



TPEX: 6589

*YOUR RELIABLE
BIOLOGICS PARTNER*



Cathay Securities Healthcare Corporate Day
Aug 16, 2022

Dr. Chih-Jung Chang
Vice President, COO

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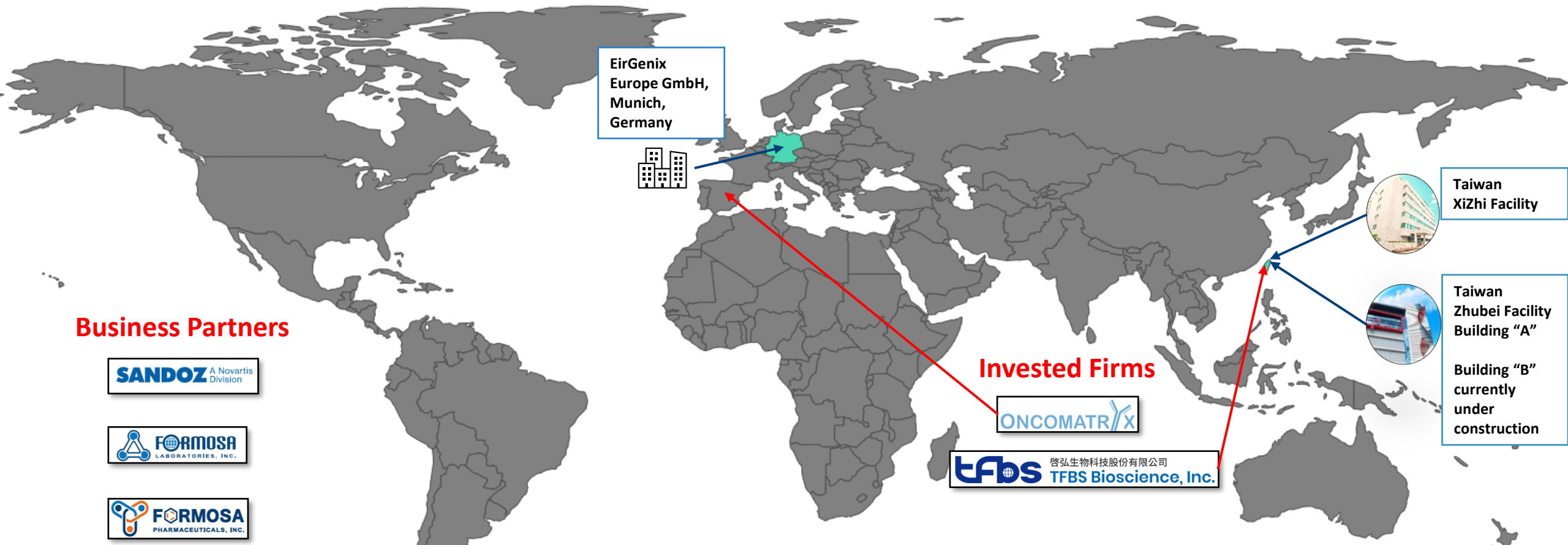
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EirGenix Profile and USPs

