EirGenix

TPEx: 6589

YOUR RELIABLE BIOLOGICS PARTNER

CSFB Asia Healthcare Corporate Day 2022
June 14-16, 2022

Lee-Cheng (LC) Liu
Founder, Chairman & CEO

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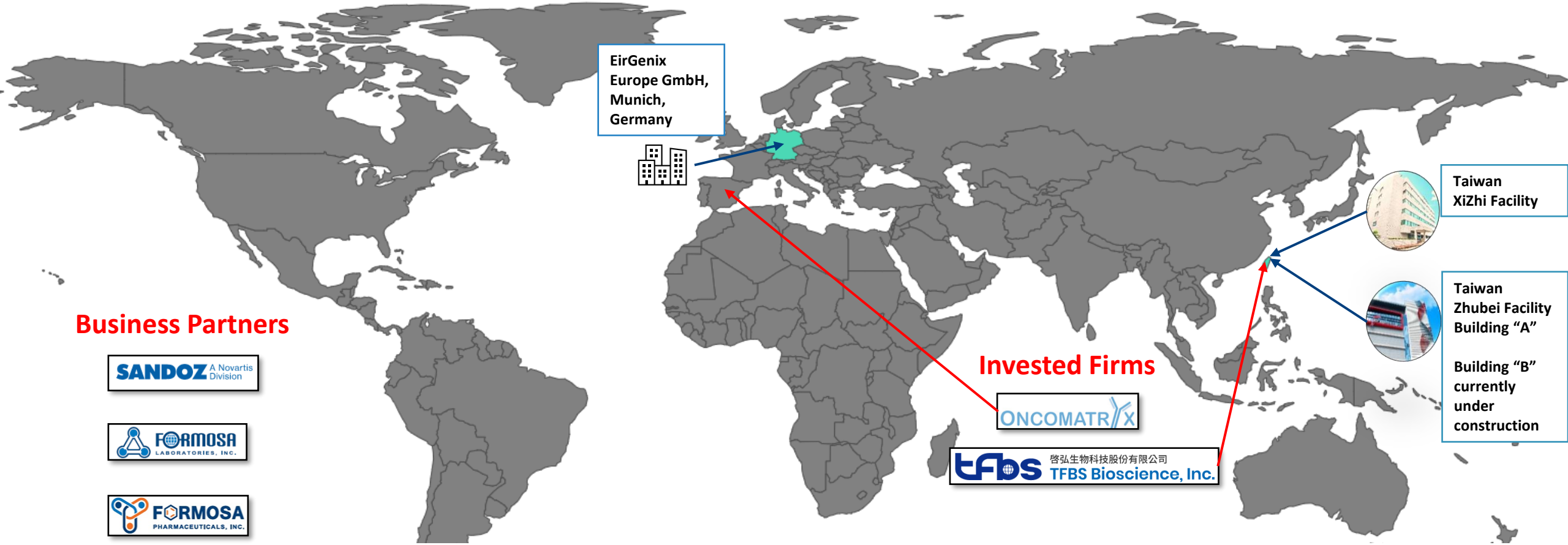
EirGenix Profile and USPs

