41st Annual J.P. Morgan Healthcare Conference

EirGenix, Inc. 6589.TWO

Lee-Cheng (LC) Liu, PhD Founder, Chairman & President



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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



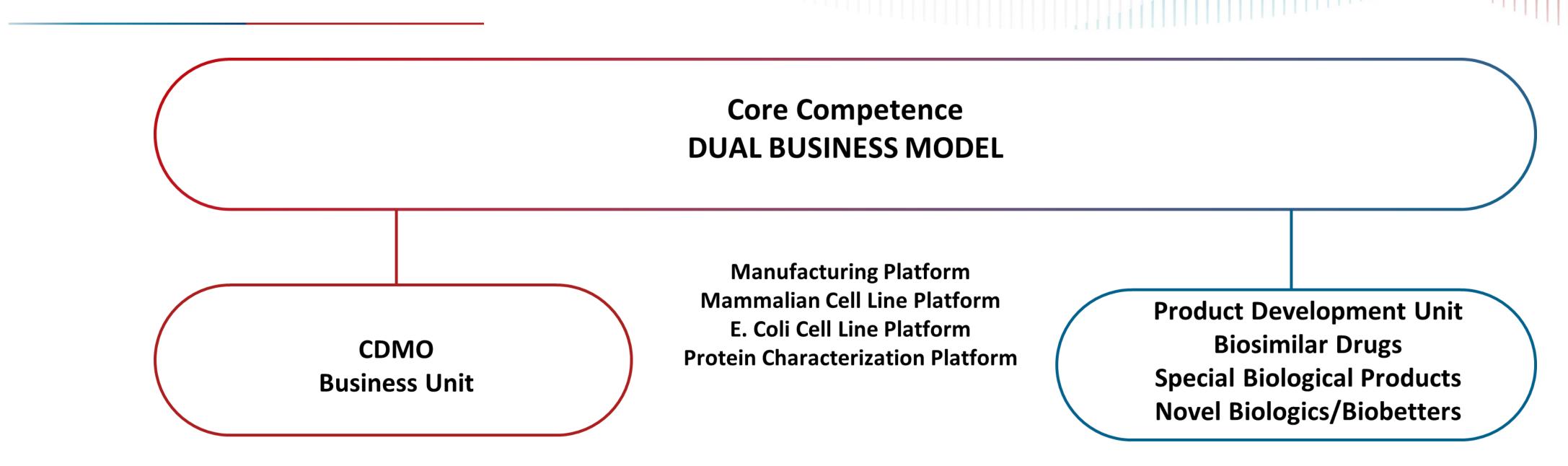
- Founder of Foxconn, Terry Gou
- Government and pan-government investment funds
- Formosa Laboratories (4746.TW), and other initial investors

Honored to be rated Top 5% Corporate Governance Evaluation in 2021, among over 800 listed companies at TPEx Board, and this is only the second year after EirGenix's IPO.