- 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

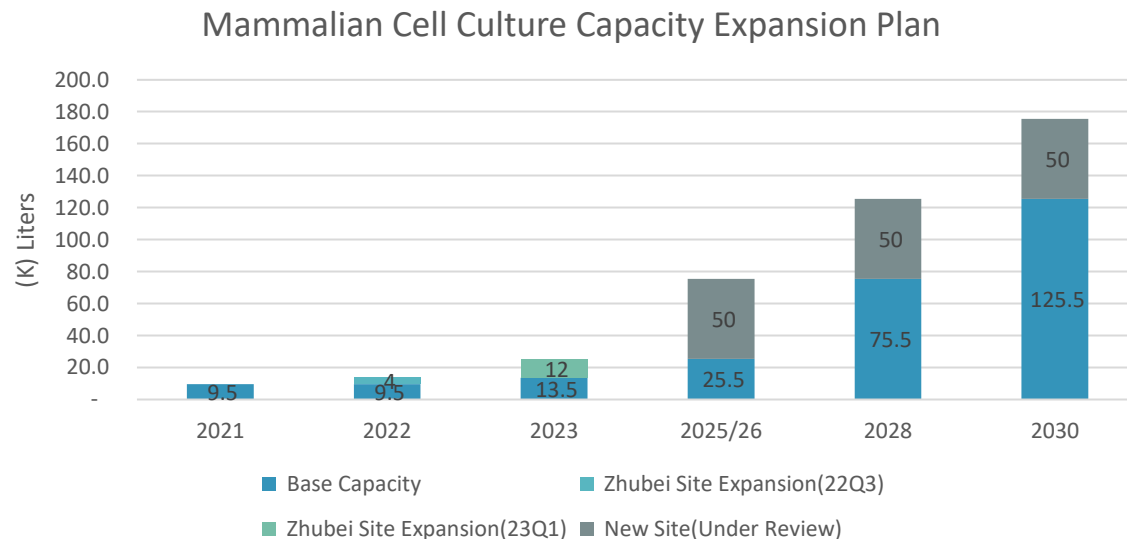


5F: New production line to ready by 2023 Q1 for 3 sets 2x 2000L

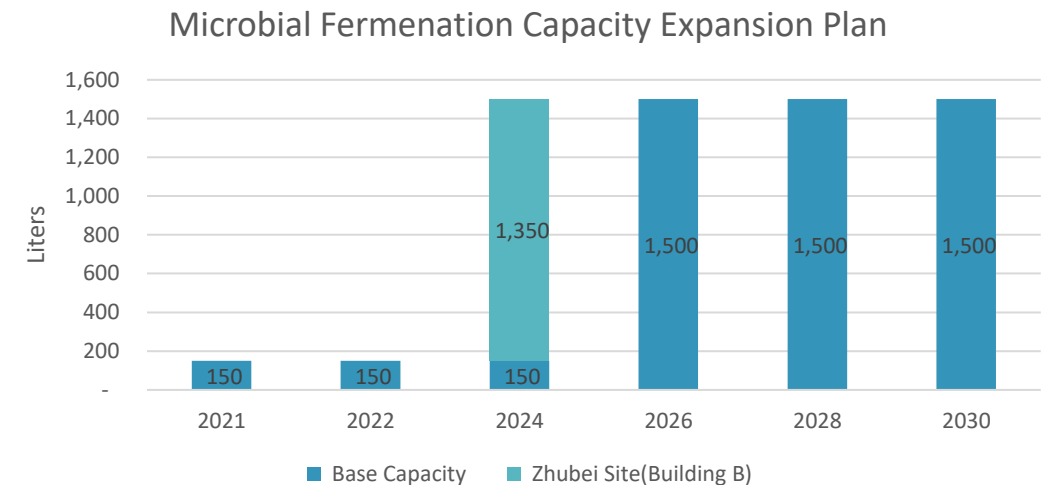
3F: Original capacity
2 sets 2x 2000L
2022 Q3 will complete install additional 1 set 2x 2000L

Capacity and Expansion Schedule (Xizhi, Zhubei + New Site)

Mammalian cell culture capacity – 9,500 L (**25,500L by 2023 Q1**) | Microbial fermentation capacity – 150 L (**1,500L by 2024**)

