



TPEX: 6589

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*YOUR RELIABLE  
BIOLOGICS PARTNER*

12th QIC Taiwan CEO Week  
Sept 30, 2022

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Founder, Chairman & President

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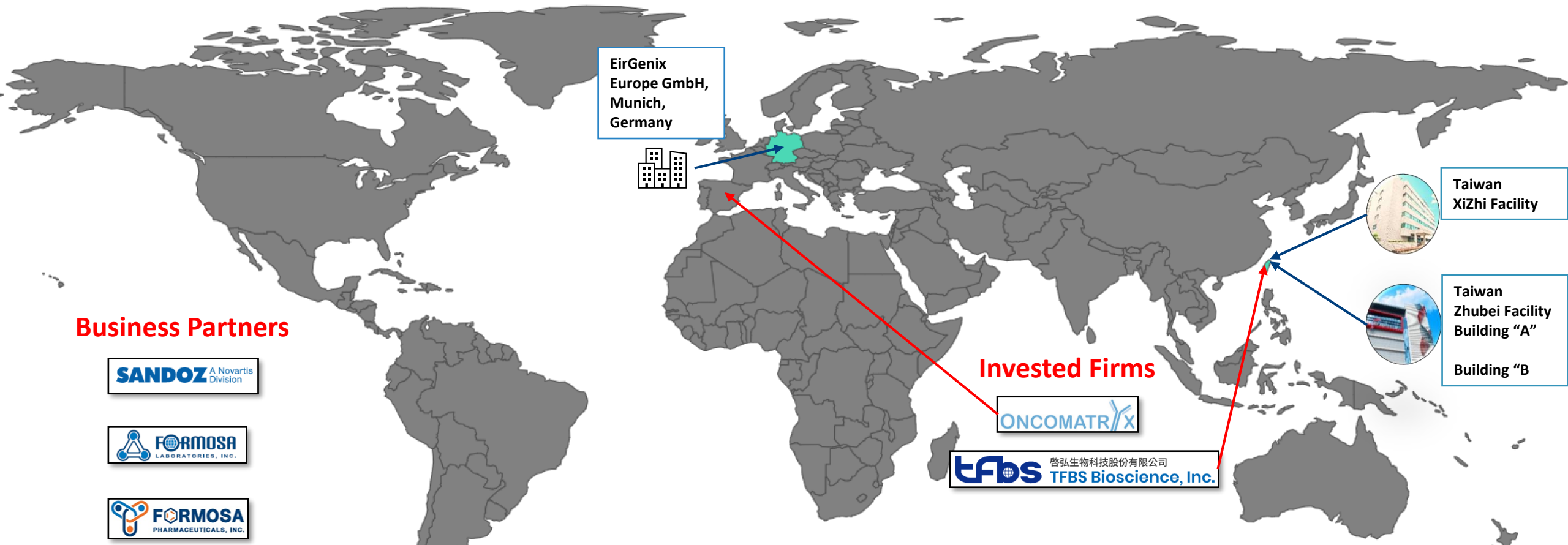
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# EirGenix Profile and USPs

- Established Dec. 21, 2012
  - 2013/03 Completed acquisition of DCB's Biopharmaceutical Pilot Facility
  - 2019/06 IPO on TPEx (Code: 6589.TWO ) China Area Award
- Back up by very strong and stable investors include:
  - **Founder of Foxconn, Terry Gou**
  - **Government and pan-government investment funds**
  - **Formosa Laboratories**
- Dual business model : **CDMO Services** and **Own-Product Development (Biosimilars)**
- CDMO Achievements
  - 2018 Asia's Best Biologics CMO Award
  - 2019 BioProcessing Excellence in Taiwan Award
  - 2020 BioProcessing Excellence in Greater China Area Award
- **Rated 2021 Top 5% Corporate Governance Evaluation at TPEx after second year of the IPO**



# EirGenix Office, Facilities & Business Partners





# Recent Zhubei Facility Expansion Update

## Zhubei - Building B (Microbial Production Line)

Currently under construction, expect to be ready by 2024-end for

1x 350L and,

1x 1000L

production lines

## Zhubei- Building A (Mammalian Production Line)

Started production since 2019

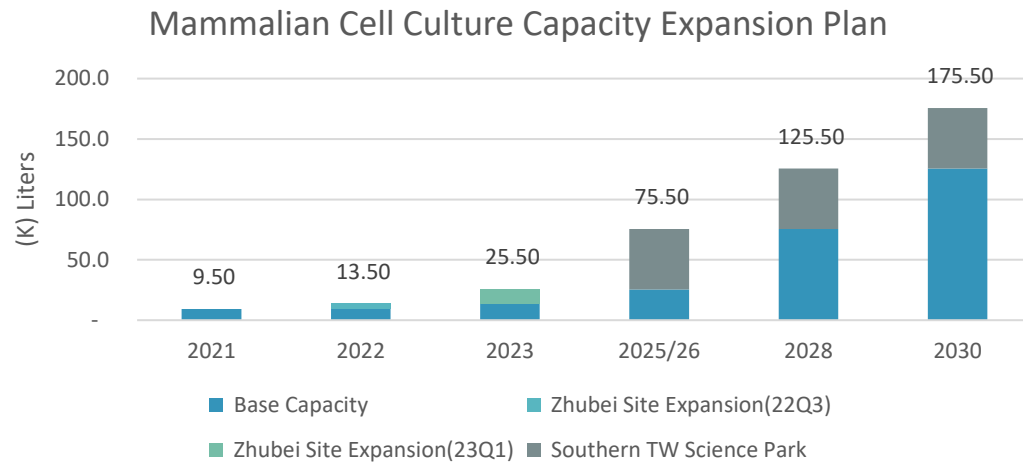


5F: New production line to ready by 2023 Q1 for 3 sets 2x 2000L

3F: 3Q2022 Expansion completed. Latest 3F production line has 3 sets 2x 2000L capacity