EirGenix

Core Competence | Dual Business Model

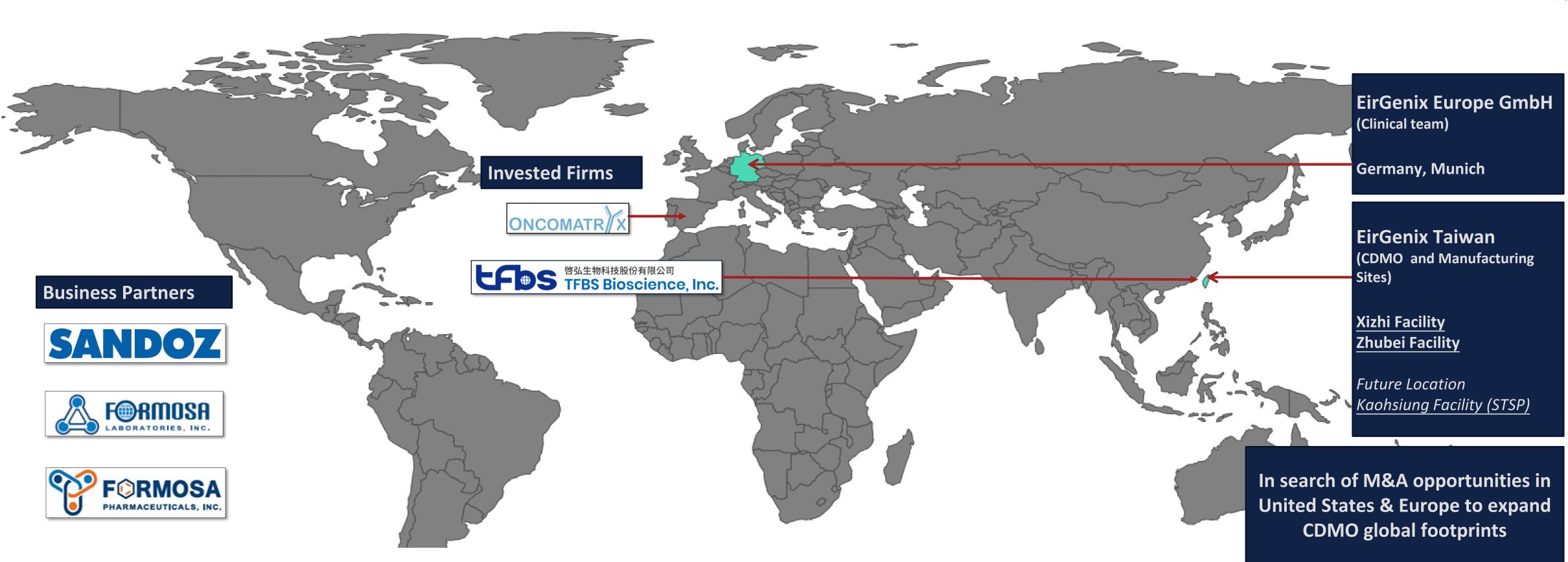


- EirGenix is the largest CDMO service provider in Taiwan, either by manufacture capacity or CDMO revenue scale
- Target to be the first Taiwan developed Biosimilar drug (EG12014, Trastuzumab Biosimilar candidate) with global launch, follow by a series of Her2 family product pipeline launch through 2030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



EirGenix

Office, Facilities & Business Partners



Office, Facilities & Business Partners

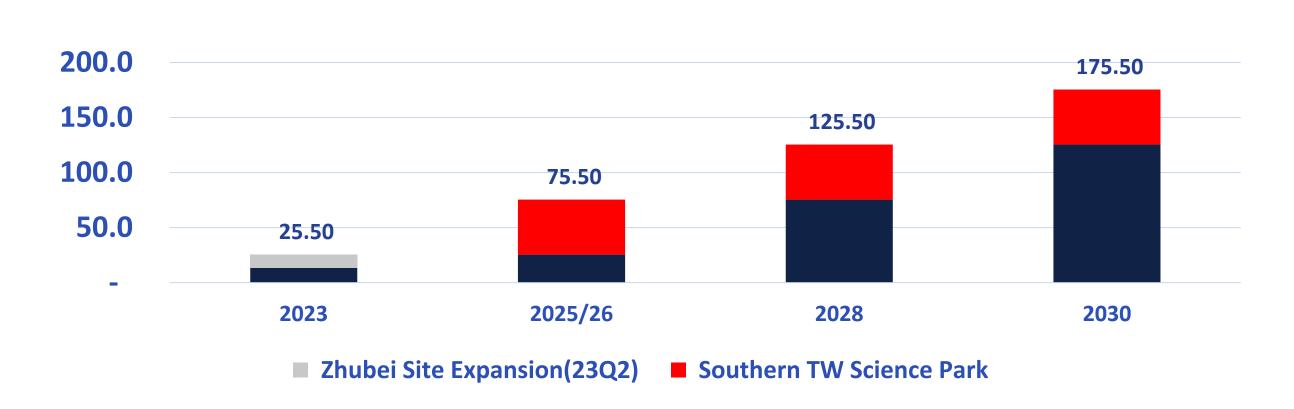


Capacity and Expansion Schedule

(Xizhi | Zhubei | Kaohsiung STSP)

Mammalian Cell Culture Capacity 13,500 L (2023 Q2 to reach 25,500 L)