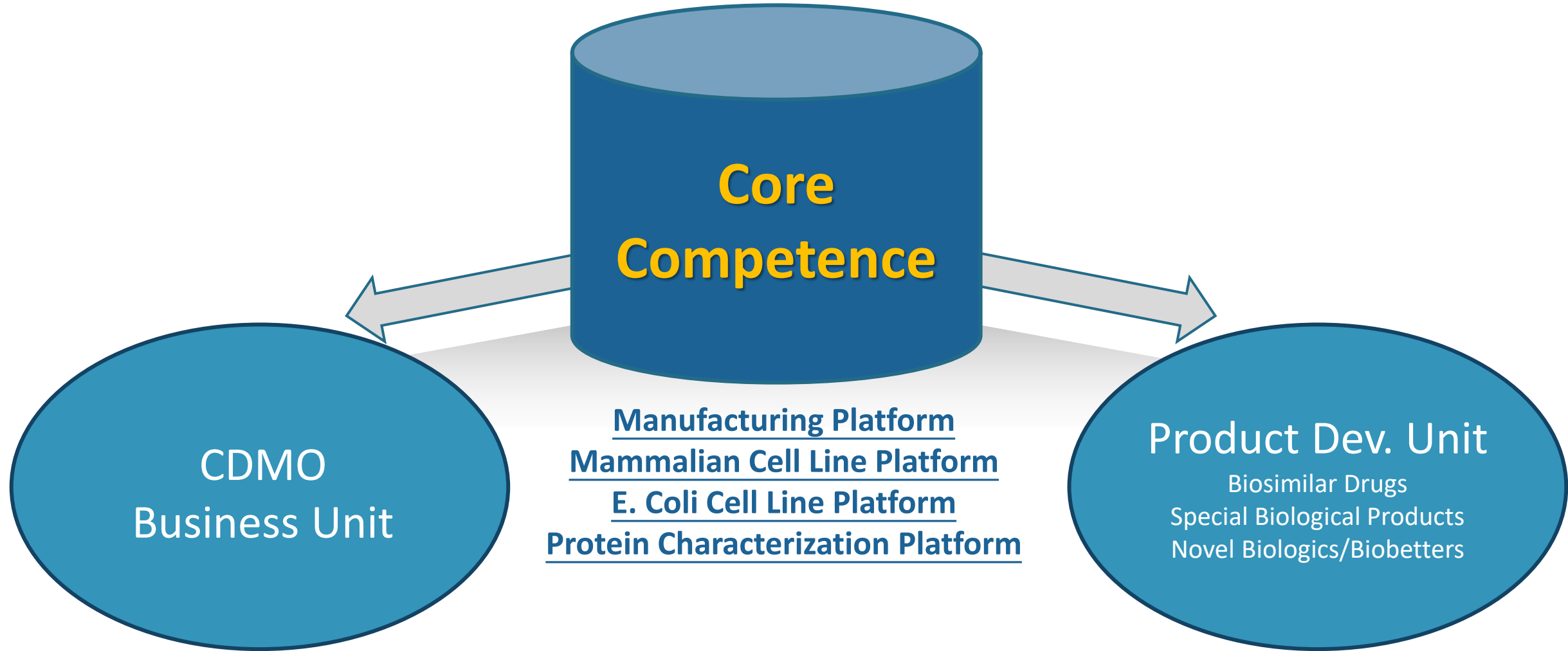


- 2019/Q1 The first large scale mammalian commercial production in the Zhubei facility on stream
- 2022/Q3 Additional 2 sets of 2x2000L mammalian capacity expansion to complete. Totaled 13,500 L
- 2023/Q1 The 2nd mammalian cell culture production line to complete (3 sets of 2x2000L). Totaled 25,500 L
- A 6-8 years plan to build up a 150,000 L very large-scale mammalian cell culture facility in 3 stages (50 KL by 2025/26, 100 KL by 2028, and 150 KL by 2030). **Total mammalian capacity to reach 175,500L**