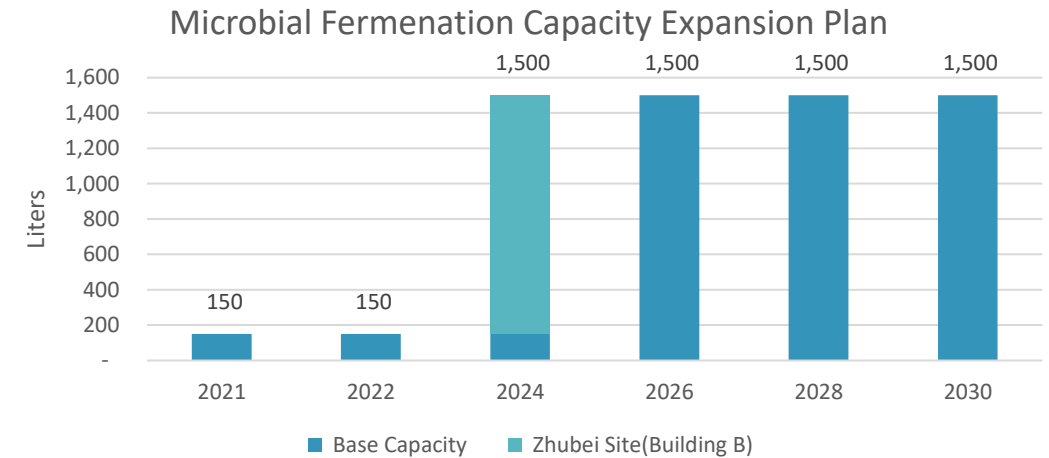
# Capacity and Expansion Schedule (Xizhi | Zhubei | STSP)

Mammalian Cell Culture Capacity 13,500 L  
(2023Q1 to reach 25,500 L)



- 2019/Q1 The first large scale mammalian commercial production in the Zhubei facility on stream (3F)
- 2022/Q3 Additional 1 sets of 2x2000L mammalian capacity expansion completed. Totaled 13,500 L
- 2023/Q1 The 2<sup>nd</sup> mammalian cell culture production line to complete (3 sets of 2x2000L). Totaled 25,500 L
- Southern Taiwan Science Park (STSP) – 150 KL very large-scale mammalian cell culture facility. Over three stages, 50 KL each at 2025/26, 2028, and 2030. Total mammalian capacity to reach 175.5 KL by 2030.

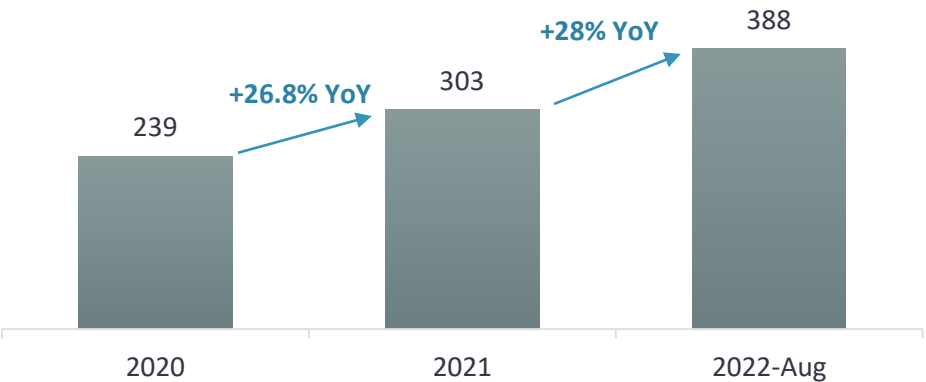
Microbial fermentation capacity – 150 L  
(2024-end to reach 1,500L)



- 2024 Expansion of Zhubei facility Building “B” for microbial fermentation capacity (350 + 1000 L) with 2-3 downstream purification suites; **Total microbial fermentation capacity to reach 1,500 L by 2024**

# Rapid Headcount Growth Over Past Two Years

Number of employees

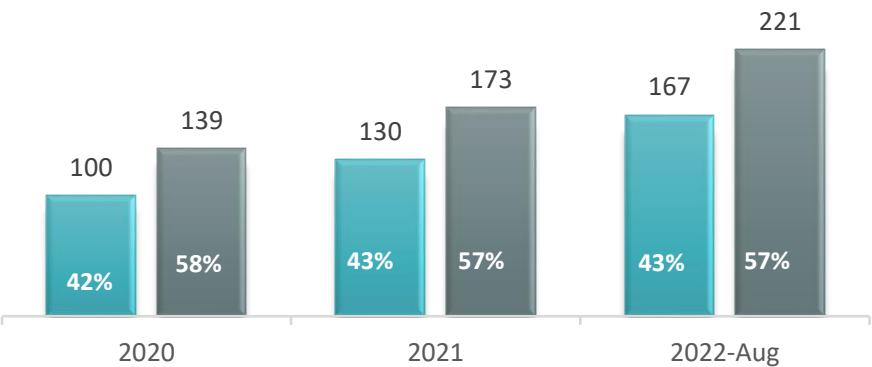


Headcounts increased by 62% over the past 20 months.

