# Goldman Sachs Asia Pacific Healthcare Forum 2022

6589.TWO EirGenix, Inc. FirGenix

www.eirgenix.com

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## **EirGenix**

#### **Profile and USPs**

#### Established Dec. 21, 2012

- 2013-March, Completed acquisition of DCB's Biopharmaceutical Pilot Facility
- 2019-June, IPO on Taiwan Stock Exchange (TPEx Board: 6589.TWO)
- Latest market cap ~USD 1.2bn



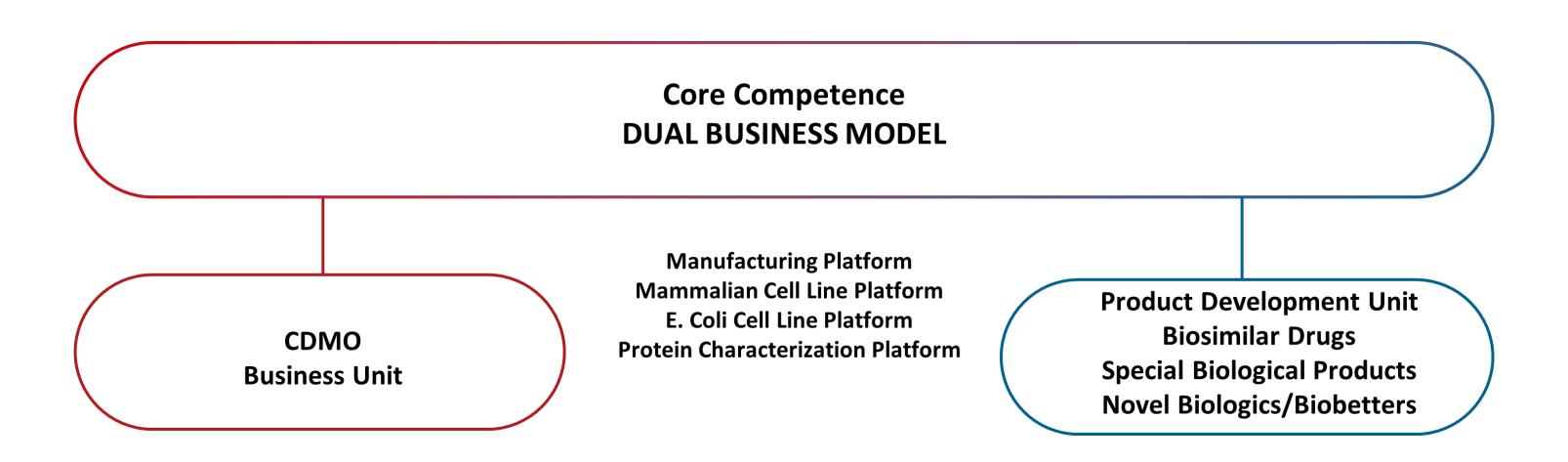
- Founder of Foxconn, Terry Gou
- Government and pan-government investment funds
- Formosa Laboratories (4746.TW)

Rated Top 5% Corporate Governance Evaluation among 800+ listed companies at TPEx in 2021



## **EirGenix**

### **Core Competence**



- Largest CDMO service provider in Taiwan, either by manufacture capacity or CDMO revenue scale
- Target to be the first Taiwan developed Biosimilar drug (EG12014, Trastuzumab Biosimilar candidate) with global launch, follow by a series of Her2 family product pipeline launch through 2030 and beyond