- 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**

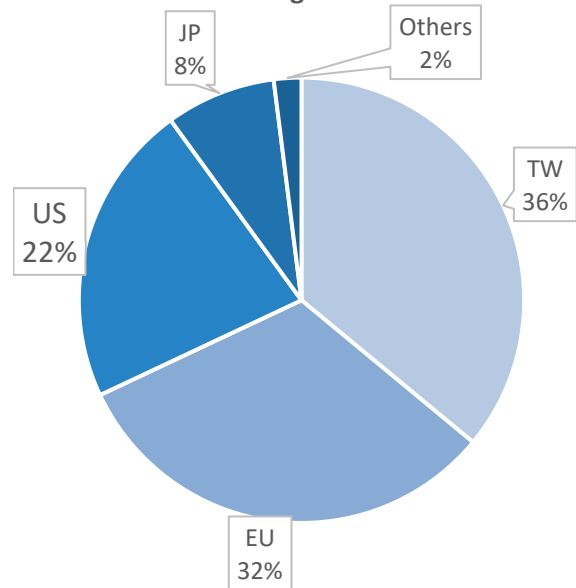
Business Overview



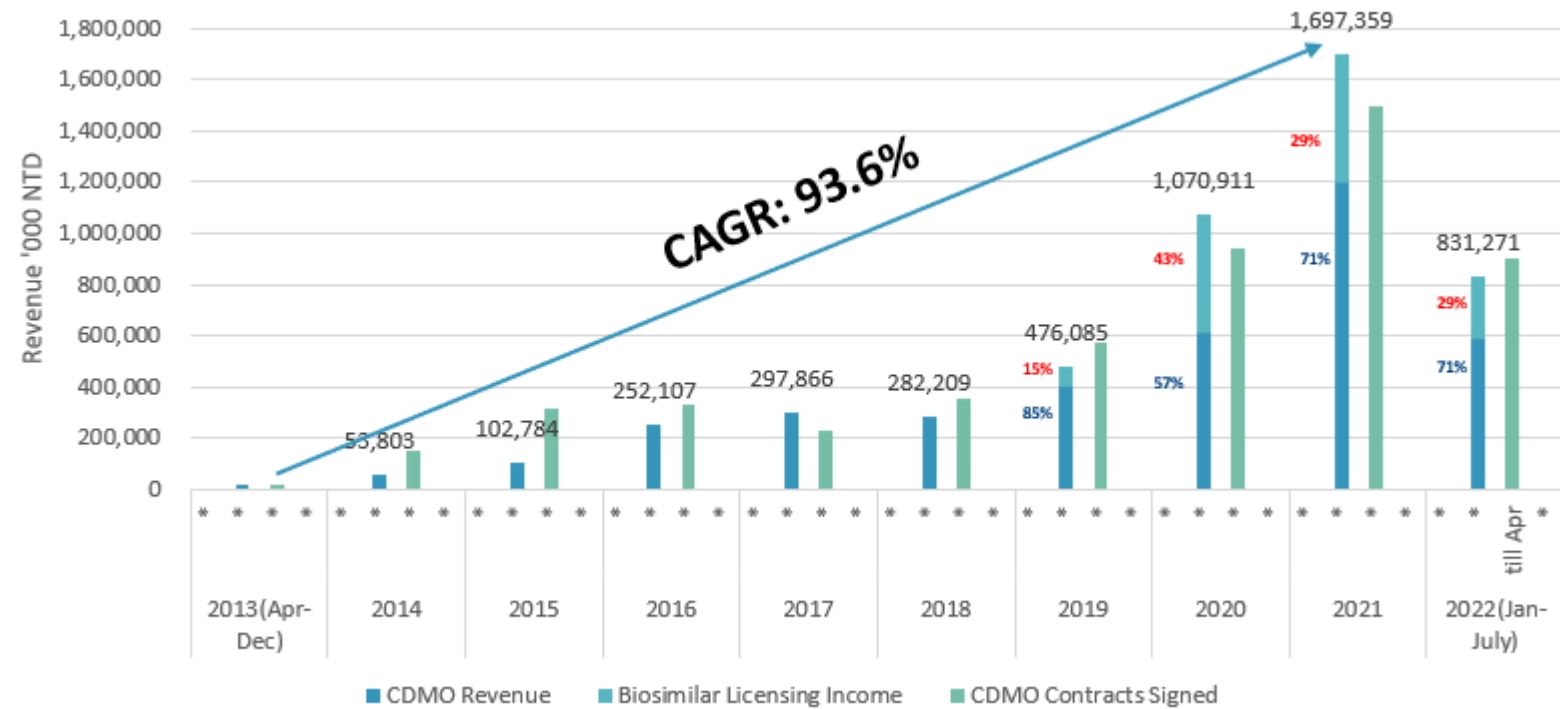
Revenue Momentum

- ◆ 2022 Jan-Apr CDMO newly signed contracts exceed 60% of 2021 full-year contracts