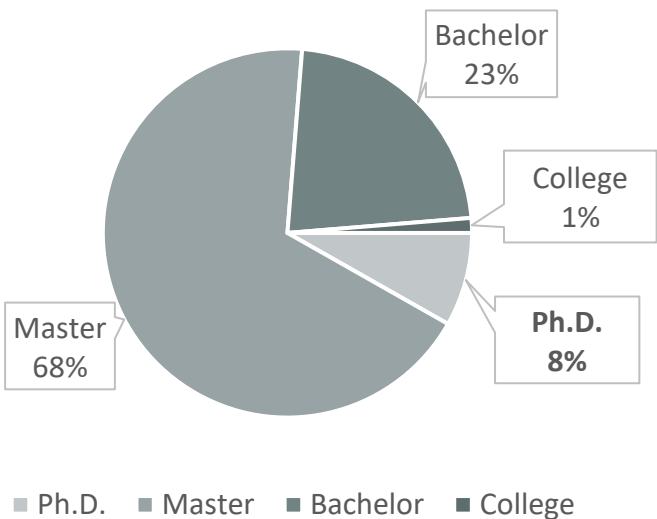
Top 2 increased functions:

- Manufacturing & Technical Operation (MTO) +114%
- Analytical Science & Quality Control (AS&QC) +56.5%

Female Male



Employee Education (2022)



# Future Capacity Planning (Xizhi | Zhubei | STSP)

## Southern Taiwan Science Park (STSP)

150 KL Mammalian Cell Culture Capacity (15,000L x 10)

### **Self-Products**

Mainly for self-products, Biosimilar drug commercial projects

(include EG12014, EG1206A and other self-product market launch after 2026)

### **CDMO Client**

Commercial Projects

**Zhubei Facility** 24,000L Mammalian Cell Culture Capacity (2,000L x 12)

1,350L Microbial fermentation capacity (350L + 1000L)

### **Self-Products**

Biosimilar drug clinical and commercial projects

### **CDMO Client**

PH1 | PH2 | PH3 |  
Commercial Projects

**Xizhi Facility** 1,500L Mammalian Cell Culture Capacity (50L, 200L, 1000L)

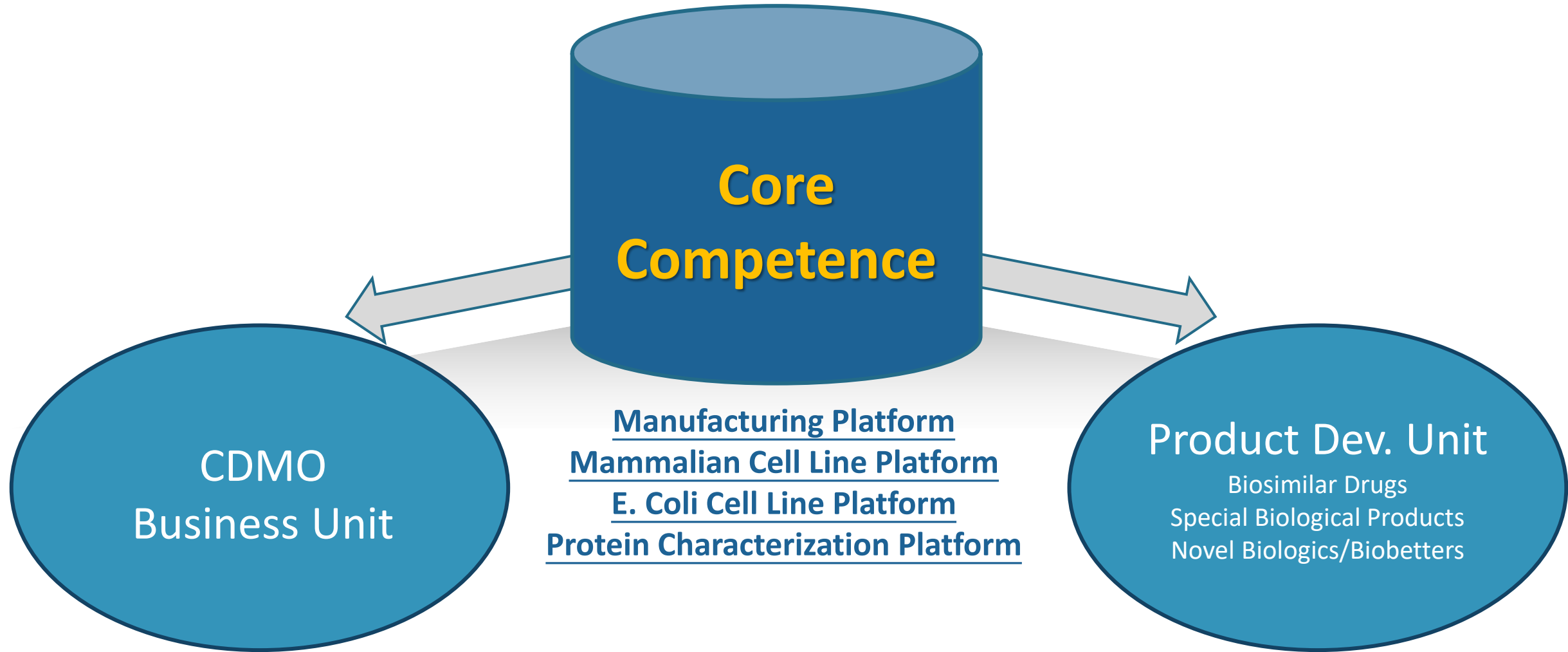
150L Microbial fermentation capacity (30L, 150L)

### **CDMO Client**

Mammalian - R&D | Pre-Clinical | PH1 | PH2 Projects (ready EUA application)  
Microbial – Clinical Projects & Commercial Production Projects