# **EirGenix**

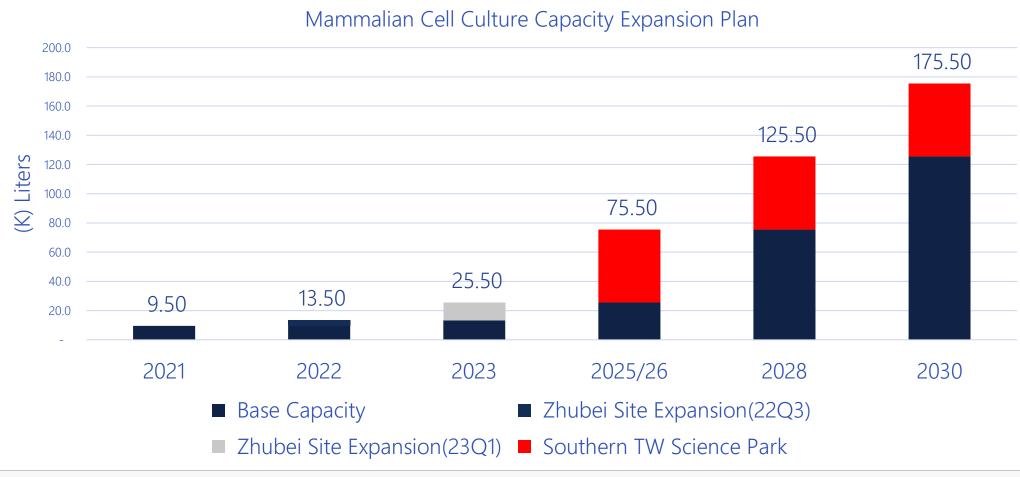
## Office, Facilities & Business Partners



# Capacity and Expansion Schedule

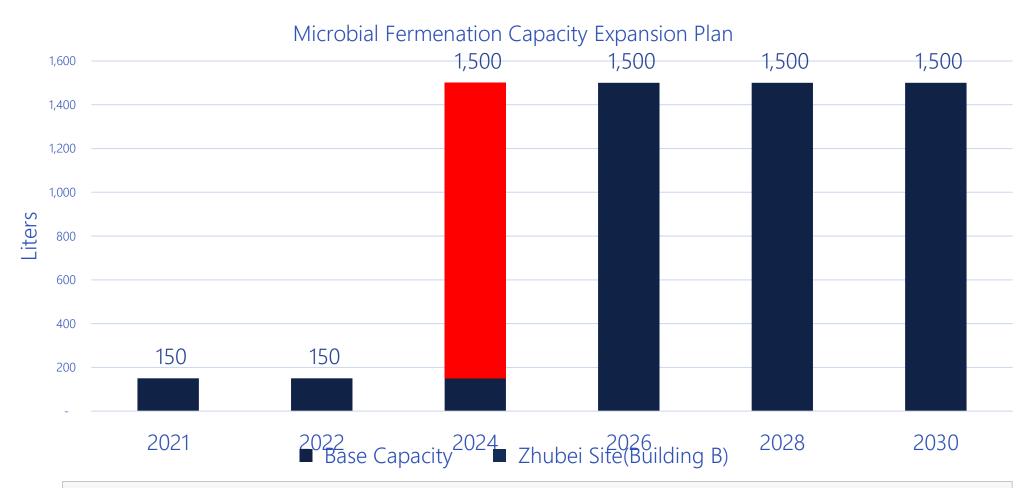
(Xizhi | Zhubei | Kaohsiung STSP)

# Mammalian Cell Culture Capacity 13,500 L (2023 Q1to 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 2nd 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



Capacity and Expansion Schedule

# Future Capacity Usage Planning

(Xizhi | Zhubei | Kaohsiung STSP)