2021 Total Revenue Break-Down by Region

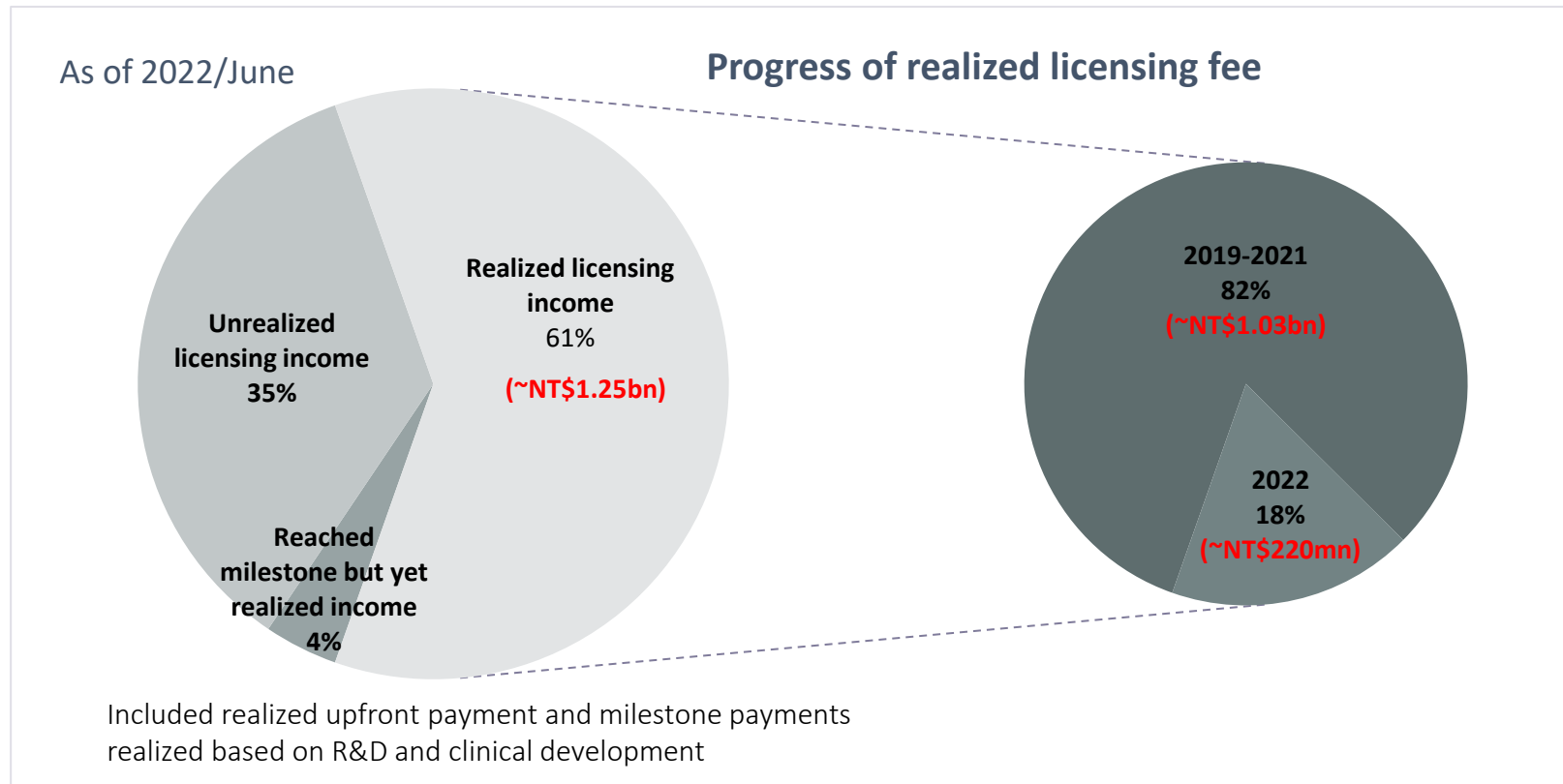


EirGenix Revenue Trend Summary



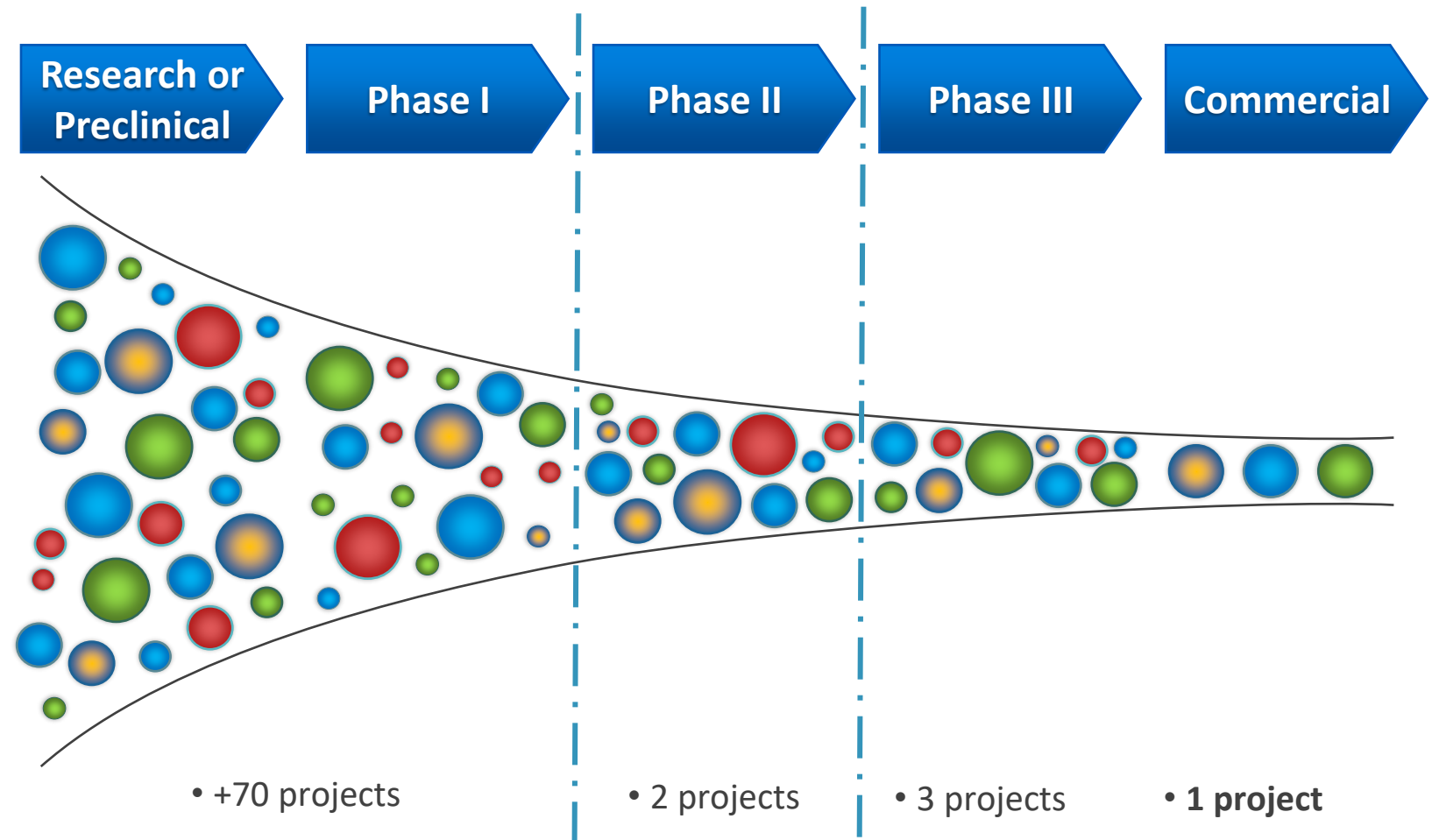
Revenue Momentum (from EG12014 Licensing fee)

- Total licensing fee US\$70mn (Upfront Payment US\$5mn + Milestone US\$65mn)



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



Global Compliance & Certifications

- EirGenix strongly believes in adherence to global standards and continually seeks to meet these standards year after year

65+

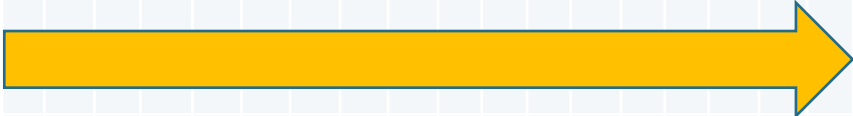
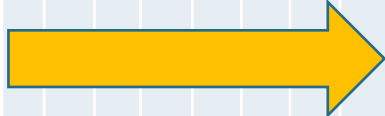
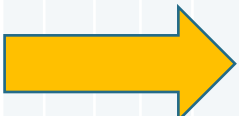
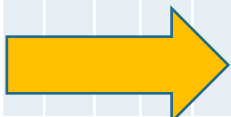