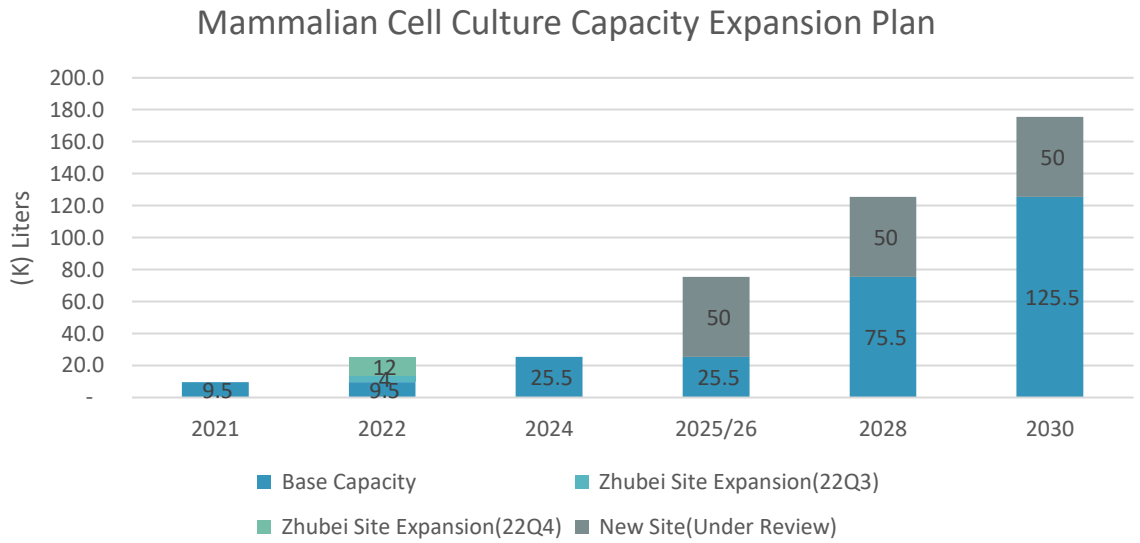
- Established Dec. 21, 2012
  - 2013/03 Completed acquisition of DCB's Biopharmaceutical Pilot Facility 財團法人生物技術開發中心 Development Center for Biotechnology
  - 2019/06 IPO on TPEx (Code: 6589.TWO) China Area Award
- Back up by very strong and stable investors include:
  - **Founder of Foxconn, Terry Gou**
  - **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**

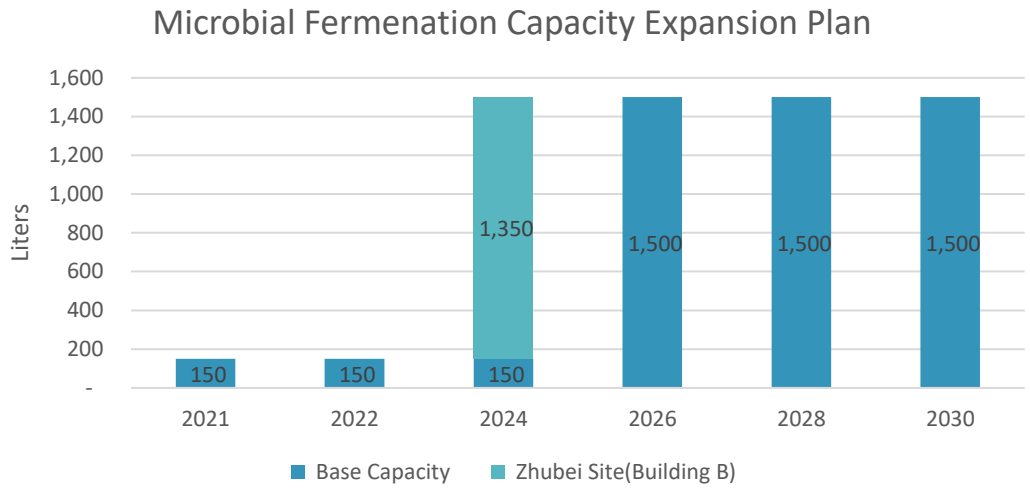
EirGenix Office, Facilities & Business Partners



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

Mammalian cell culture capacity – 9,500 L (**25,500L by 2022-end**) | Microbial fermentation capacity – 150 L (**1,500L by 2024**)