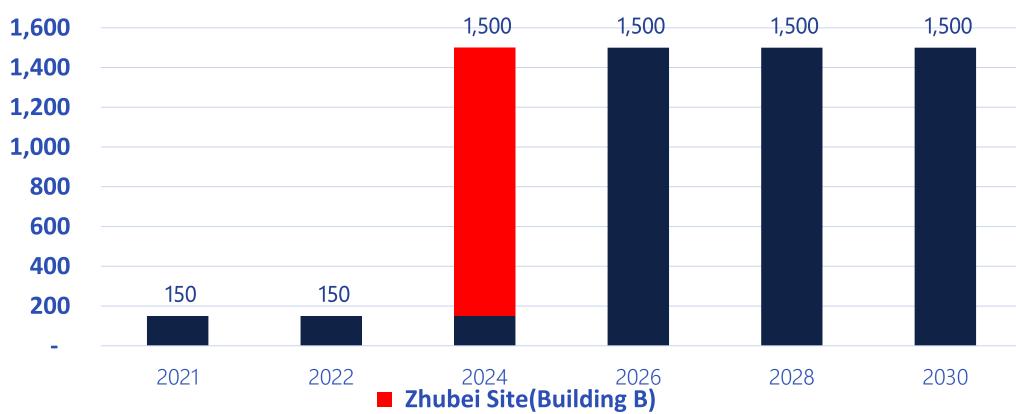
Mammalian Cell Culture Capacity Expansion Plan (Thousand Liters)



- 2019/Q1 The first large scale mammalian commercial production in the Zhubei facility on stream
- 2023/Q2 The 2nd mammalian cell culture production line to complete at Zhubei facility (Additional 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 in 2026, 2028, and 2030. Total mammalian capacity to reach 175 KL by 2030.

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

Microbial Fermentation Capacity Expansion Plan (Liters)



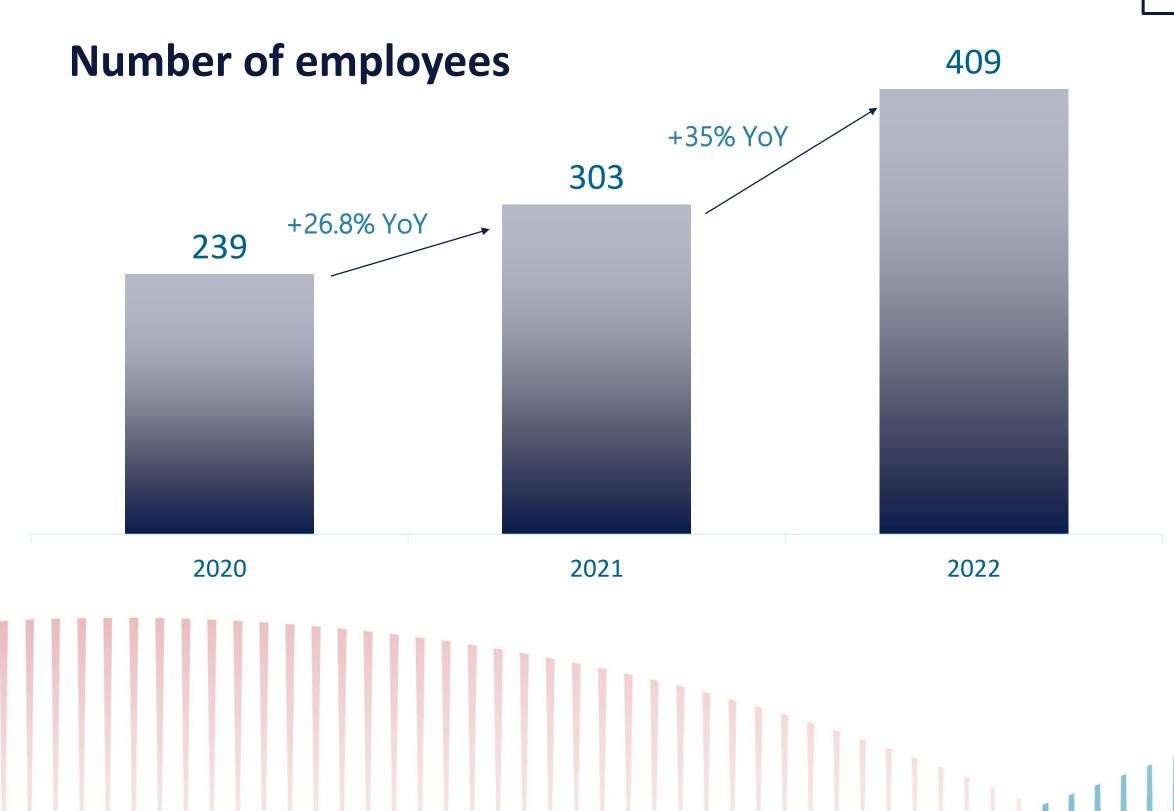
- 2024 Expansion of Zhubei facility Building "B" for microbial fermentation capacity (350 + 1000 L) with 2-3 downstream purification suites;
- Total microbial fermentation capacity to reach 1,500 L by 2024-end