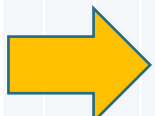
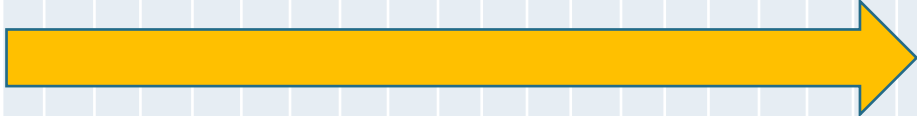
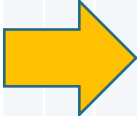
External audits/inspections by TFDA & clients throughout the world since 2005

YEAR	PREVIOUS CERTIFICATION OR INSPECTION
2005	<u>Mammalian Cell culture production facility</u> granted GMP certificate by TFDA
2013	<u>Microbial production facility</u> granted GMP certificate by TFDA
2014	<u>Mammalian cell culture and microbial production facilities</u> were certificated by TFDA as a PIC/S GMP facility
2017	Granted Accreditation Certificate of Foreign Manufacturer by <u>Minister of Health, Labor and Welfare, Japan</u>
2020	Granted approval by Pharmaceuticals and Medical Devices Agency (PMDA), Japan
2020	Zhubei facility passed the inspection by Taiwan FDA
2022	Inspected by US FDA pending for inspection result
2022-end/2023	Expected inspection by EU EMA

IO Biosimilars Potential

- The global market size of Immuno-Oncology products in 2021 is around \$63 billions USD, and is expected to reach \$93 billions USD at a CAGR of 10% in 2025
- It is believed that the growth rate has been hammered due to the treatment cost with IO drugs. Successfully early launch IO biosimilar products would immediately increase the volume of use though the price competition
- Potential development alliance to reduce the high development cost and the risks

Own Product Pipeline

Project Name	Drug Class	Indication	Target	PROGRESS					Partner
				Pre-Clinical	Phase I	Phase II/III	MAA/BLA		
EG12014 / EGI014 Trastuzumab Biosimilar	Monoclonal Antibody	Cancer	HER2						PARTNERED WITH SANDOZ A Novartis Division
EG1206A Pertuzumab Biosimilar	Monoclonal Antibody	Cancer	HER2						CURRENTLY CONFIDENTIAL
EG13074 TRZ (SC formulation)	Monoclonal Antibody	Cancer	HER2						CURRENTLY CONFIDENTIAL
EG12043 (TSY0110) Antibody Drug Conjugate	Antibody Drug Conjugate	Cancer	HER2						PARTNERED WITH 
EG13084 TRZ+PTZ (SC formulation)	Monoclonal Antibody	Cancer	HER2						
EG74032 CRM197 Carrier Protein	Carrier Protein for Vaccine Conjugates	N/A	Infectious /cancer						
EG62054 Biosimilar	Fusion Protein	Ophthalmology / Cancer	VEGF						

Why Her2 Family Products?

- 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)
- The global market size of Her 2 positive breast cancer is around \$13 billions USD
- To develop EirGenix's own pertuzumab (EG1206A) and be the top 2 to launch the product would have the complimentary effect to enhance 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 Her 2 family products penetration in the market, and it will help EG dominate the Her 2 biosimilar market

