# KGI Securities' 1Q23 Investment Forum

台康生技 EirGenix, Inc. 6589.TWO

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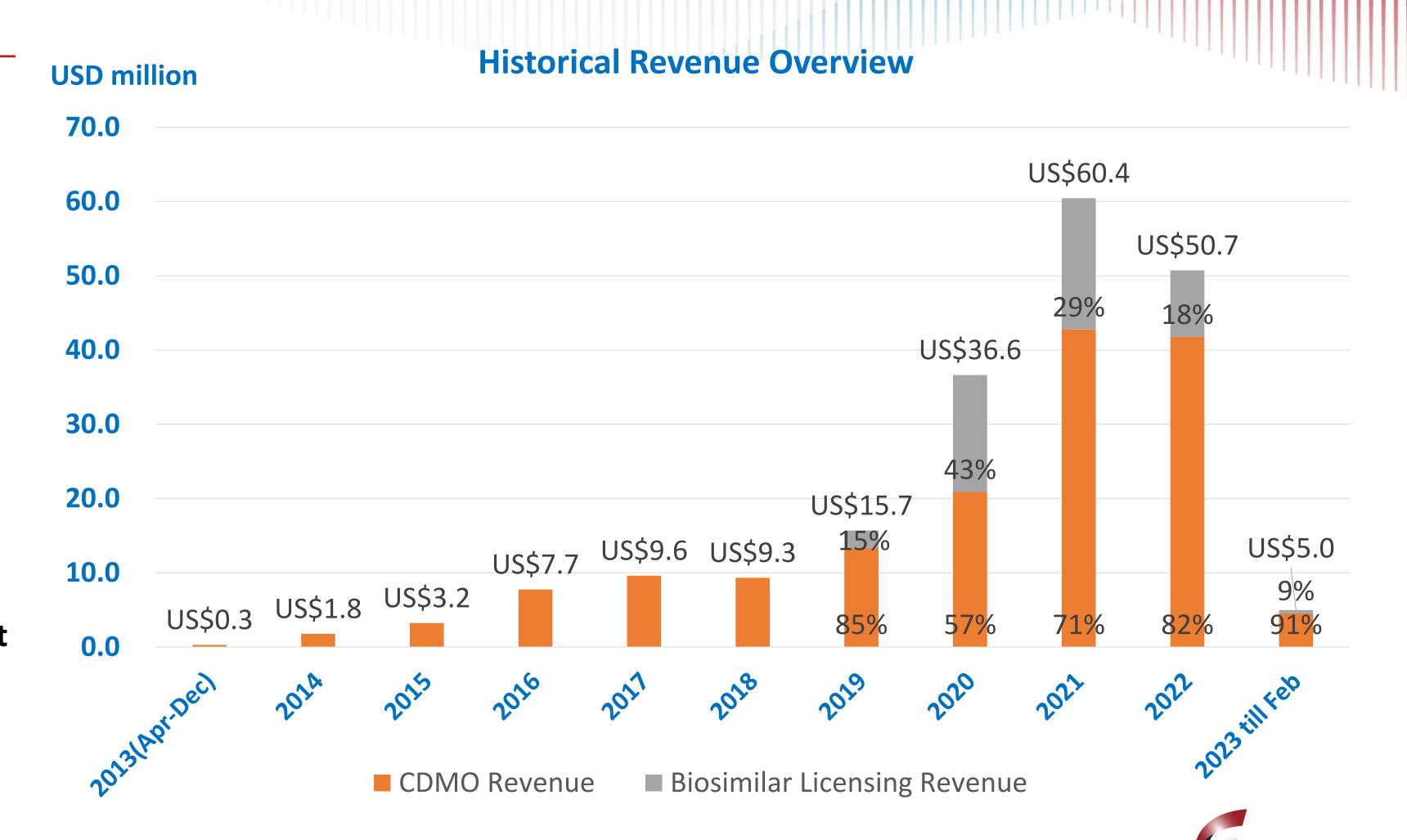


## **2022 Key Summaries**

#### **Revenue Breakdown**

## 2022 full year revenue US\$50.7 million , declined 12.9% YoY

 The key short fall came from the product licensing revenue, as accounted US\$9 million in 2022 (vs 2021 US\$18 million). This is due to US and Europe marketing license approvals push back, and the remaining milestone payment dependency on the approvals.