Talent Pool

Headcount Growth

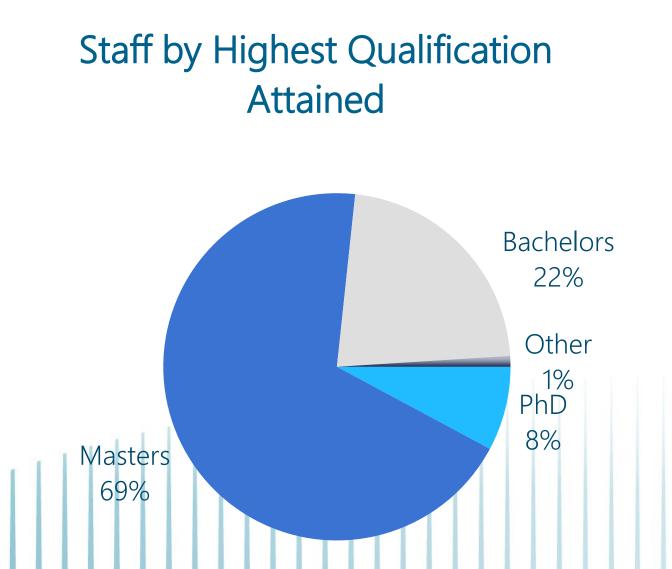
Headcount Growth

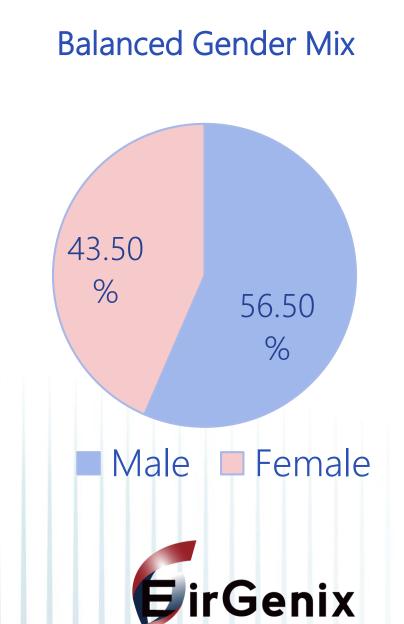


Headcounts grew by 71% over the past two years followed by CDMO business expansion and upcoming biosimilar product global launch. Top 2 increased functions in:

- Manufacturing & Technical Operation (MTO)
- Analytical Science & Quality Control (AS&QC)

EirGenix has highly qualified and educated talent pool with 77% Masters and PhDs. Also is a gender balance work environment.