# Southern Taiwan Science Park (STSP)

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

#### **Self-Products**

Mainly for selfproducts, 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**

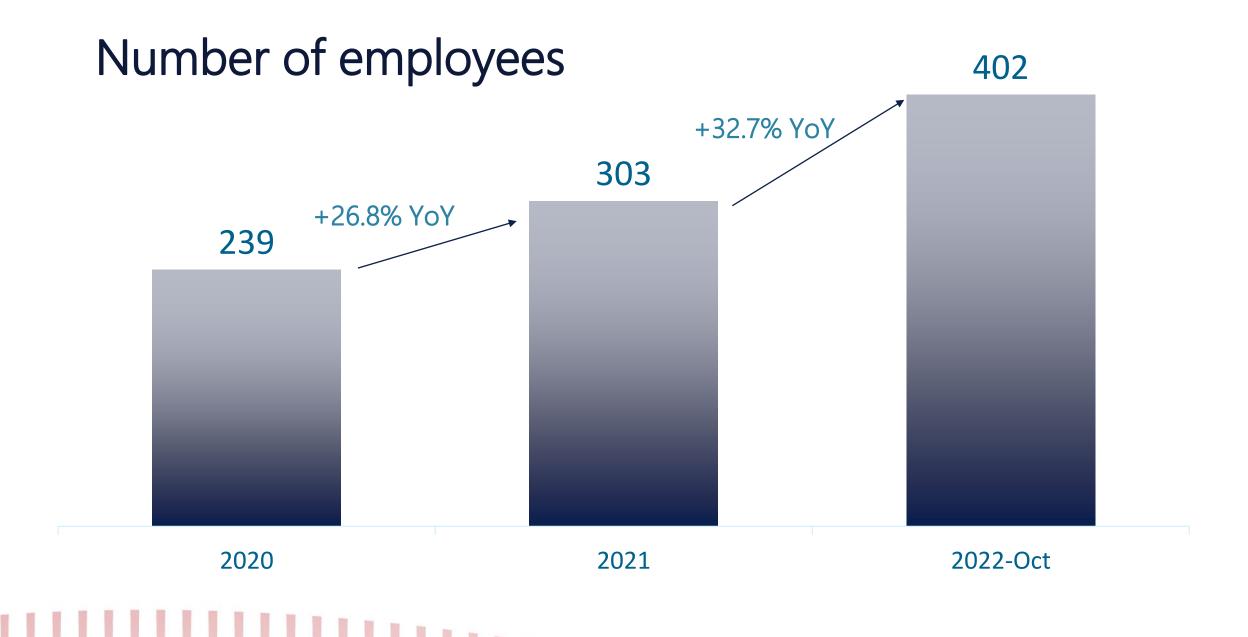
Mammalian - R&D | Pre-Clinical | PH1 | PH2 Projects (ready EUA application)

