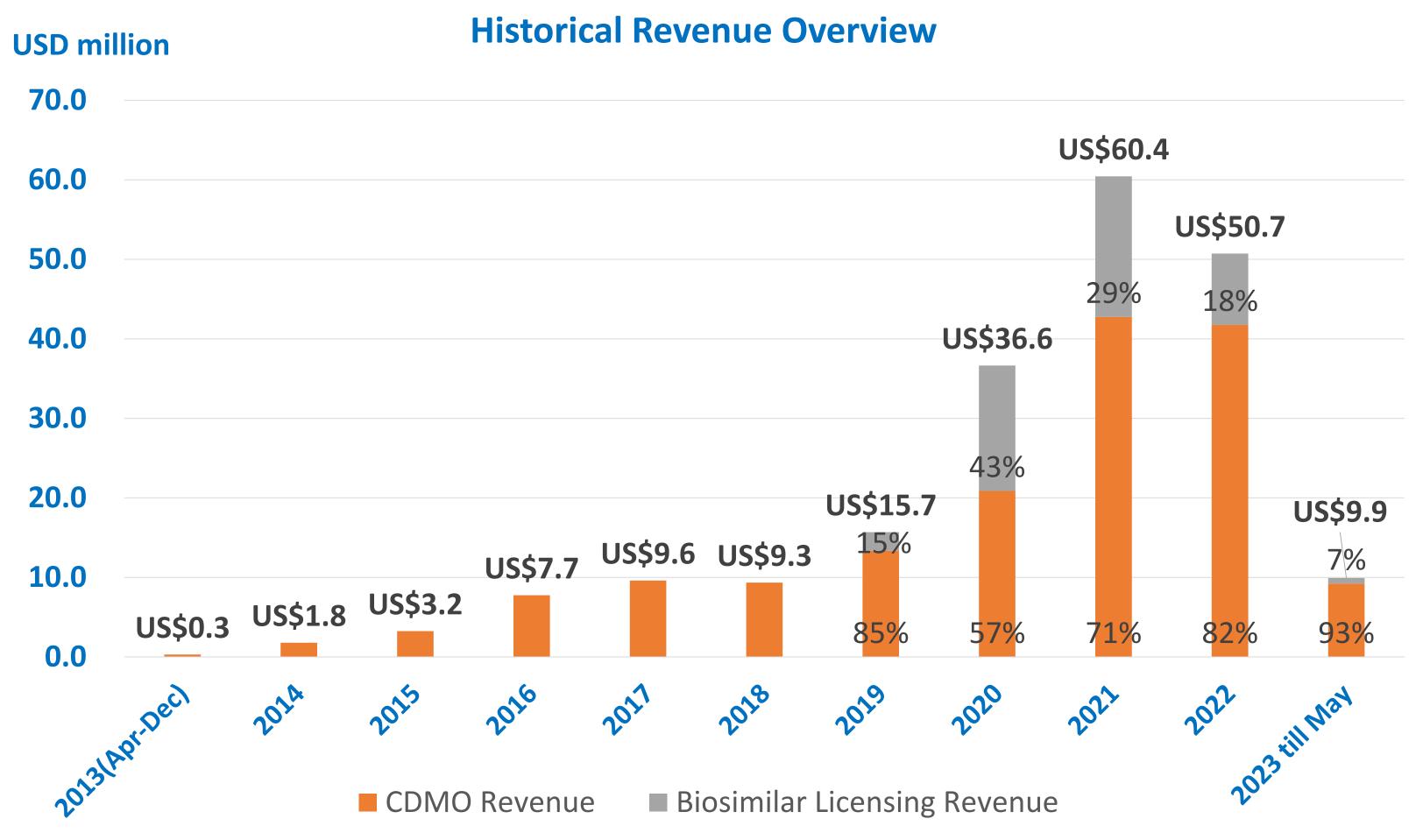
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#### Revenue Breakdown