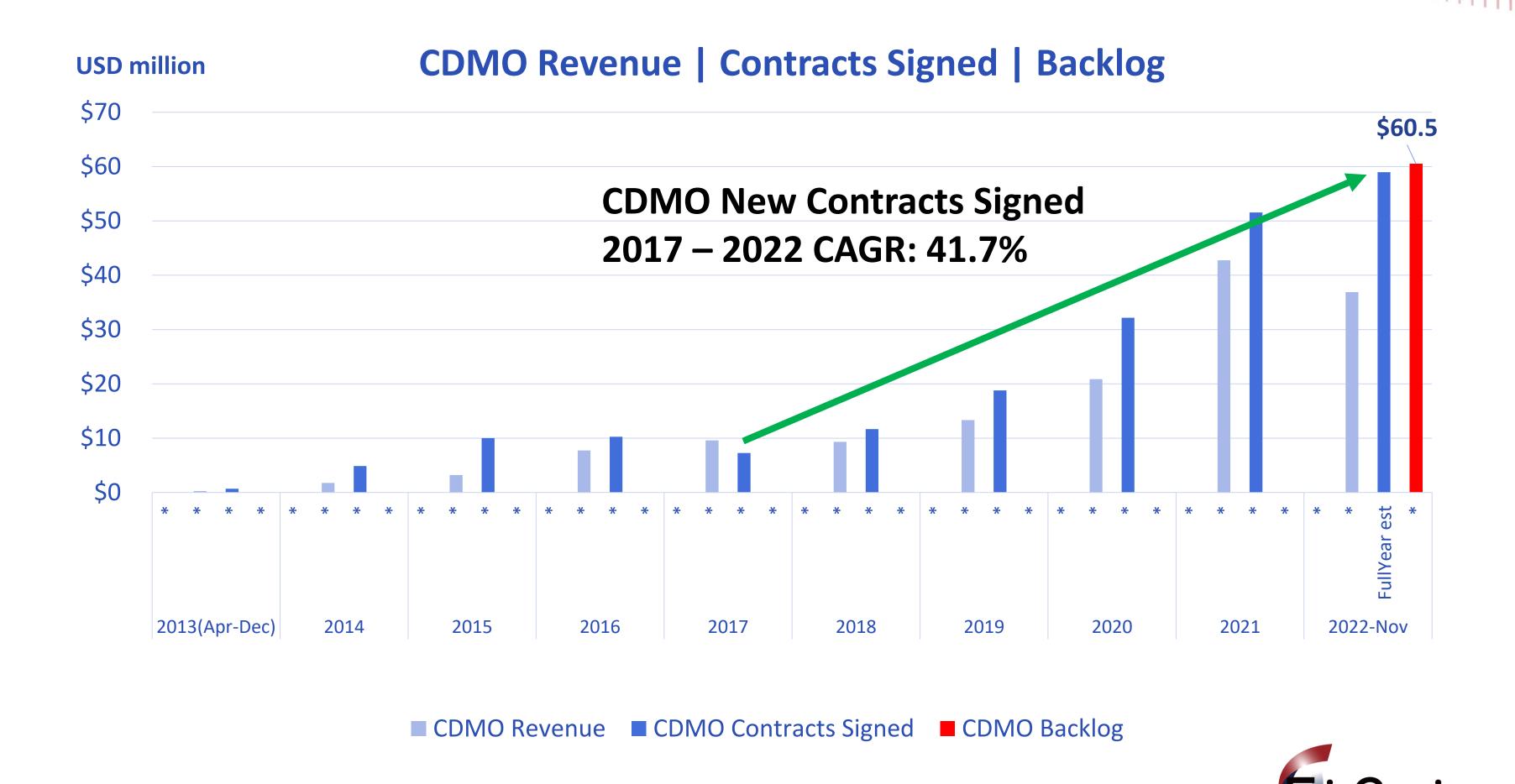




CDMO Business

Strong CDMO Order Growth

- 2022 Full year CDMO
 new contracts signed
 reaching USD 59mn, up
 14%YoY (USD term).
 With 2017 to 2022
 compound annual
 growth rate 41.7%.
- Estimate USD 60.5mn
 order project backlog to
 complete/realize over
 the next two years.
- Average CDMO projects backlog 1.5 to 2 years