Microbial – Clinical Projects & Commercial Production Projects



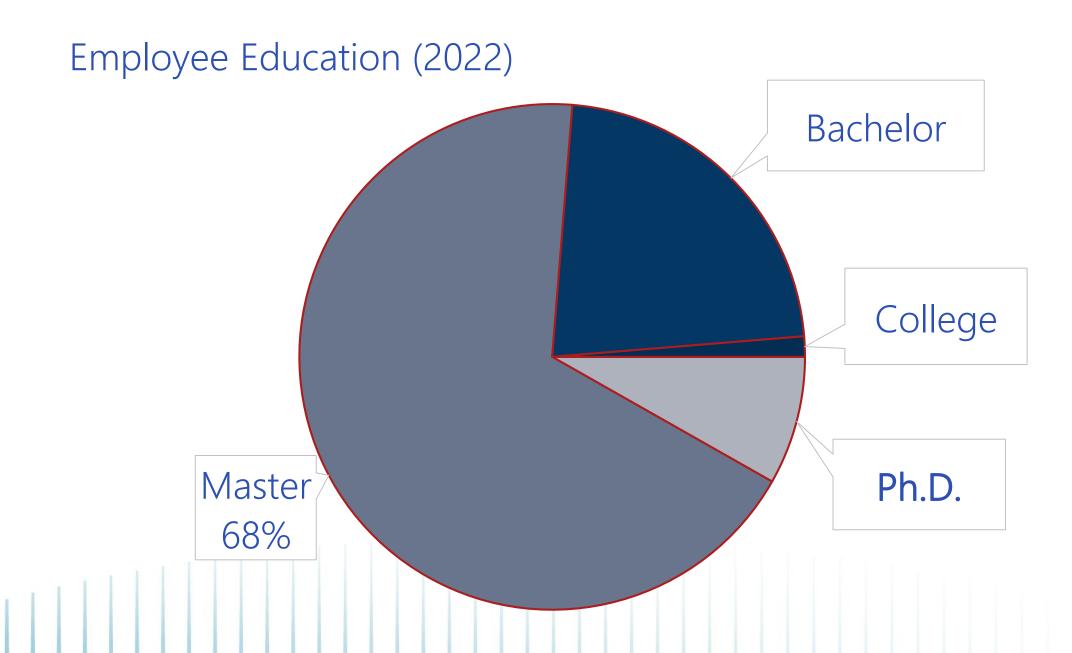
# Talent Pool

#### **Headcount Growth**



Headcounts increased by 68% over the past 22 months. Top 2 increased functions:

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





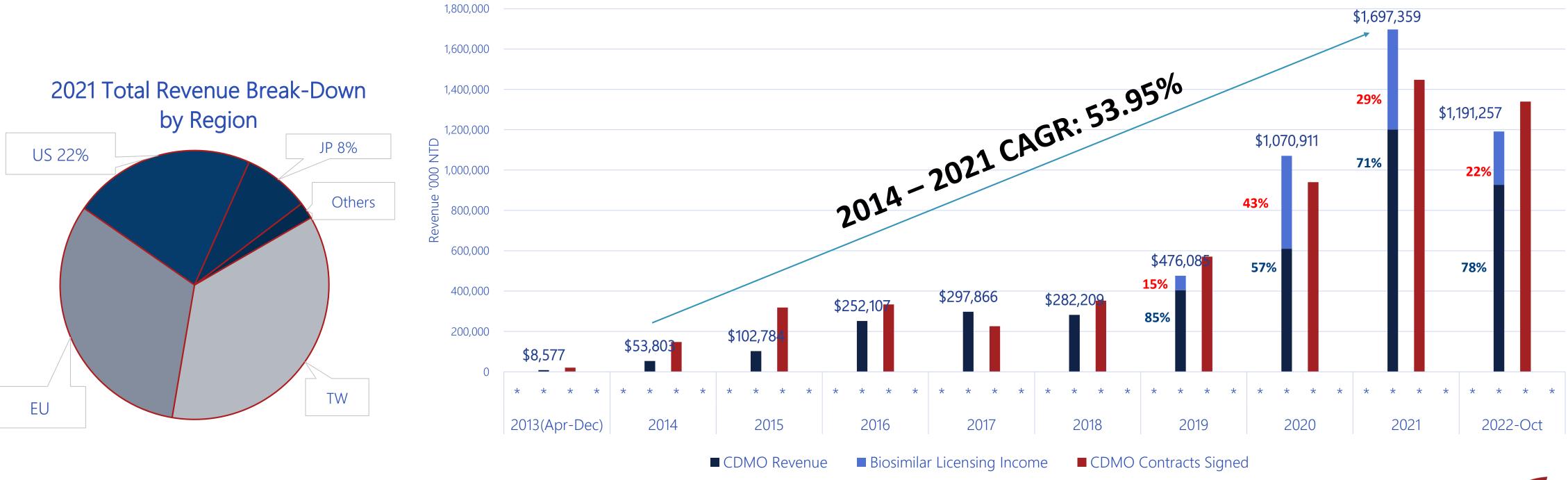
Headcount Growth

# Revenue

#### **Growth Momentum**

- ◆ 2022 Jan-Oct CDMO newly signed contracts reaching 92.5% of 2021 full-year contracts
- Average CDMO projects backlog 1.5 to 2 years