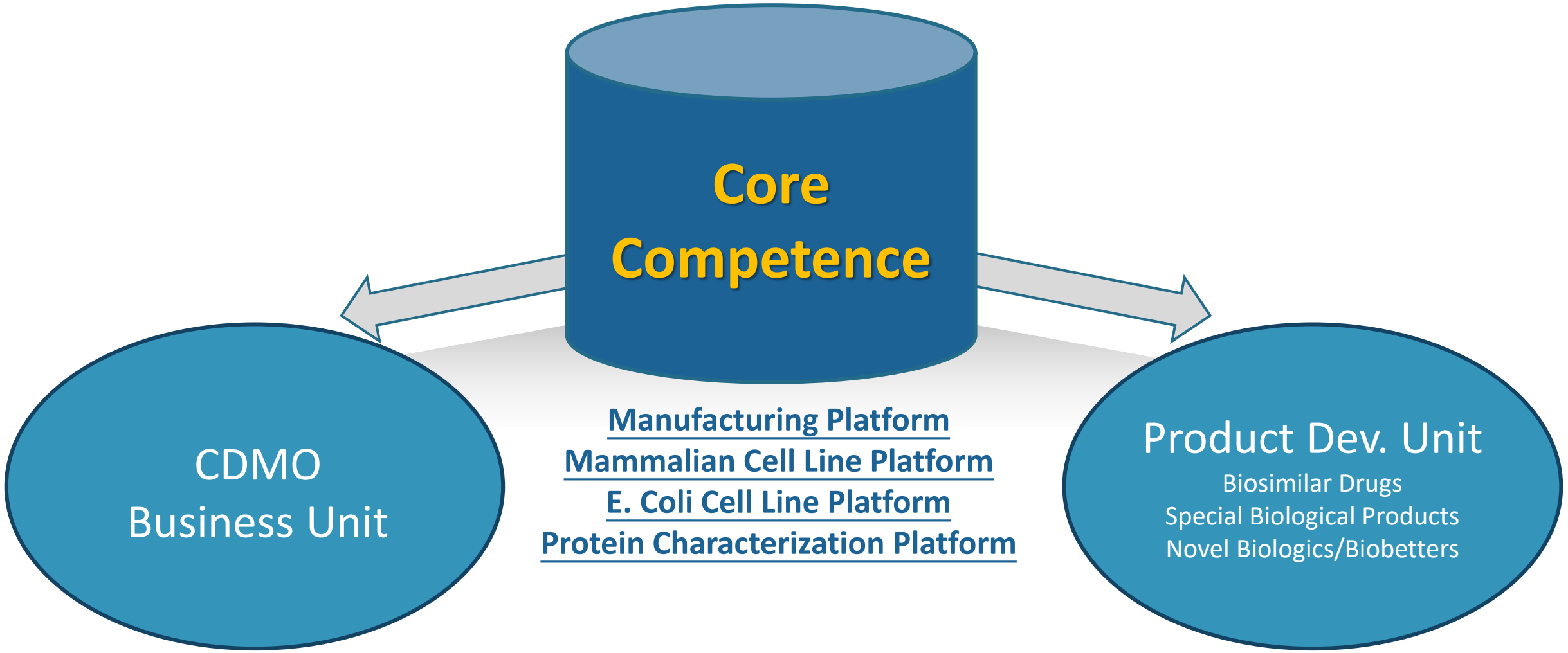




- 2019/Q1 The first large scale mammalian commercial production in the Zhubei facility on stream
- 2022/Q3 Additional 2 sets of 2x2000L mammalian capacity expansion to complete. Totaled 13,500 L
- 2022/Q4 The 2nd mammalian cell culture production line to complete (3 sets of 2x2000L). Totaled 25,500 L
- 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**

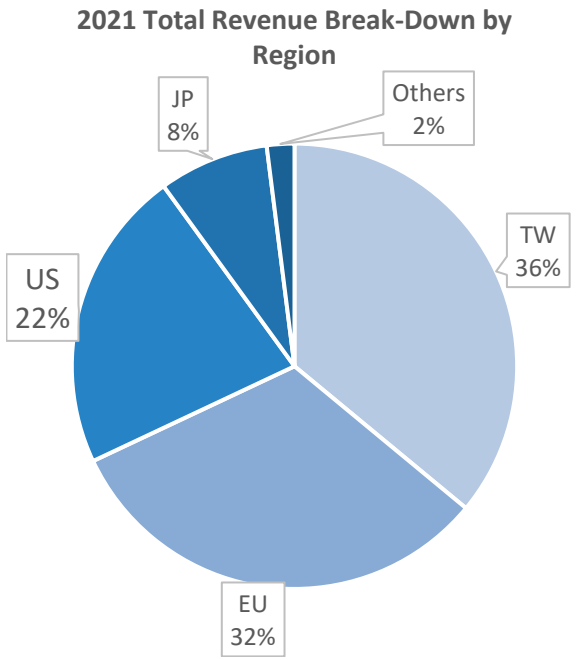
- 2024 Expansion of Zhubei facility Building "B" for microbial fermentation capacity (350 + 1000 L) with 2-3 downstream purification suites; **Total microbial fermentation capacity to reach 1,500 L by 2024**