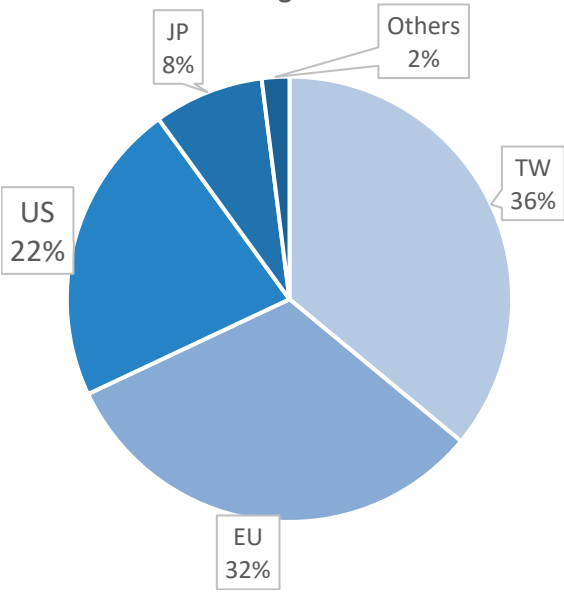
# Business Overview



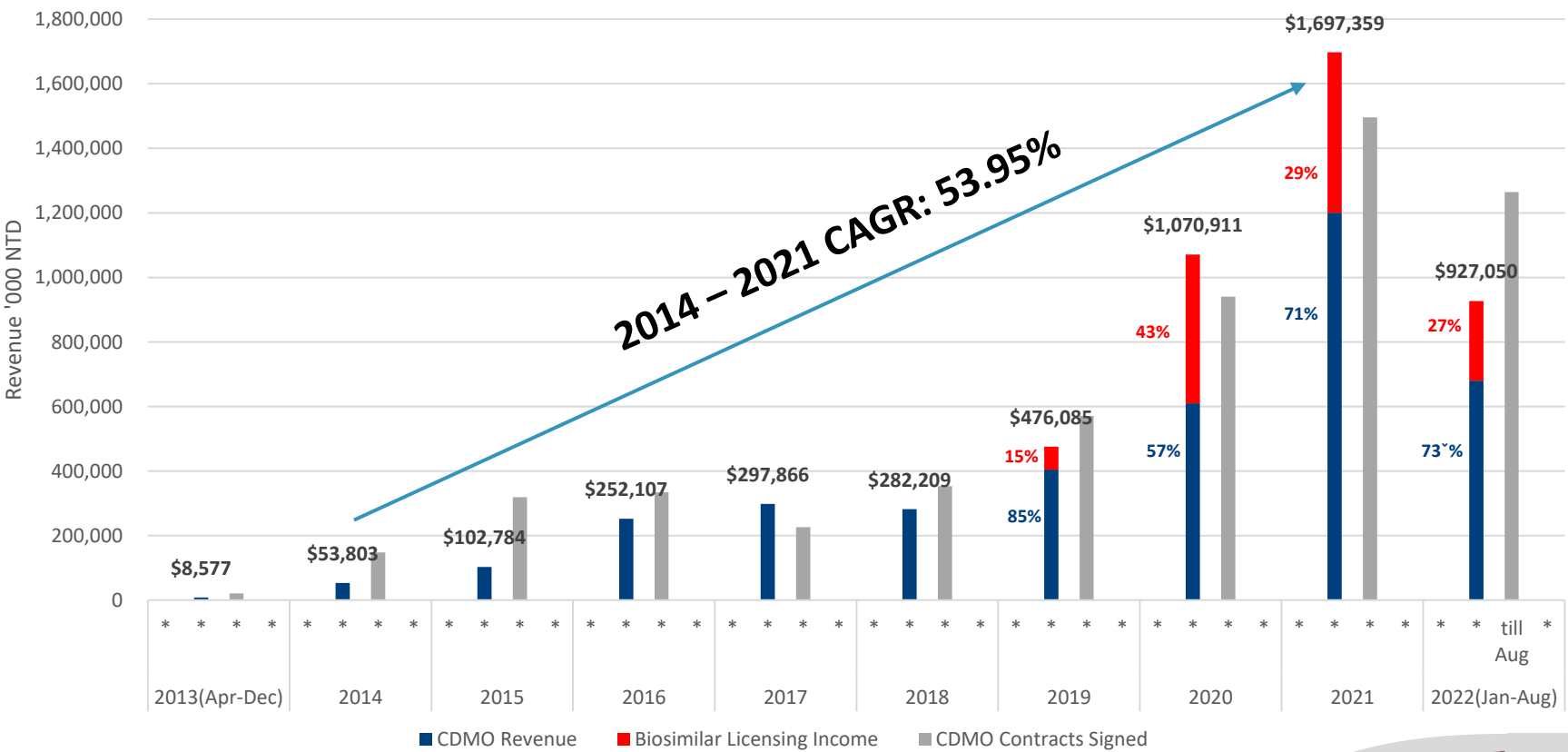
# Revenue Momentum

- ◆ 2022 Jan-Aug CDMO newly signed contracts reaching 84.5% of 2021 full-year contracts
- ◆ Average CDMO projects backlog 2 to 3 years