#### EirGenix Revenue Trend Summary

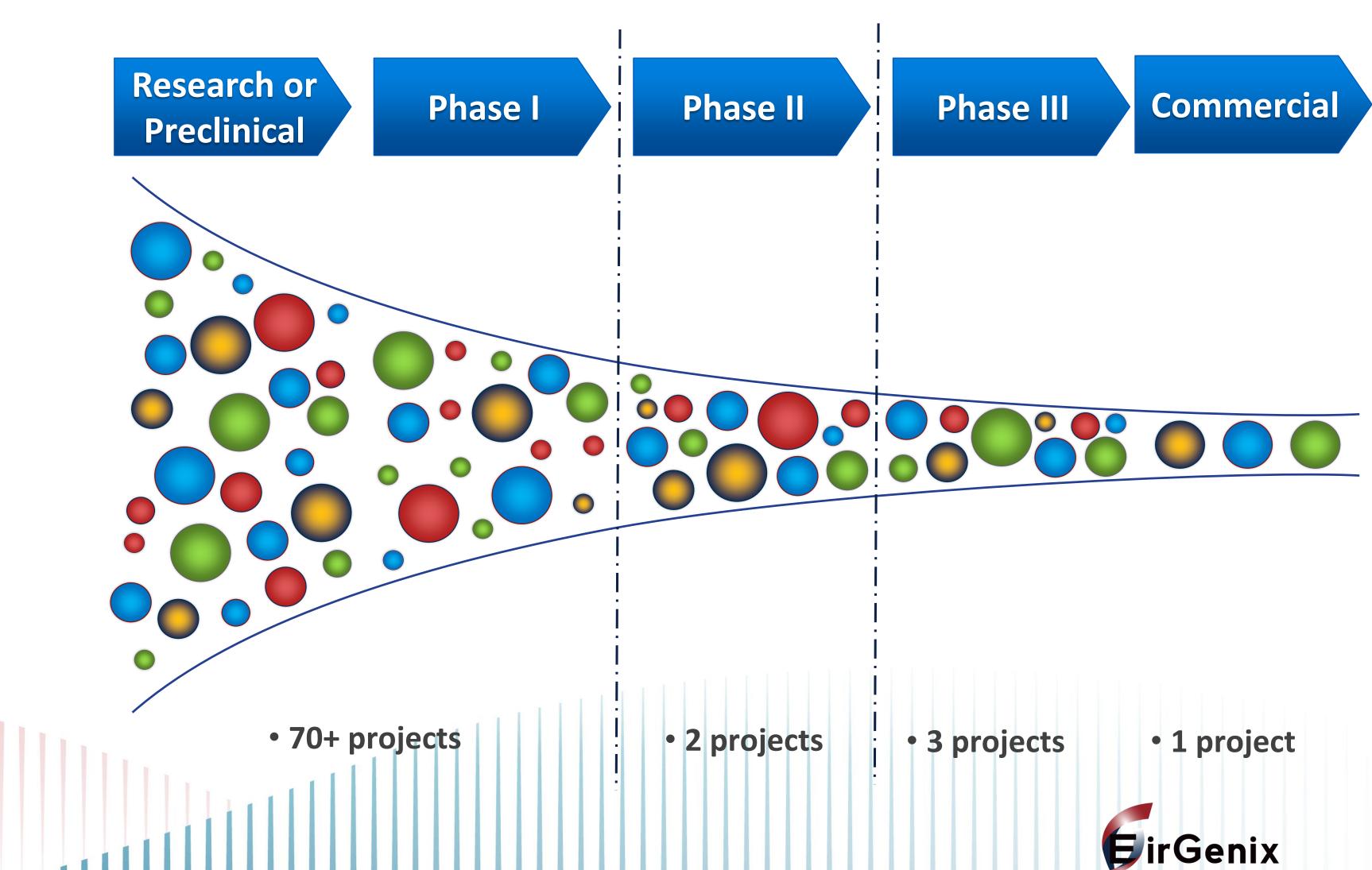




# CDMO

#### **Project Pipeline (2020-2021)**

- Mammalian & Microbial Dual Expression Systems
- Over 70 CDMO projects in 2020-2021
   (over 40 new projects added in 2022)
- 4 late-stage projects with near-term value
- Accelerated CDMO business momentum driven by cumulated experience