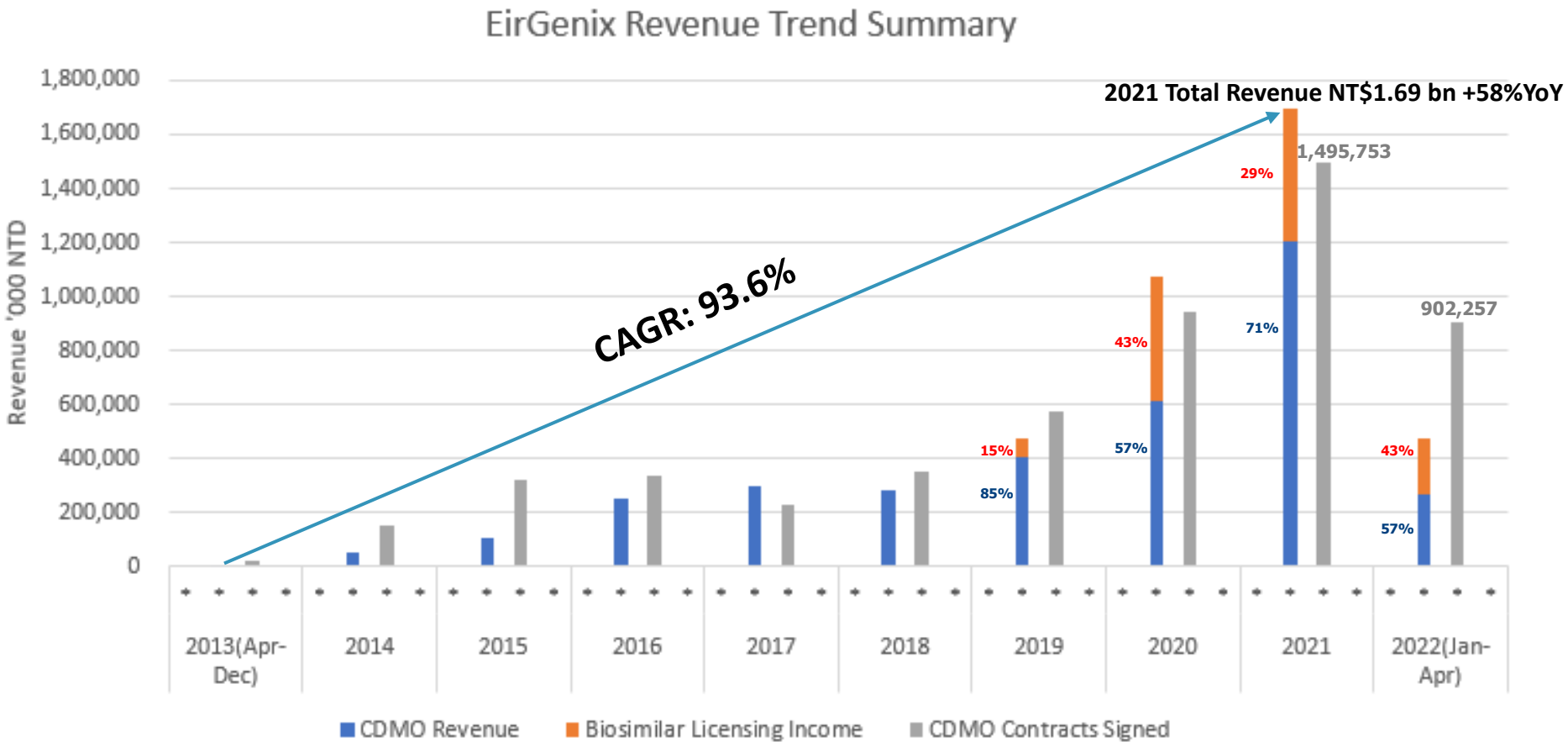
Business Overview



Revenue Momentum

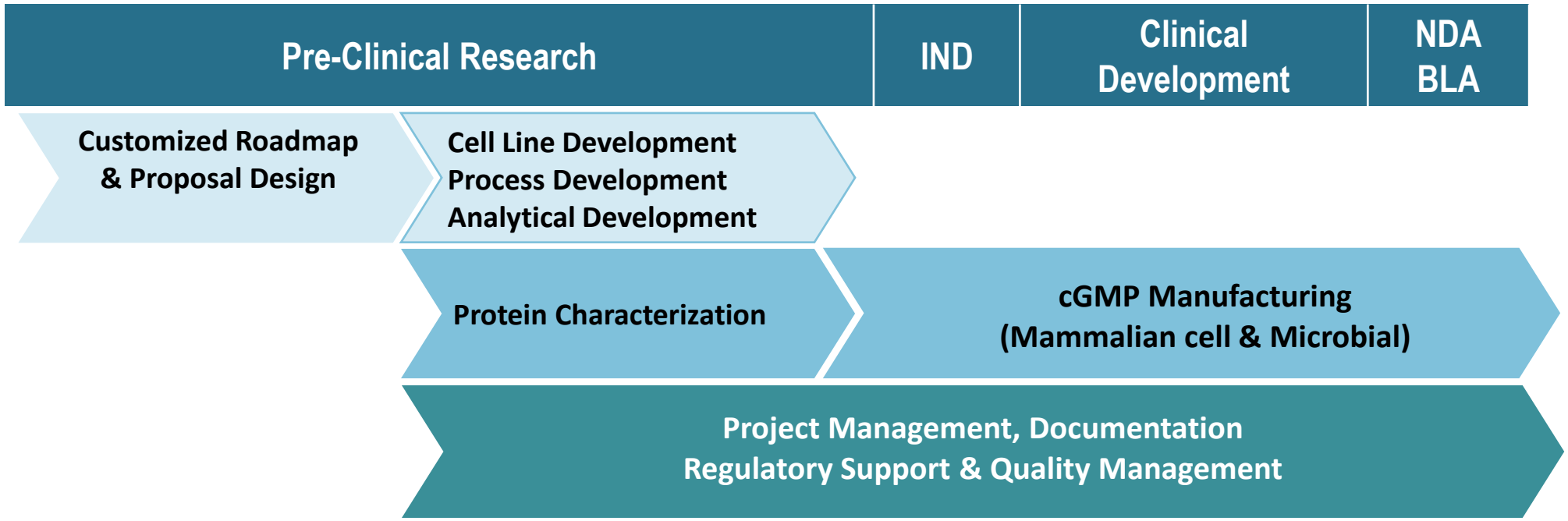
- 2022 Jan-Apr CDMO newly signed contracts exceed 60% of 2021 full-year contracts





Full-Service CDMO Services | One-Stop Solution from DNA to NDA/BLA

EirGenix provides customized, tailor-made service packages to meet client needs



CDMO – Protein Characterization Service

Quality Control Methods for Protein Characterization

PRIMARY STRUCTURE ANALYSIS

- HPLC, UPLC
- LC / MS / MS
- Peptide map; total sequence analysis
- N-/C-terminal variants
- Disulfide linkages
- Oxidation, deamidation, and other post-modifications

SECONDARY/HIGHER ORDER STRUCTURE ANALYSIS

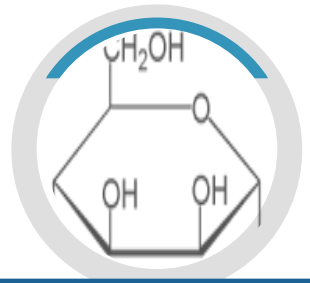
- CD (Circular Dichroism)
- DSC (Differential Scanning Calorimetry)
- Fluorescence Spectrometer

HETEROGENEITY ANALYSIS

- IEF/cIEF
- CIX HPLC

GLYCAN ANALYSIS

- N-, O-linked carbohydrates site and structure by LC/MS/MS