2021 Total Revenue Break-Down by Region

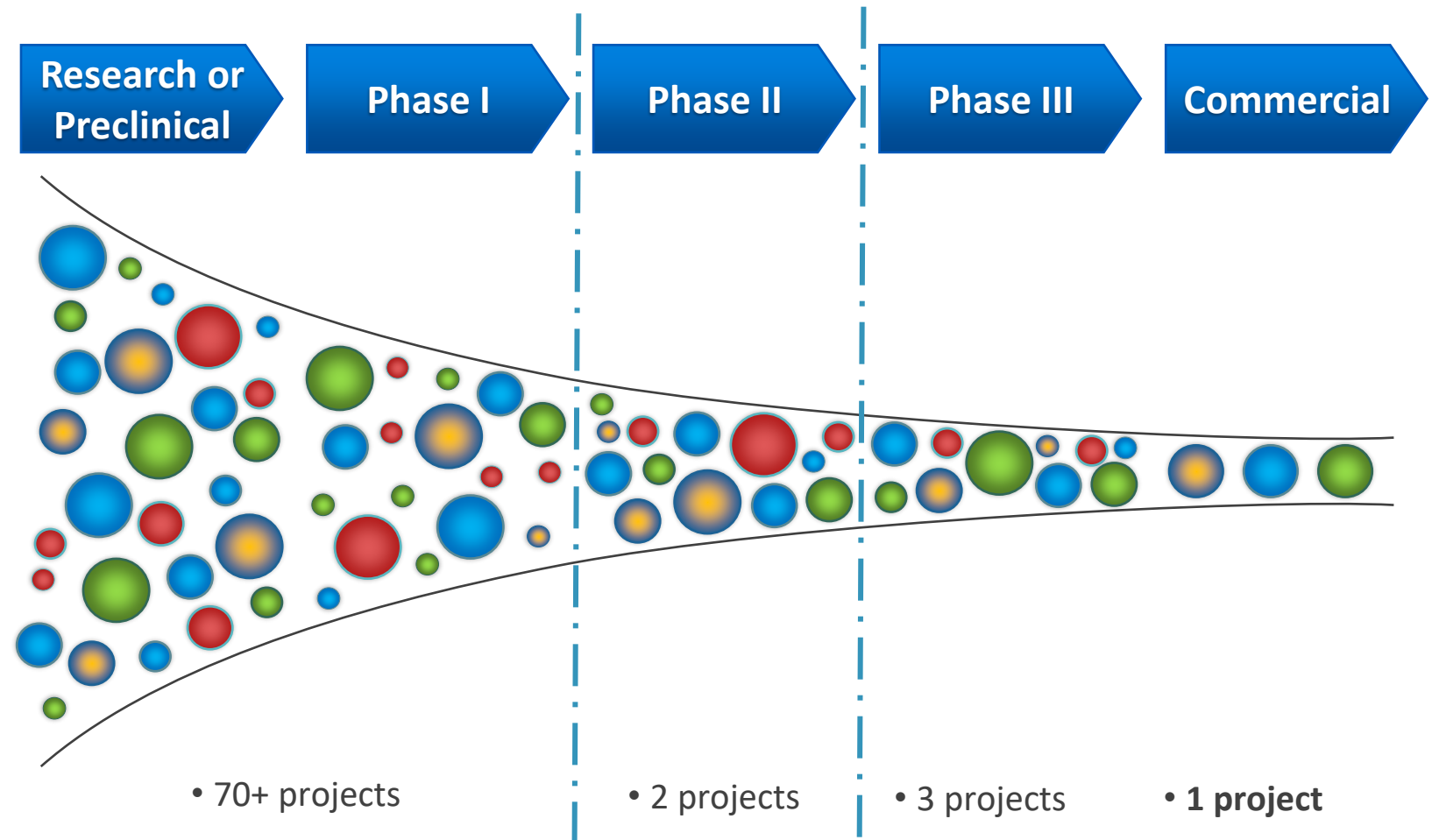


EirGenix Revenue Trend Summary



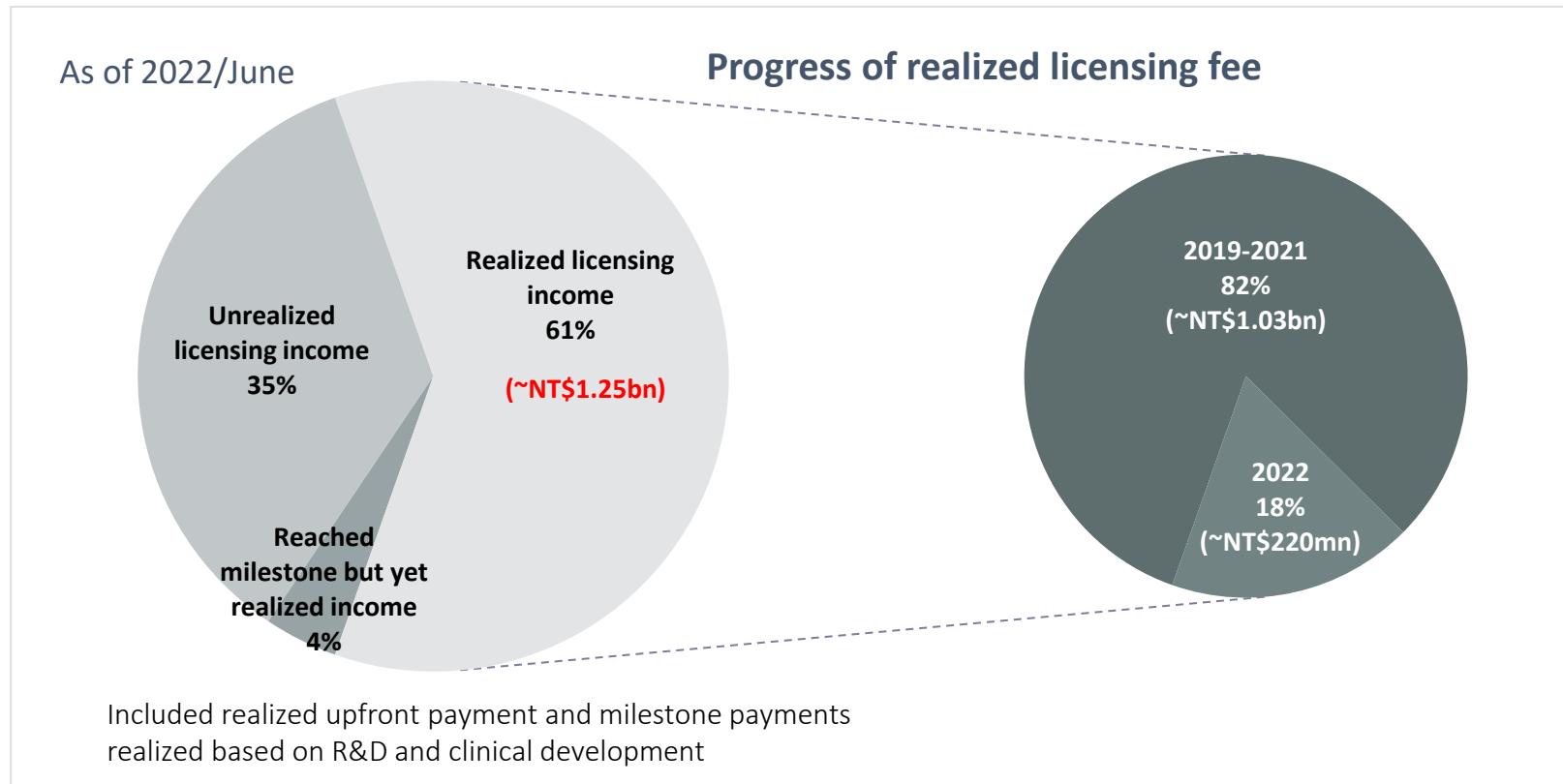
# CDMO Projects & Stages (2020-2021)