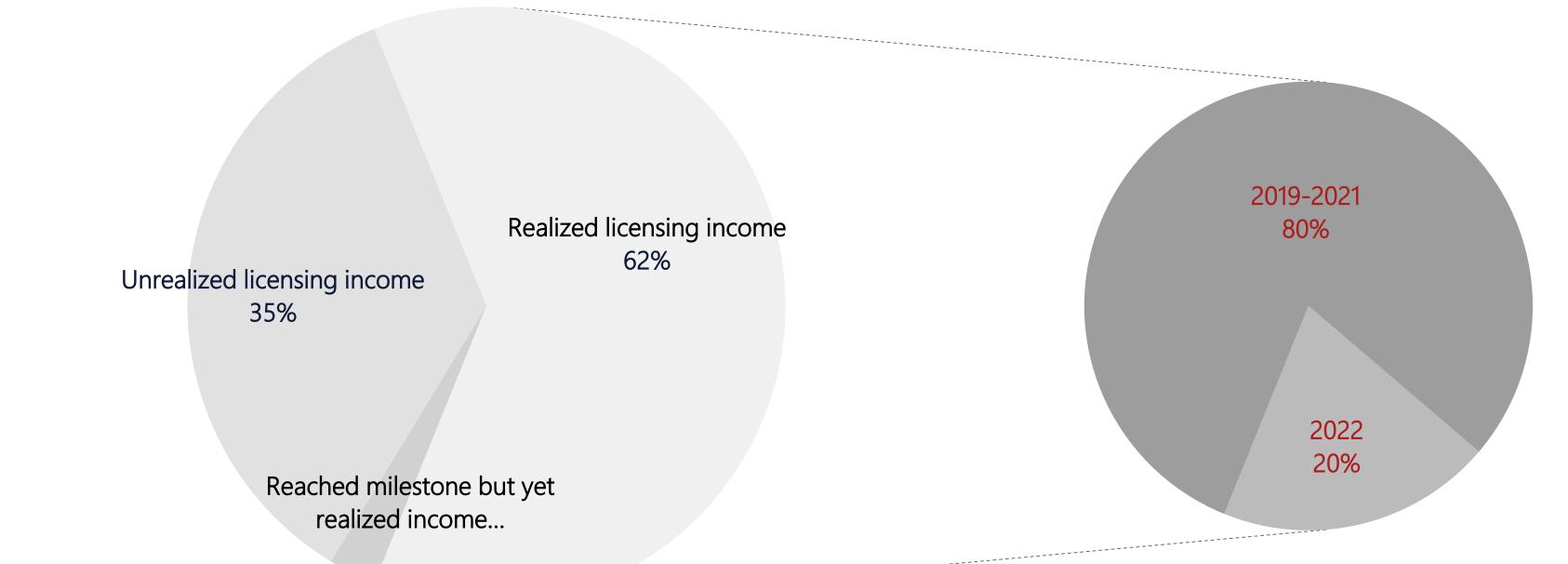
Product

Licensing Revenue Progress (EG12014 with Sandoz)

- The first product EG12014 (Trastuzumab Biosimilar) licensed to Sandoz in 2019 for USD 70mn.
- As of Sept 2022, ~USD
 43.4mn (62%) was realized,
 and ~USD 2.1mn (3%)
 reached milestone but yet
 realized.
- Still USD 24.5mn (35%) of the licensing fee to be realized, following the milestones such as global marketing license approvals.
 Product Licensing Revenue Progress

As of 2022/Sept

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



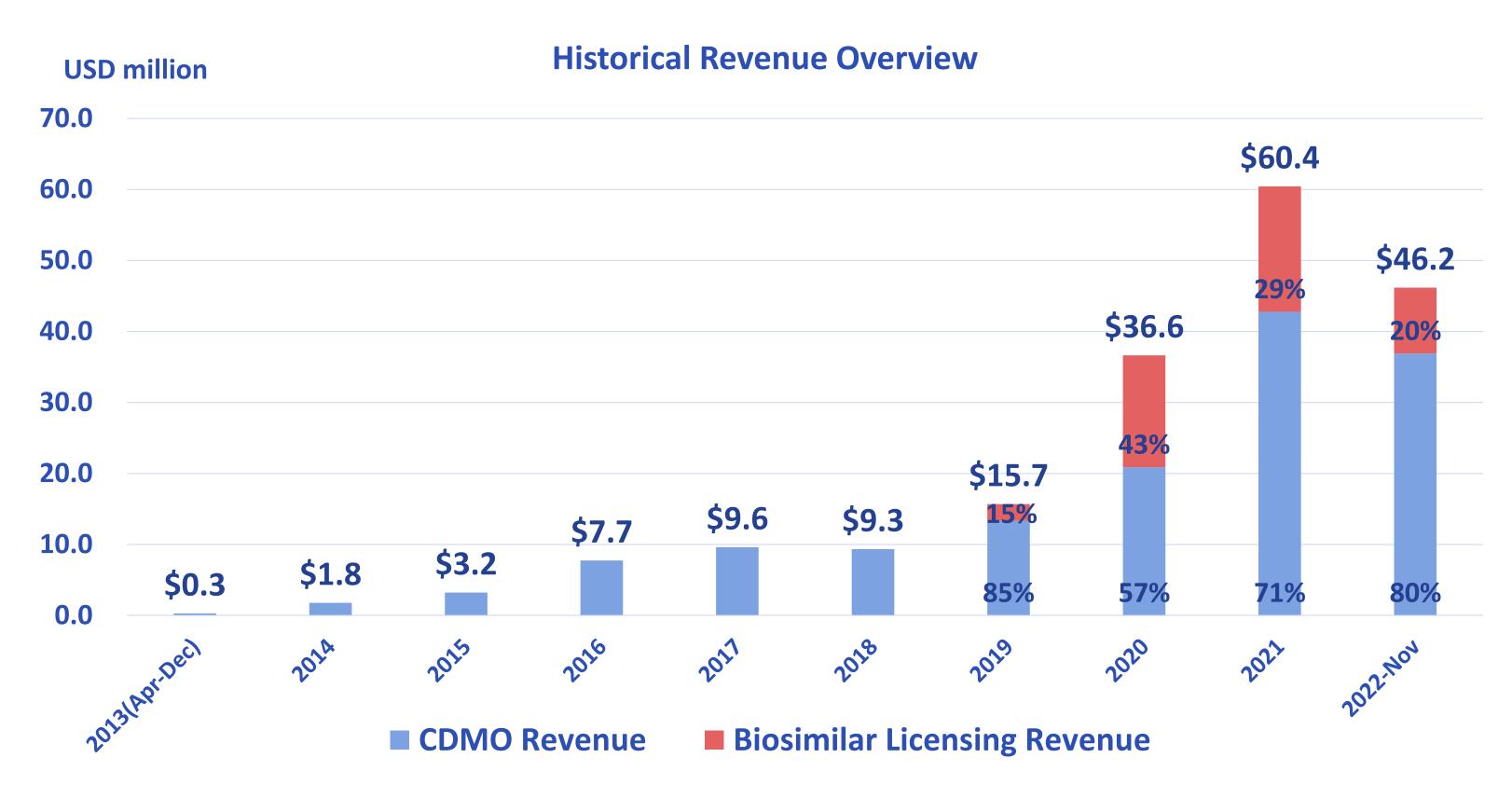
Included realized upfront payment and milestone payments realized based on R&D and clinical development