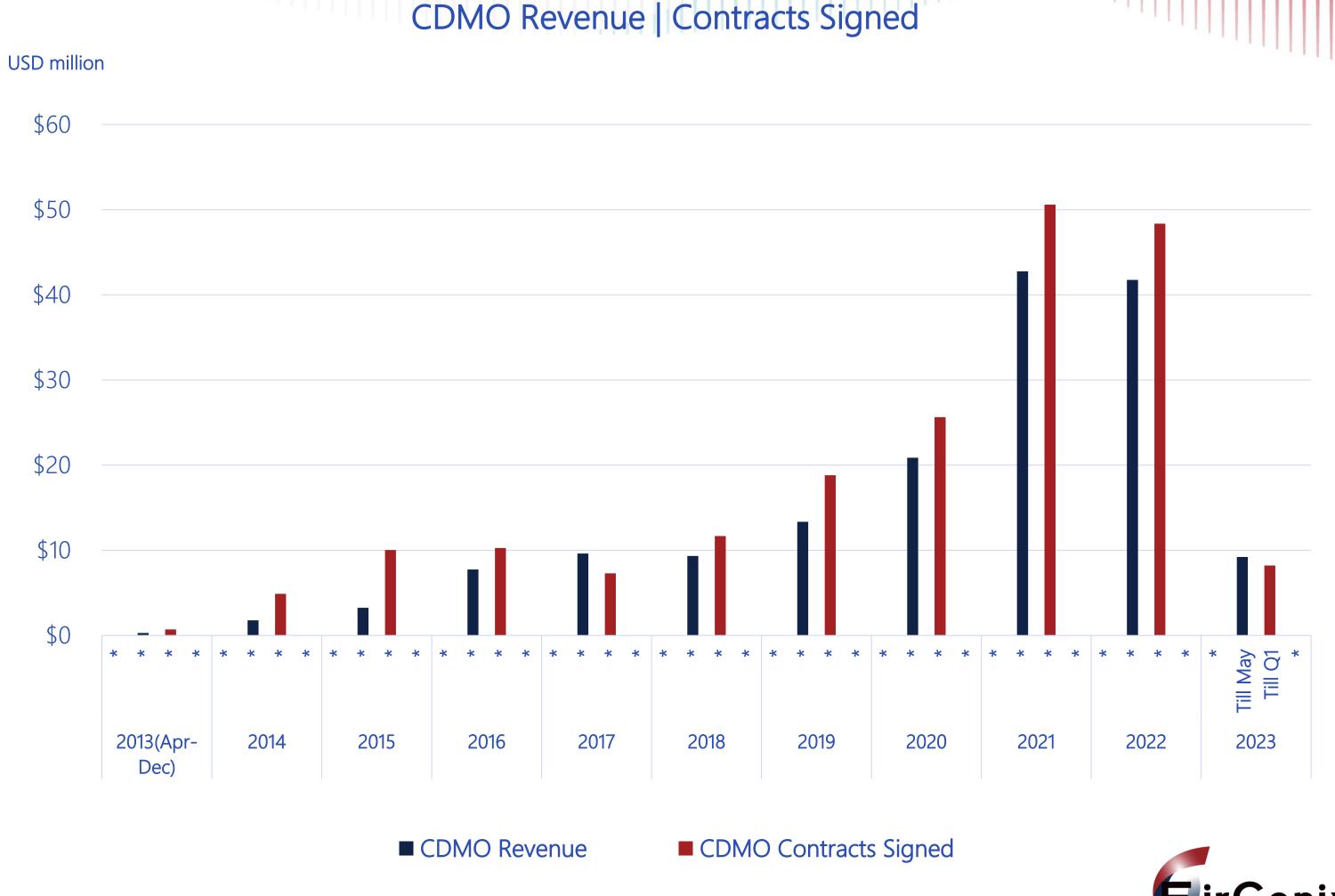


## **CDMO Revenue and Contracts Signed**

2023 full year CDMO revenue realized and newly signed contracts to target growth

2022 CDMO revenue reached NT\$1.2 billion, grew 1.5% YoY

- Overall CDMO client project realized revenue continue to grow YoY, despite Xizhi facility suspended operation ~4 months in 2022 for major renovations.
- 2022 newly signed CDMO contracts reached nearly USD 48 million.





#### **2023 Key Focuses**

#### **Developing Products/ Biosimilars**

- The market approval of EG12014 (biosimilar of trastuzumab, EIRGASUN®/HERWENDA®) status is:
  - 2023/5 received the market approval letter from Taiwan Ministry of Health and Welfare for the biosimilar drug Eirgasun 150 mg powder for concentrate for infusion.
  - 2023/4 received the approval letter from TFDA that the API Trastuzumab has obtained the license and the DMF number.
  - The review at EMA is still in the clock of "D180" and is expected to received the approval in Q4 of 2023.
  - The contract manufacturing partner for the lyophilized fill of EG12014 has completed hardware improvements and functional testing, and ready for sterility validation. We had a Type 1 meeting with FDA on 6/5. In the meeting, most of the improvements has met the requirement of FDA, however, FDA requested to complete 3 full scale GMP lots in the resubmission. We expected the approval will be in the Q1 of 2024.
- 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 end of May, we had a good responses from EMA Scientific Advisory. A pre-IND meeting request with US FDA for the discussion of Phase 3 protocol will be submitted in July. At the same time, global licensing negotiation is actively on going.
- The product EG12043 (TSY-0110, a biosimilar of Kadcyla®) co-developed with Formosa Pharmaceuticals has completed a pre-IND meeting with the FDA at the end of January. The next step is to integrate the different clinical trial requirements from both the FDA and the EMA before submitting the IND.
- Actively developing a subcutaneous injection platform.
- We are in discussion the Immuno-Oncology Biosimilar Drug Development Alliance with the global pharma.



## **2023 Key Focuses**

#### **Capacity Expansions and Technology Platform**

- The second mammalian cell production line (5F) at EirGenix's Zhubei facility is expected to be completed by the end of Q3 2023 and will begin production in Q4 2023. At that time, the total production capacity of mammalian cells will increase from 13,500 liters to 25,500 liters.
- The third production site, located in the Southern Taiwan Science Park, will expand the mammalian cell culture production line by 150,000 liters over the next 10 years.
- EirGenix is actively optimizing the existing plasmid DNA technology platform, which is expected to be completed by Q2/Q3 2023.

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.



# **2023 Key Focuses**

#### **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 target companies located in the United States and Europe.



# End of the Presentation

Q & A