- Mammalian & Microbial Dual Expression Systems
- Over 70 CDMO projects (2020-2021)
- 4 late-stage projects with near-term value
- Accelerated CDMO business momentum driven by cumulated experience



# Revenue Momentum (from EG12014 Licensing fee)

- Total licensing fee USD 70mn (Upfront Payment USD 5mn + Milestone USD 65mn)



# Self-Own Product Development Progress

## Broad & diversified product pipeline; unique strategy of Her2 products franchise management

- The 1st own product, Herceptin Biosimilar EG12014 (Herwenda® - Sandoz | Eirguson® - EirGenix)
  - 2019/04 Signed global licensing (excluding Taiwan, Mainland China, Japan, S. Korea and Russia) agreement with **Sandoz AG** for the upfront and milestone payment of USD 70 millions plus the profit sharing of the future sales
  - 2021/03 Global Phase III Clinical Trial met no clinically and meaningful differences standard
  - 2022/6 US FDA finished Zhubei facility inspection, pending for inspection results  
(Due to Covid-19 condition, EMA may follow FDA's results based on the mutual recognition agreement )
  - **Expect to receive marketing licensing approval by 2022-end/early-2023**
- The 2<sup>nd</sup> own product Pertuzumab Biosimilar EG1206A
  - 2022for Phase I PK bio-similarity clinical study from German National Competent Authority /Q1 Submitted Phase 1 clinical (German PEI & EC)
  - 2022/05 Received approval and corresponding Ethic Committee.
  - 2022/08 80% healthy subjects enrolled for PH1 clinical trial





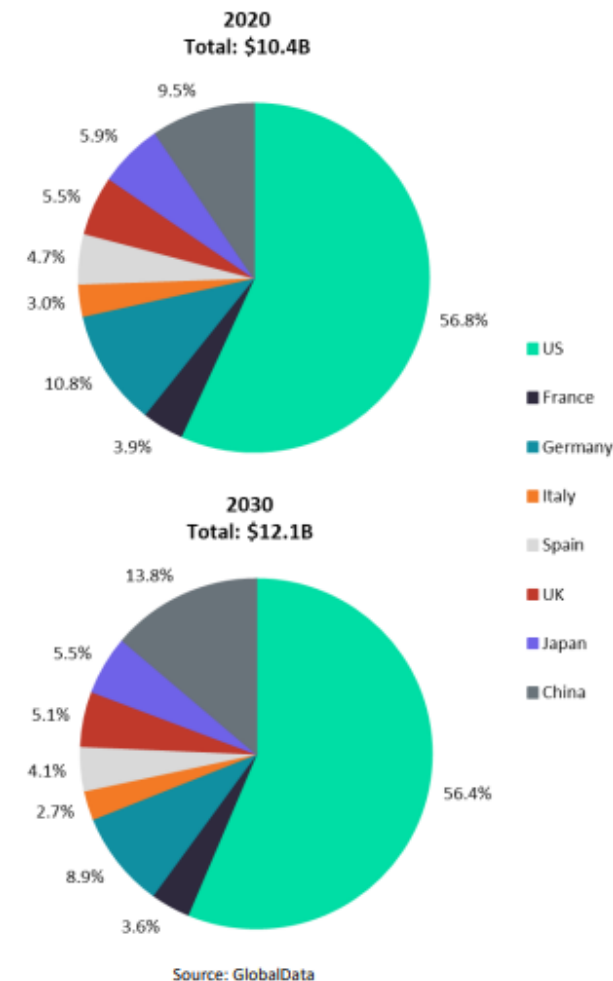
# Why Her2 Family Products?

The combination treatment using trastuzumab + pertuzumab for Her2 positive breast cancer is becoming the trend for standard treatment method.

EirGenix's own pertuzumab (EG1206A) target to be the first two biosimilar drug with global market launch when reference drug patent expires in 2026. Together, it is also expecting to increase the market penetration of EirGenix's trastuzumab (EG12014).