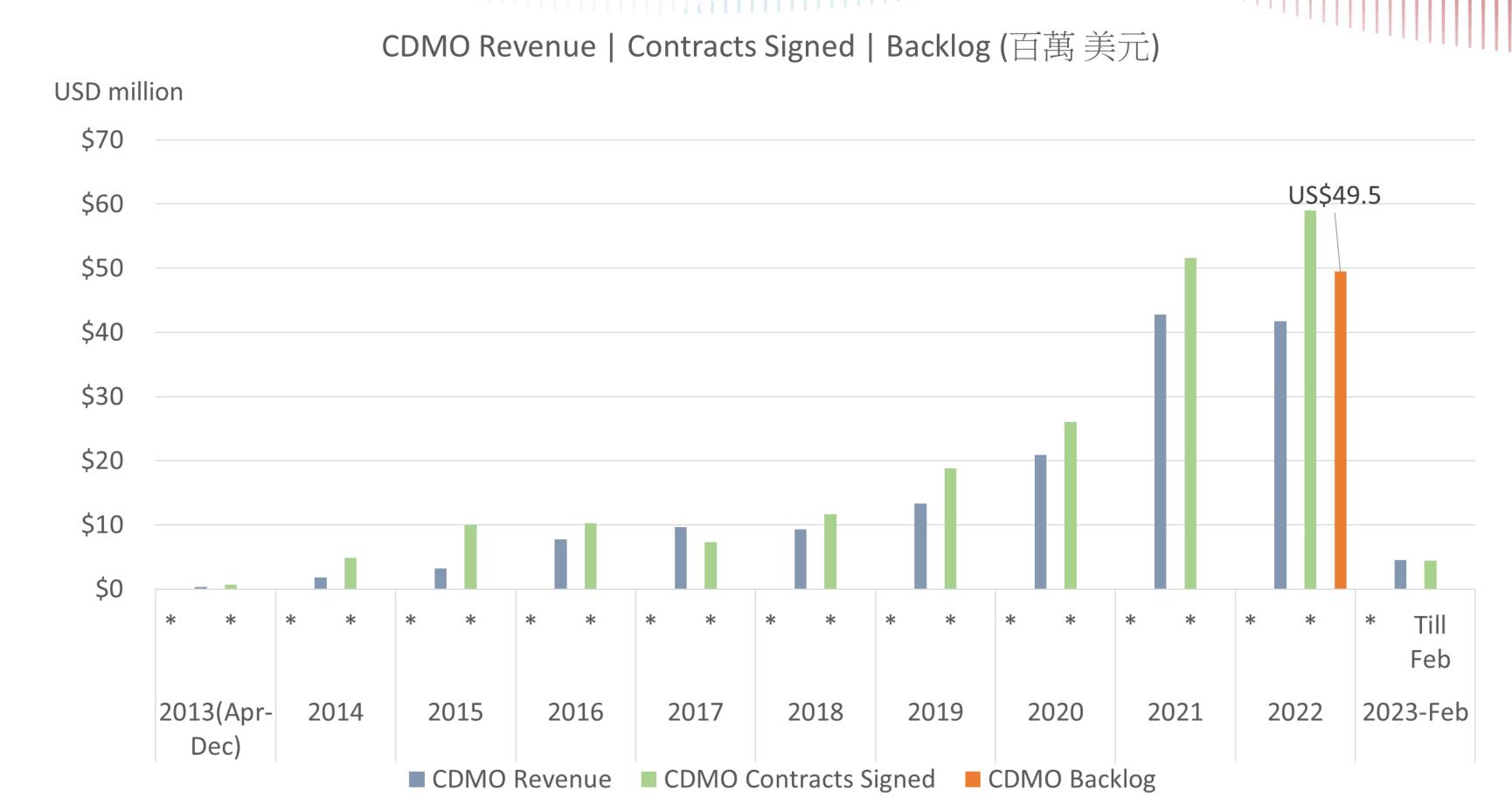


## 2022 Key Summaries

#### **CDMO** Revenue and Contracts Signed

# 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 59 million, +14%YoY.
- Estimate USD 49.5mn order project backlog to complete /realize over the next two years.





### 2022 Key Summaries

#### **Other Key Achievements**

- The EirGenix Zhubei facility passed was inspected by the US FDA (in June 2022), and received the Establishment Inspection Report (EIR) issued by the US FDA in January 2023. This important international credential not only applies to other products under development by EirGenix, but will also serve as a stepping stone for EirGenix to acquire more global clients in the CDMO business in the future.
- The second product under development, EG1206A (a biosimilar of Pertuzumab), began its Phase I clinical trials, and completed enrollment of the last healthy volunteer in November, 2022. On January 24th, 2023, the last healthy volunteer observation was completed.
- The 3F production line expansion at EirGenix's Zhubei facility. The production capacity of mammalian cell culture increased from 9,500 liters to 13,500 liters as of Q3 2022.
- The construction of the microbial plant at Building B of EirGenix's Zhubei facility has been initiated and is expected to be completed by the end of 2024.
- The production line at EirGenix's Xizhi facility has undergone significant renovation and update, resulting in increased production efficiency and extended lifespan.
- EirGenix has launched a 10-year, 150,000-liter mammalian cell culture production line construction project (in the Southern Taiwan Science Park),
  in response to the future demand of several self-developed products and CDMO business.
- Honored to be rated Top 5% Corporate Governance Evaluation in 2021, among over 800 listed companies at TPEx Board.