- N-glycan ratio by CE



MONOSACCHARIDE ANALYSIS

- HILIC
- LC / MS / MS

Additional Service Offerings

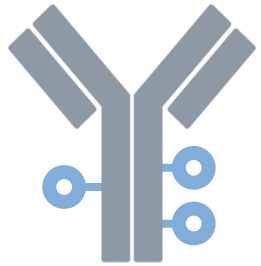
Antibody Drug Conjugate (ADC) Development

- Integrated expertise in ADC Development with strategic partner, Formosa Laboratories

Monoclonal Antibody
(EirGenix)

- Cell Line Development from cDNA
- Cell Banking
- Process Development
- Scale-Up
- GMP Manufacturing
- 15 to 21 Months

EirGenix



Antibody Drug Conjugate

- Bio-Conjugation
- Process Development
- Protein Characterization
- Formulation Development
- Scale-up & GMP Manufacturing from Lab Scale to 1000L Scale
- Pre-Clinical, Clinical, and commercial Material Supply from G to KG Scale
- 6-12 Months

Linker & Payload
(Formosa)

- Customized Synthesis Strategy
- Screening
- Analytics and Quality Control
- Process Development
- GMP Manufacturing from G to KG scale
- 12 to 18 Months

FORMOSA LABORATORIES, INC.