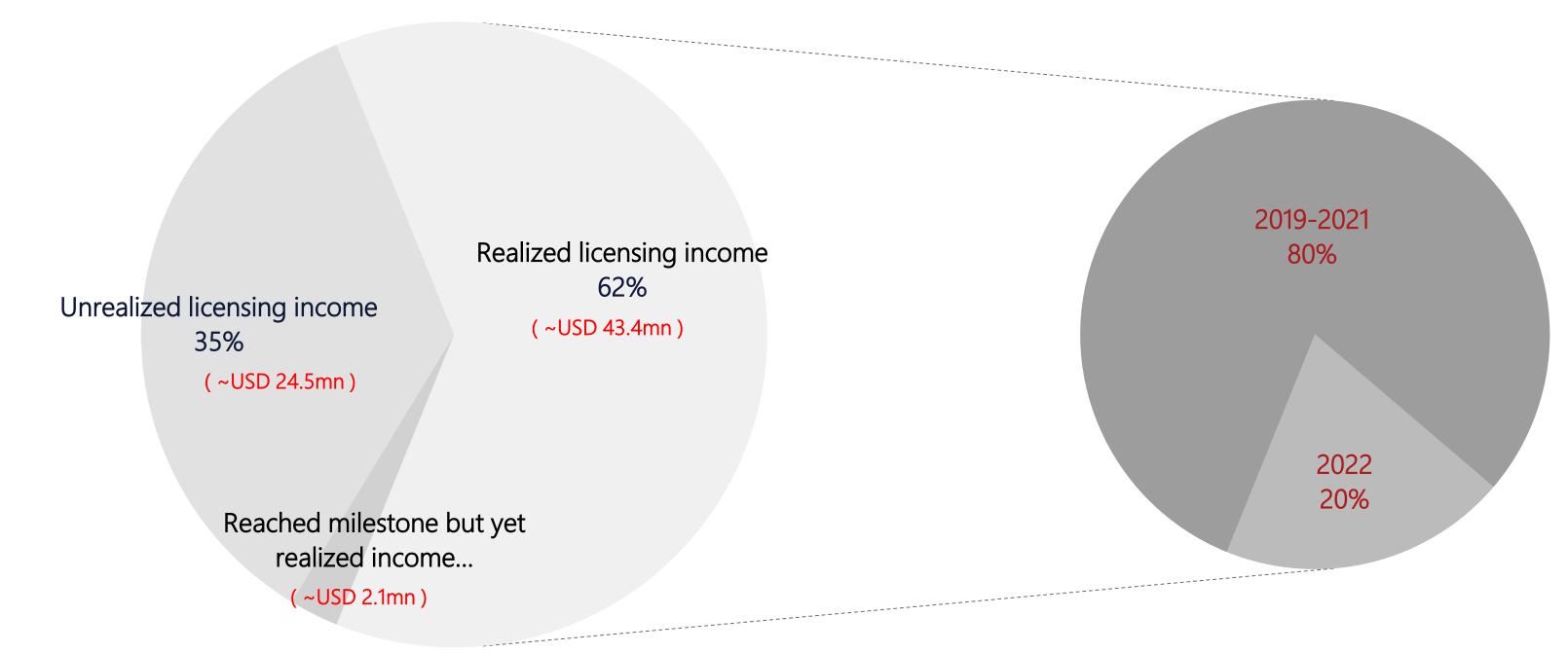


# **Product**

# Licensing Revenue Progress (EG12014 with Sandoz)

As of 2022/Sept

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

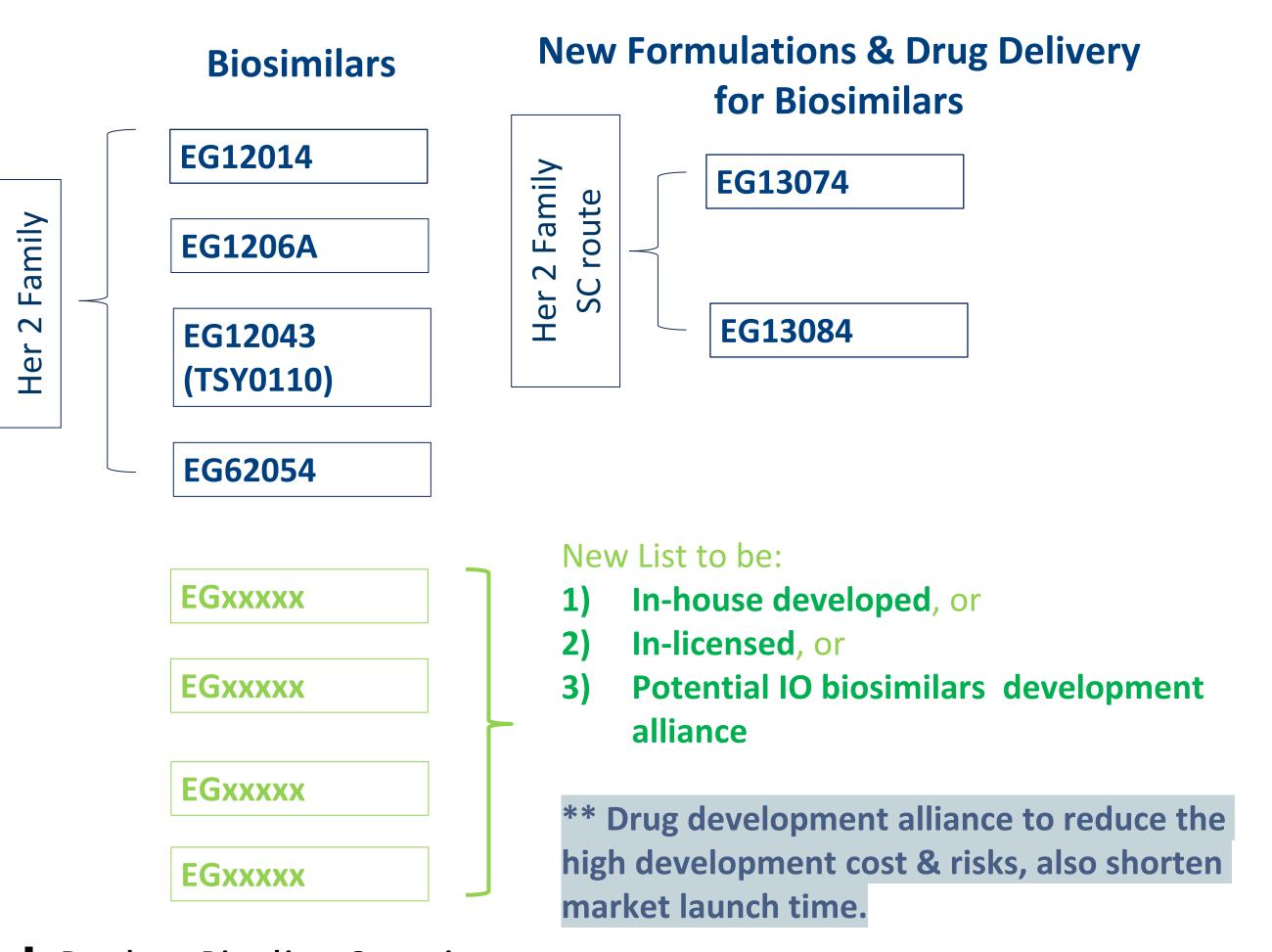


Included realized upfront payment and milestone payments realized based on R&D and clinical development



# **Products in Development**

#### **Pipeline Overview**



**Specialty Biologics** 

EG74032 CRM 197

EG74091 HRV3C

Me-too/Novel (NCE)

**BDC-1001** 

\* Immune Stimulating Antibody Conjugate (ISAC) - collaboration

**F**irGenix

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

# **The First Product**

Trastuzumab Biosimilar - EG12014 (HERWENDA® - Sandoz | EIRGASUN® - EirGenix)

| 2019-Apr, 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 million, plus the profit sharing of the future global sales. EirGenix will be in charge of the product manufacturing.