Self-Owned Product Development Progress

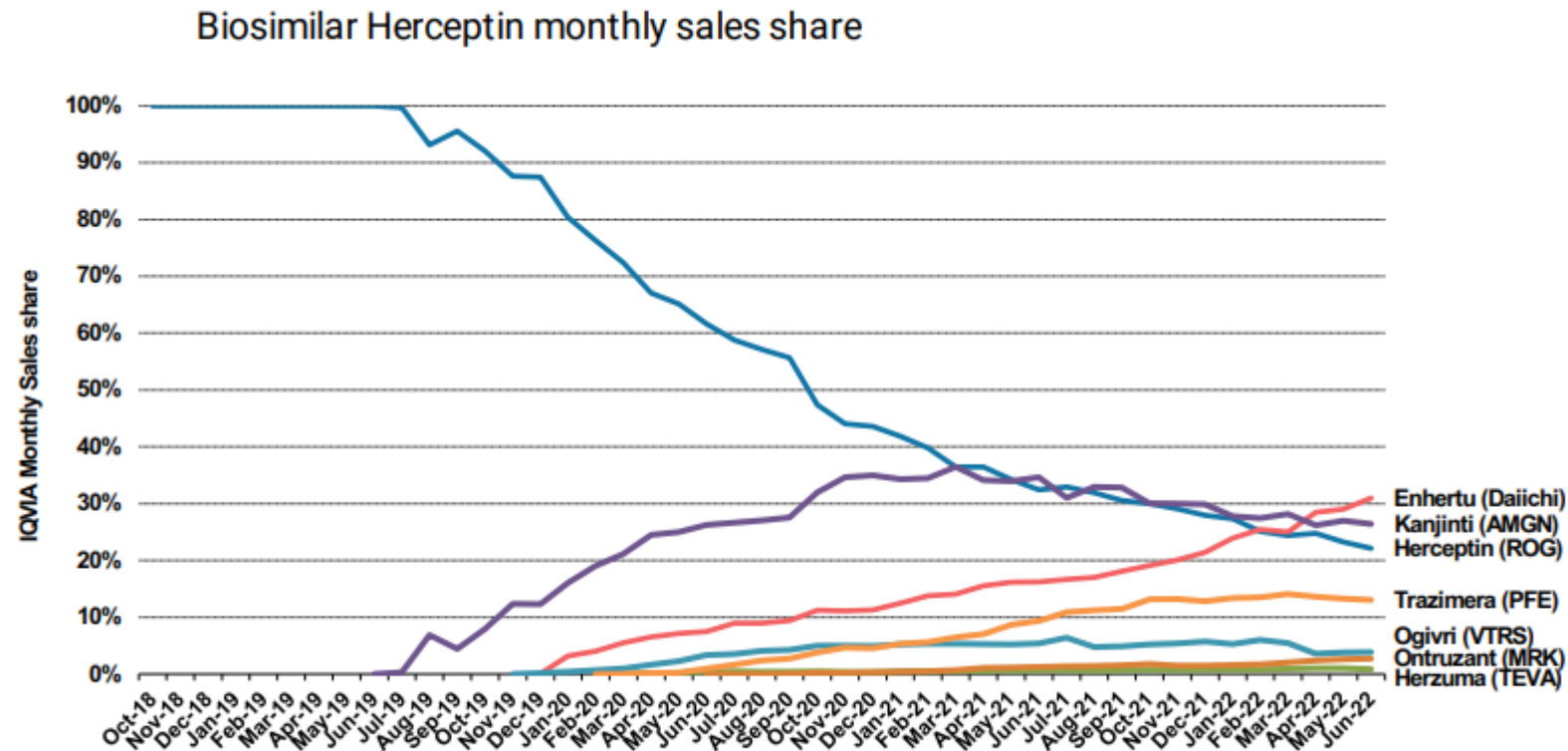
Broad & diversified product pipeline; unique strategy of Her2 products franchise management

- 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 (of the Novartis Group)** for the upfront and milestone payment of US\$ 70 millions plus the profit sharing of the future sales
 - 2021/03 Global Phase III Clinical Trial met no clinically and meaningful differences standard
 - 2021/12 Submitted both BLA in US and MAA in EU almost at the same time
 - 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 2nd own product Pertuzumab Biosimilar EG1206A
 - 2022/Q1 Submitted Phase 1 clinical (German PEI & EC)
 - 2022/05 Received approval for Phase I PK bio-similarity clinical study from German National Competent Authority and corresponding Ethic Committee.