CDMO Track Record & Experience

Cell Line Experience

Mammalian Cell Lines

- CHO S
- HEK 293
- Hybridoma
- CHO K-1
- PER. C6
- NS0

Microbial Cell Lines

- E. coli
- Pichia

Product Experience

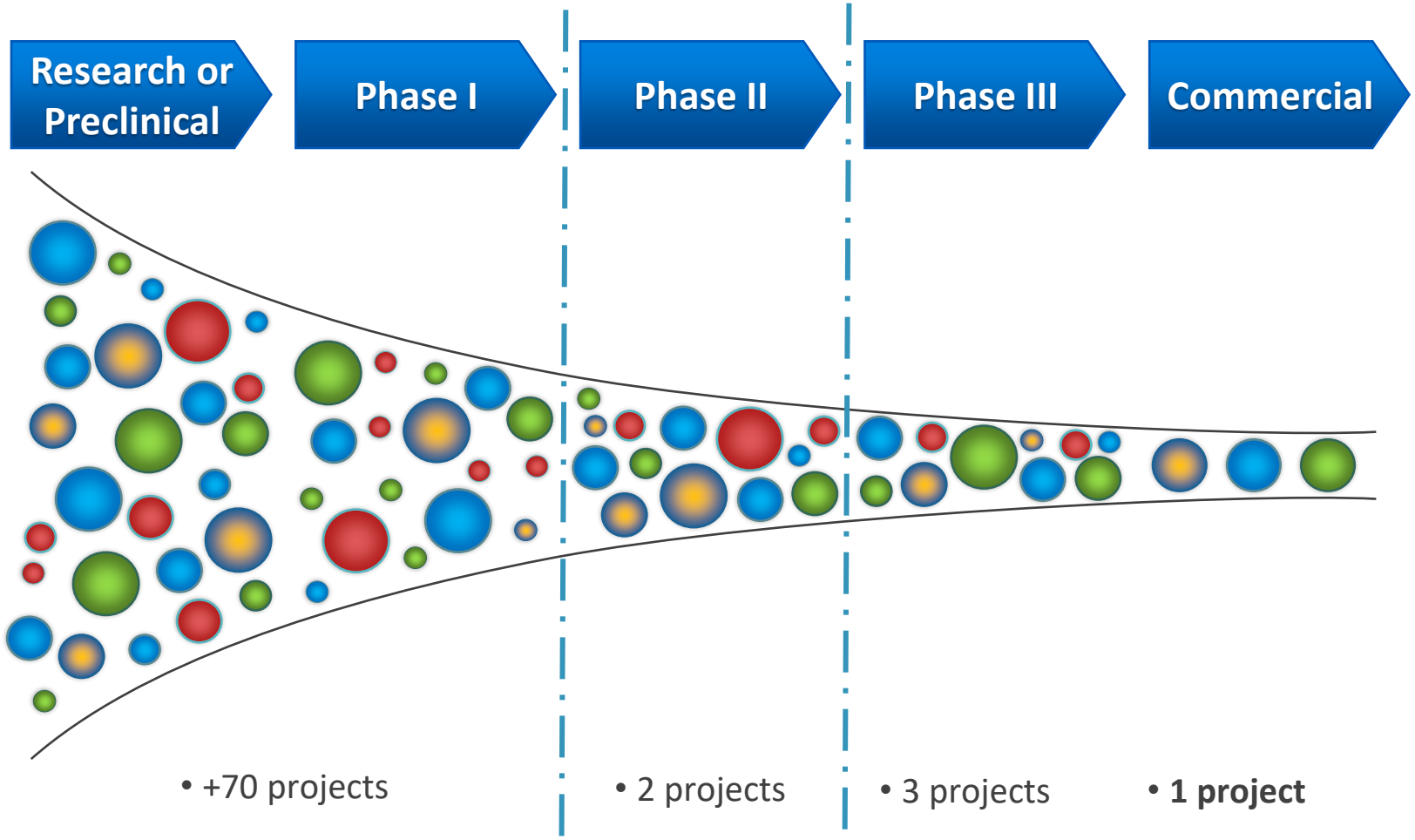
36	Monoclonal Antibodies (Novel Biologics & Biosimilars)
11	Bi-specific mAb Fc-fusion Proteins
22	r-Protein (3 with PEGylation)
10	Protein Vaccines
11	Plasmid DNAs