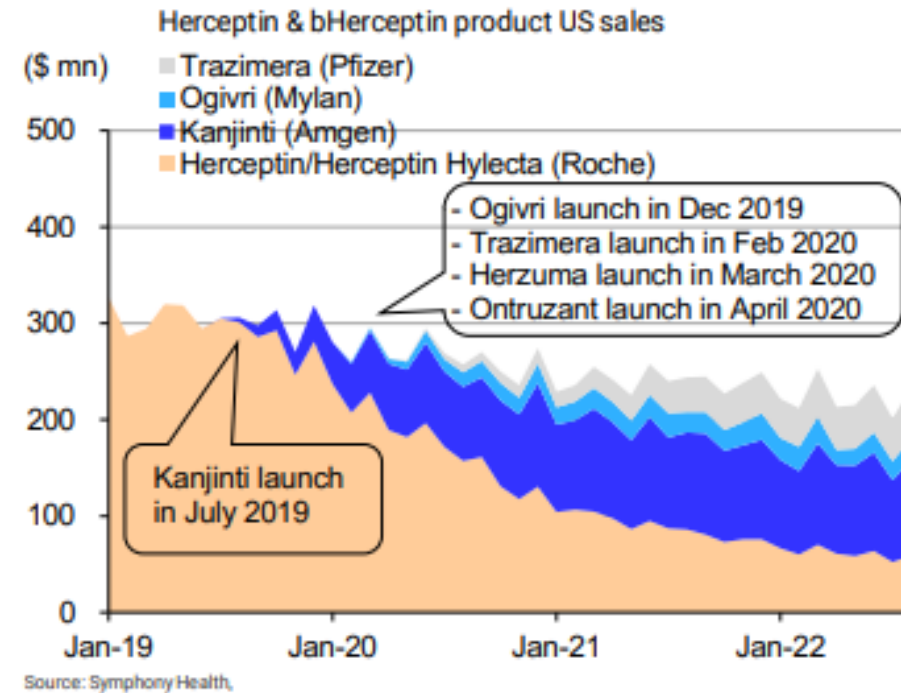
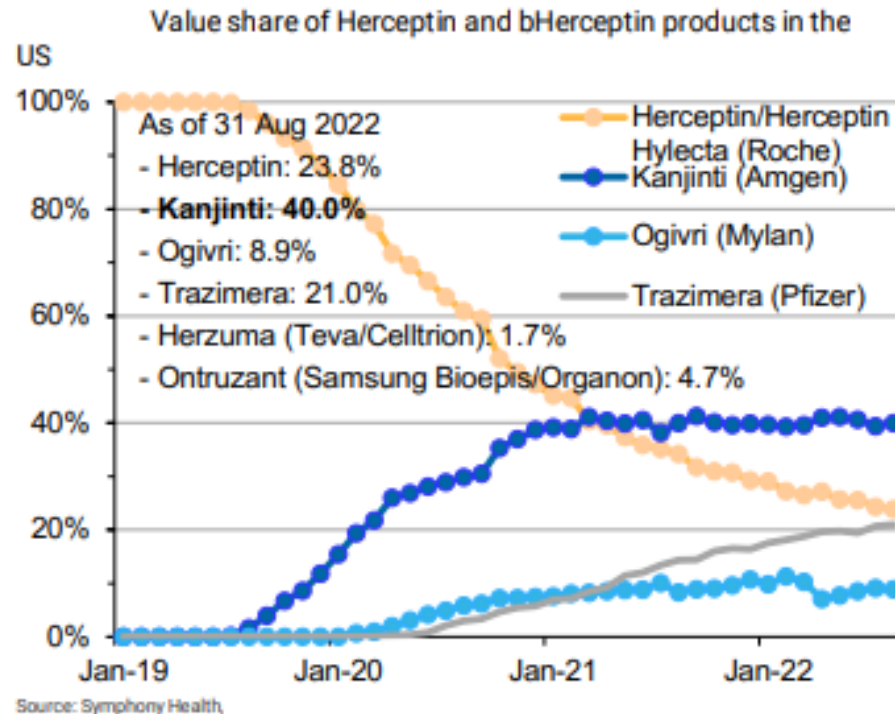
EG has developed the proprietary high concentration SC formulations for trastuzumab. High concentration SC formulation of EG12014 + EG1206A is being developed. The successful development of high concentration SC formulation will further enhance EG's Her2 family products penetration in the market, and it will help EG to further penetrate the Her 2 biosimilar market.