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

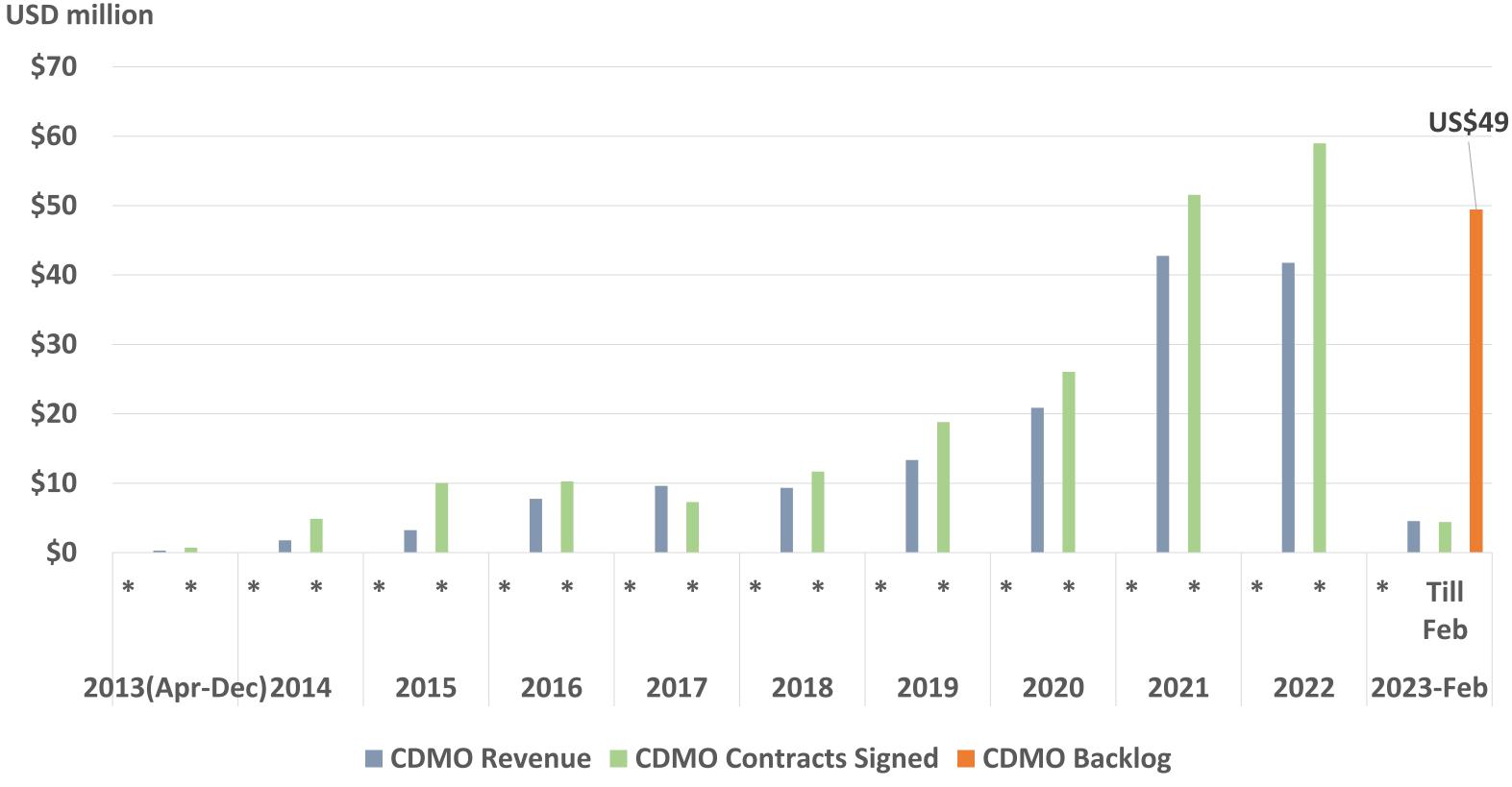
- The first developed product, EG12014 (biosimilar of trastuzumab), is expected to obtain marketing licenses in Taiwan, , the United States, and Europe before the end of 2023.
  - \* A meeting with the FDA to discuss EG12014 is scheduled for mid-May.
  - \* The contract manufacturing partner for the lyophilized fill of EG12014 has completed hardware improvements and is currently conducting functional testing. After passing the testing, they will begin retesting the sterile manufacturing process to ensure efficacy.
- The second product, EG1206A (biosimilar of pertuzumab), is expected to pass the Phase I clinical trial and will start the Phase III clinical trial before the end of 2023. At the same time, starting the international licensing.
- 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.
- Additional four new compounds to begin development, under the Immuno-Oncology Biosimilar Drug Development Alliance.



#### **CDMO** Business

- 2023 Jan-Feb CDMO revenue reached NT\$138mn (vs 2022 same period +24%YoY)
- Cumulated 2023 (as of Feb) CDMO newly signed contracts ~USD 4.4 million
- Order backlog (as of Feb) ~USD 49 million
- 2023 full year CDMO revenue realized and newly signed contracts to target double digits growth







#### **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 Q2 2023 and will begin production in Q3 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.



#### **Capital Investment and M&A**

- After investing in 富耀生醫創投 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