Overall Historical Revenue Momentum

CDMO + Product Licensing Revenue

- As of Nov-end 2022, EirGenix's overall revenue USD 46.2mn with 20% from product licensing, and 80% contributed from CDMO.
- Expect 2023 revenue moment to be driven by growing CDMO projects in the pipeline, executing the licensing milestones and new product licensing.





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

| 2022-Jun, US FDA conducted separate inspections at EirGenix Zhubei cGMP manufacture facility and collaboration partner's facility.

| 2022-Dec/13, Sandoz received US FDA Complete Response Letter (CRL), mainly due to some process and equipment improvements are required at aseptic filling and lyophilization collaboration partner. It is expected to be completed in the Q1/Q2 of 2023.

| 2023-Jan/5, EirGenix received US FDA's Establishment Inspection Report (EIR), indicating Zhubei cGMP manufacturing facility has passed the FDA's Pre-License Inspection (PLI).



The First Product (...continued)

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

| US FDA BLA Resubmission review schedule:

- Sandoz is in close contact with the FDA to meet the satisfactory resolution of the FDA observations in a timely manner and plans a BLA resubmission in due course.
- US FDA will require to conclude the BLA review in 6 months, follow by the resubmission

| EU EMA MAA review schedule:

- Still working parallel in progress, as part of the reviews are contingent upon FDA's review and is expect to conclude by 2023 Q2/Q3.

| TW TFDA NDA review schedule:

- EirGenix submitted TFDA NDA review on Sept 30th, 2022
- Expect the review results to be concluded by Q2-2023



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 Phase I clinical trial
- | Expect to have the Phase I clinical trial results in 1H-2023
- | Potential to global licensing follow by Phase I clinical trial
- | Schedule to kick-off Phase III clinical study before end of 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



Quick Overview of Products in Development (Details in next page)