Global (8MM) Sales Forecast by Country for HER2+ Breast Cancer in 2020 and 2030



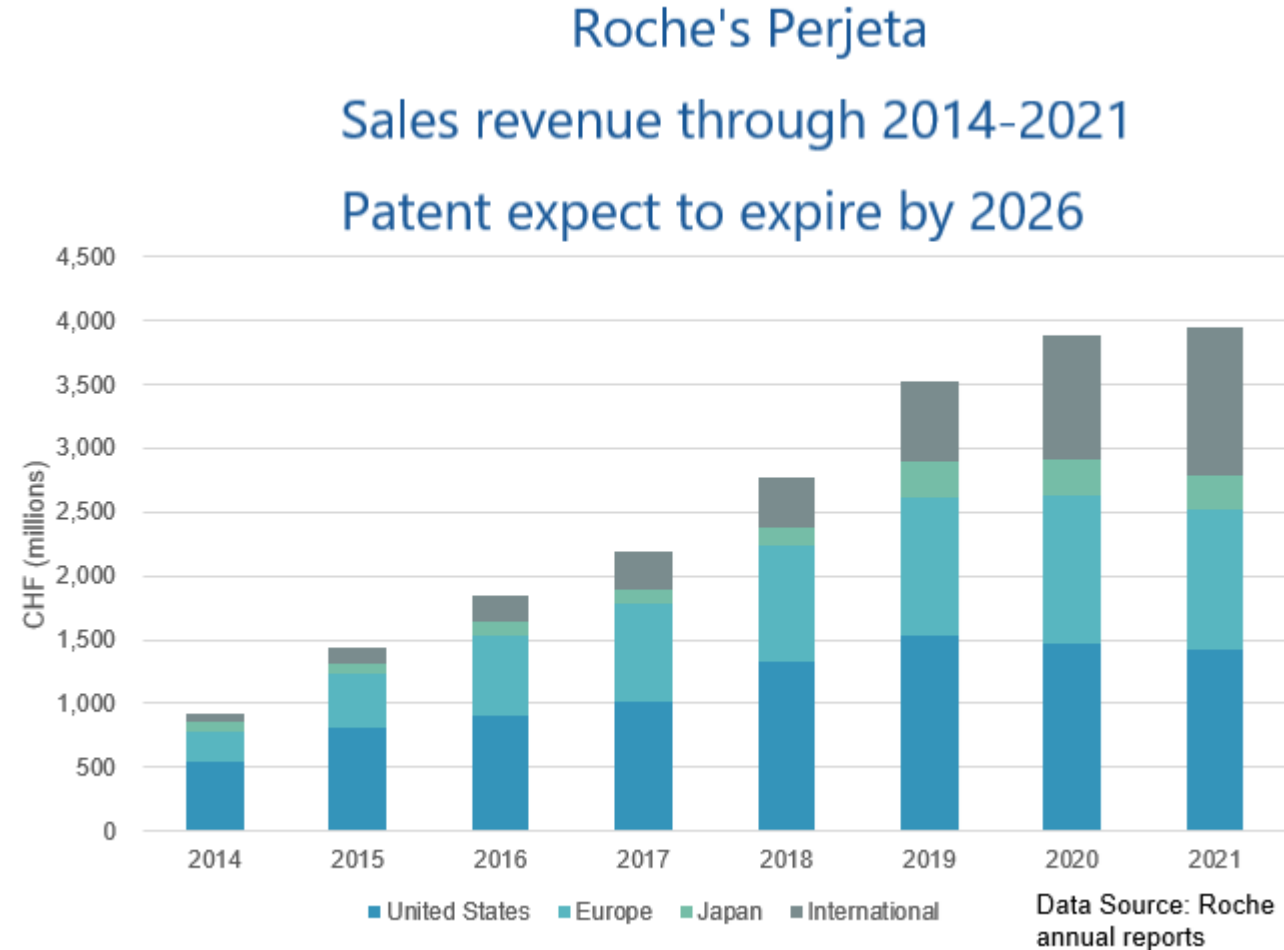
# Reference Drug and Biosimilar Drug Market Share Change After Patent Expired

- Roche's Herceptin® North American market as an example. Biosimilar drugs penetrated over 75% of its market share within three years, after patent expired since 2019.
- Early entry biosimilar drug received marketing license in US (or EU) + Strong global distribution channels to have the advantage of winning larger market share after reference drug patent expired.



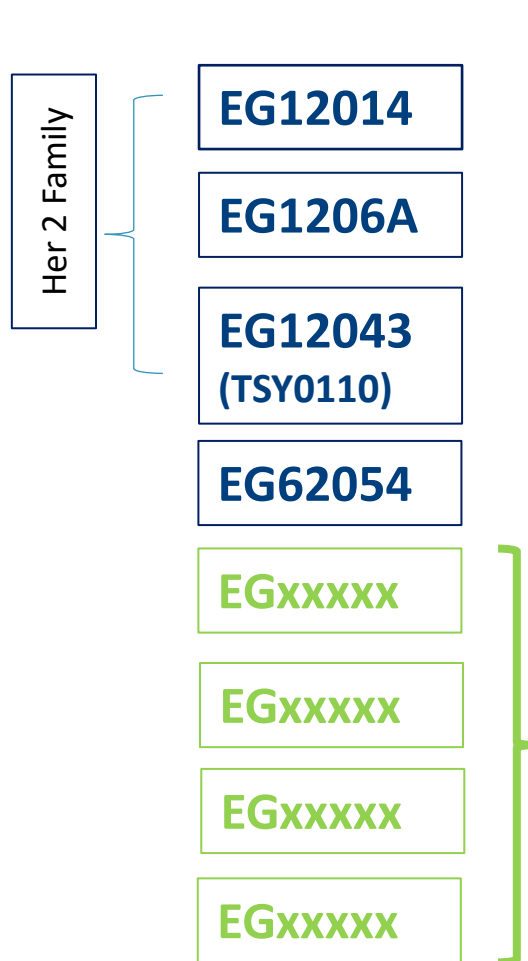
# EirGenix's EG1206A is the Biosimilar drug of Roche's Perjeta

- Perjeta is Roche's another Her2+ monoclonal antibody drug for treating breast cancer
- Perjeta's 2021 sales revenue reached CHF 3.96bn (~US\$ 4.2bn) and yet reaching sales peak
- Presuming biosimilar market value equivalent to 50% of the reference drug market value, which roughly ~US\$2.1bn (based on Perjeta 2021 sales)
- Based on above assumptions, every 10% market penetration expect to contribution US\$210mn sales revenue
- With additional combination therapy treatment using EG12014 , likely to fuel sales momentum for EirGenix's EG12014



# Future Product Pipeline Overview

## Biosimilars



## New Formulations & Drug Delivery for Biosimilars

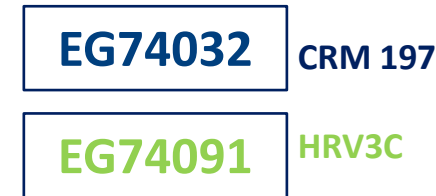


New List to be:

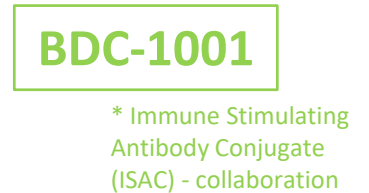
- 1) In-house developed, or
- 2) In-licensed, or
- 3) Potential IO biosimilars development alliance

\*\* Drug development alliance to reduce the high development cost & risks, also shorten market launch time.

## Specialty Biologics



## Me-too/Novel (NCE)



EirGenix expect to launch a new drug product each year after 2026, hence the large-scale commercial production capability (Southern TW Science Park site) becomes very critical.



Q & A

*The health of the humankind  
and Client's Success is Our  
Priority*