Reference Drug and Biosimilar Drug Market Share Change After Patent Expired

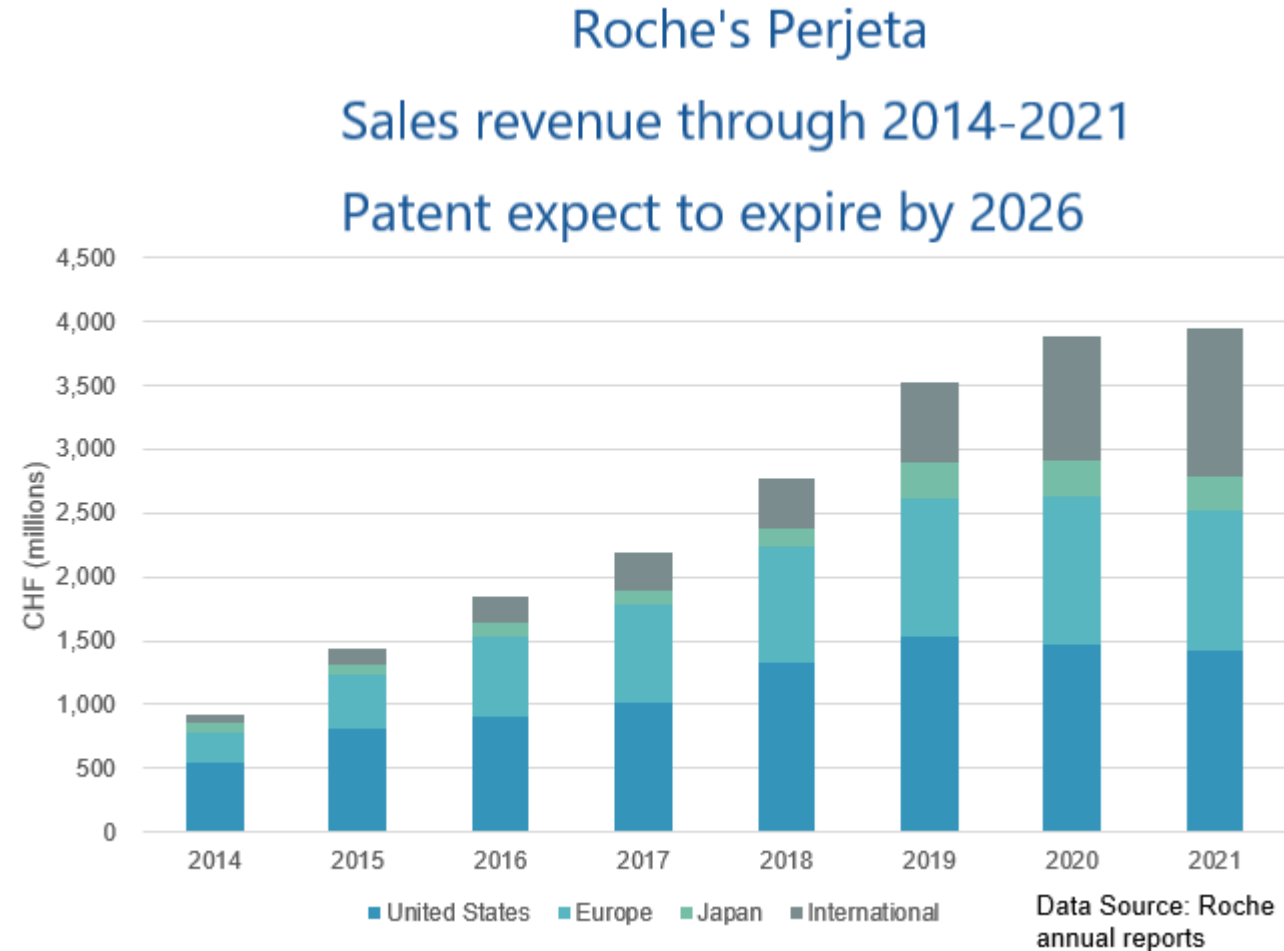
- Roche's Herceptin® as an example. Other substitute drug and biosimilar drugs penetrated over 75% of its market share within three years, after its patent expired since 2019.
- Early entry biosimilar drug received marketing license in US & EU + Strong global distribution channels to have the advantage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



Source: IQVIA

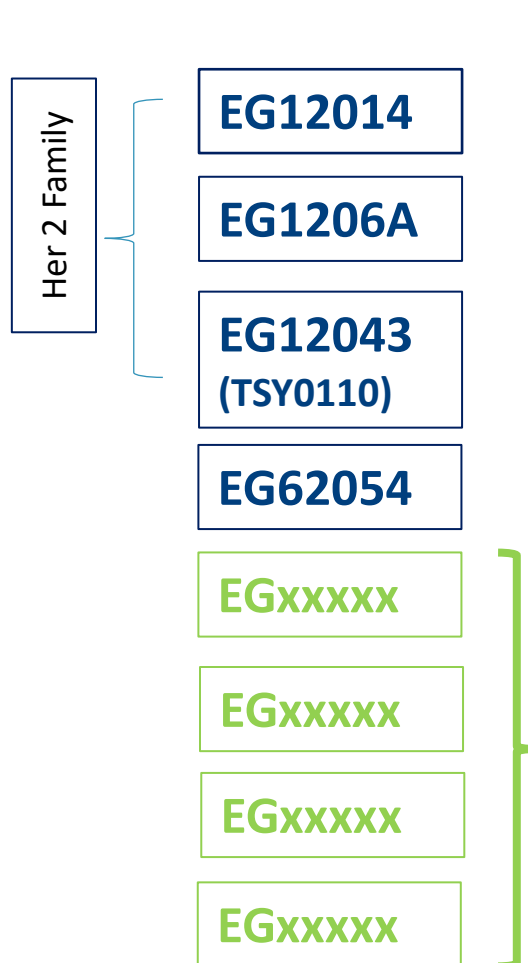
EirGenix's EG1206A is the Biosimilar drug of Roche's Perjeta

- 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

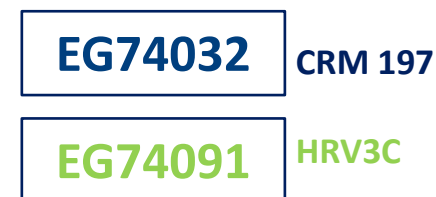
Biosimilars



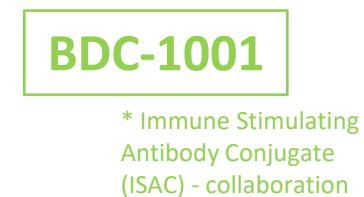
New Formulations & Drug Delivery for Biosimilars



Specialty Biologics



Me-too/Novel (NCE)



New List to be:

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

Q & A

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