| 2021-Mar, Global Phase III Clinical Trial met no clinically and meaningful differences standard

2021-Dec, Submitted both BLA in US and MAA in EU

2022-June, US FDA completed Zhubei manufacture facility inspection

**2022-12-17, US FDA PDUFA Date** 

Expect EU EMA MAA result in 1H-2023

| Target to obtain marketing licenses in US, EU and TW in 2023



# **The Second Product**

#### Pertuzumab Biosimilar - EG1206A

2022-Jan, Submitted Phase 1 clinical (German PEI & EC)

| 2022-May, Received approval for Phase I PK bio-similarity clinical study from German National Competent Authority and corresponding Ethic Committee

| 2022-Oct, 100% healthy subjects fully enrolled for PH1 clinical trial

| Aim to complete PH1 clinical trial in 1H-2023

| Targeting for market launch in 2026 (aim for the first two biosimilar drug with global launch), when the reference drug, Roche's Perjeta, patent expire



# Manufacturing And Development Partner Project

Kadcyla Biosimilar - EG12043 (TSY-0110)

| 2022-Mar, EirGenix and Formosa Pharmaceuticals establish a co-development alliance to develop EG12043 / TSY-0110 (Ado-Trastuzumab Emtansine Biosimilar) For HER2-Positive Breast Cancer

| EG12043 (TSY-0110) is a biosimilar of Antibody-Drug Conjugate (ADC), ado-trastuzumab emtansine (Kadcyla®)

| EG12043 (TSY-0110) aims to be the first-launched biosimilar of Kadcyla

| EG12043 (TSY-0110) is in late-preclinical development stages, planning for CTA filing in 1H-2023



## **Product Portfolio**

### Why Her2 Family Products?

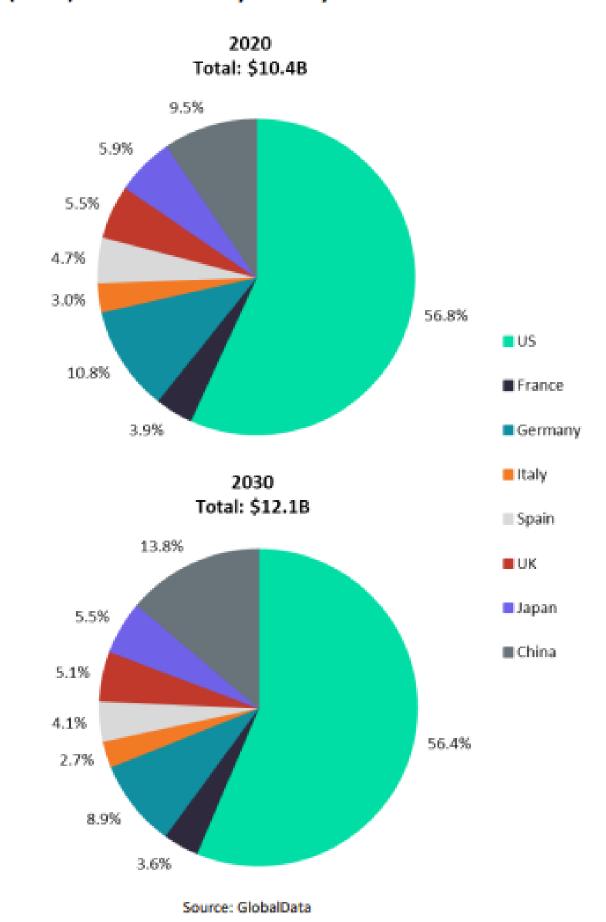
#### **Combination Treatment**

Using the combination of trastuzumab + pertuzumab to treat Her 2 positive metastatic breast cancer (MBC) is a standard procedure, and it also becomes a trend to use the combination therapy for treating early breast cancer (EBC)

# Timing

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

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



#### **Next Gen Product - SC**

EirGenix 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.



# End of the Presentation

Q & A