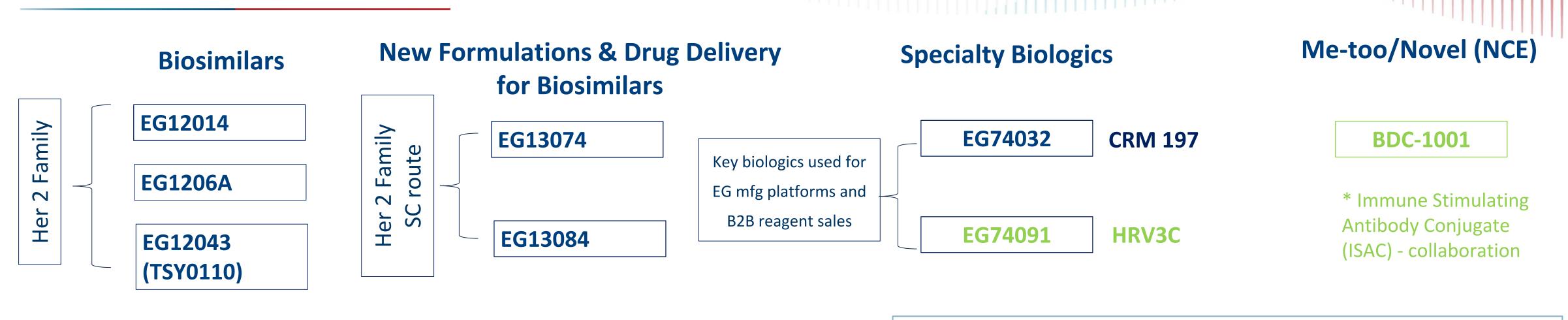
Pipeline Progress

Project Name	Drug Class	Indication	Target	PROGRESS				
				Pre-Clinical	Phase I	Phase II/III	MAA/BLA	Partner
EG12014 Trastuzumab Biosimilar	Monoclonal Antibody	Cancer	HER2					SANDOZ
EG1206A Pertuzumab Biosimilar	Monoclonal Antibody	Cancer	HER2					Currently Confidential
EG12043 (TSY0110) Antibody Drug Conjugate	Antibody Drug Conjugate	Cancer	HER2					FORMOSA LABORATORIES, INC.
EG13074 TRZ (SC formulation)	Monoclonal Antibody	Cancer	HER2					
EG13084 TRZ+PTZ (SC formulation)	Monoclonal Antibody	Cancer	HER2					
EG74032 CRM197 Carrier Protein	Carrier Protein for Vaccine Conjugates	N/A	Infectious/ cancer					



Products in Development

Pipeline Overview



EGXXXXX

EGXXXXX

EGXXXXX

New List to be:

- L) 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.

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

FirGenix

Product Pipeline Overview

Product Portfolio

Why Her2 Family Products?

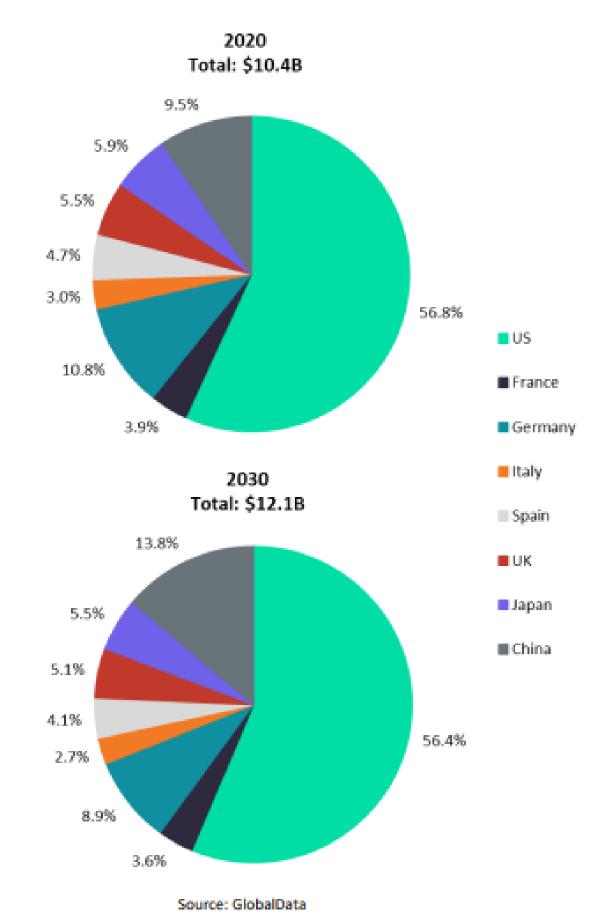
Combination Treatment

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.



Thank you

41st Annual J.P. Morgan Healthcare Conference

January 2023