IND Experience

IND submissions and materials supplied for clinical studies globally

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	**Mammalian** Cell culture production facility granted **GMP** certificate by **TFDA**
2013	**Microbial** production facility granted **GMP** certificate by **TFDA**
2014	Mammalian cell culture and microbial production facilities were certificated by TFDA as a **PIC/S GMP** facility
2017	Granted **Accreditation Certificate of Foreign Manufacturer** by Minister of Health, Labor and Welfare, **Japan**
2020	Granted approval by **Pharmaceuticals and Medical Devices Agency (PMDA), Japan**
2020	Zhubei facility passed the inspection by Taiwan FDA
2022	**Expected inspection by US FDA**
2022	**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

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 (of the Novartis Group)** for the upfront and milestone payment of US$ 70 millions plus the profit sharing of the future sales
  - 2021/03 Completed the Global Phase III Clinical Trial for Trastuzumab Biosimilar
  - 2021/12 Submitted both BLA in US and MAA in EU almost at the same time
  - 2022 US FDA scheduled facility inspection

  (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.

Own Product Pipeline

Project Name	Drug Class	Indication	Target	PROGRESS				
				Pre-Clinical	Phase I	Phase II/III	MAA/BLA	Partner
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 FORMOSA LABORATORIES, INC.
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

Future Product Pipeline Overview

Biosimilars

Her 2 Family

- EG12014
- EG1206A
- EG12043 (TSY0110)
- EG62054
- EGxxxxx
- EGxxxxx
- EGxxxxx
- EGxxxxx

New List to be:

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

New Formulations & Drug Delivery for Biosimilars

Her 2 Family SC route

- EG13074
- EG13084

Specialty Biologics

- EG74032 CRM 197
- EG74091 HRV3C

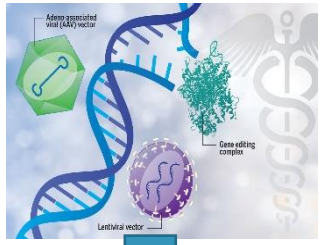
Me-too/Novel (NCE)

- BDC-1001

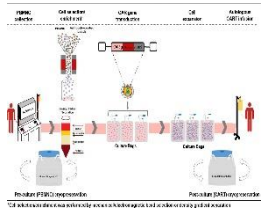
* Immune Stimulating Antibody Conjugate (ISAC) - collaboration

EirGenix's Future Roadmap

Cell & Gene Therapy CDMO

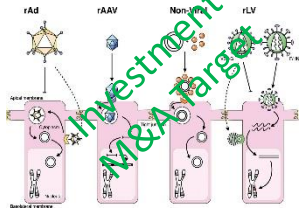


Allogenic cell processing system



Autologus cell processing system

Gene delivery system manufacturing



Biologic characterization & testing (CRO)

Special cell based testing

Viral safety testing

Biopharmaceutical CDMO

Protein & antibody engineering (CRO)

Biologic drug substance process development & manufacturing

Drug product delivery devices

Aseptic filling & Lyophilization

Alliance with Formosa Lab. & M&A

- Capacity Expansions:
  - Mammalian Cell capacity to reach 175,500 L by 2030
  - Microbial Cell capacity to reach 1,500 L by 2024
- Invest or M&A regional small-mid size CDMO, enrich global client profile
- Target to launch 6-8 biosimilar products by 2030 through:
  - In-House Developed
  - In-Licensing
  - Immuno-Oncology Biosimilar Development Alliance

Q & A

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

EirGenix

EirGenix, Inc.

台康生技股份有限公司

SUPPLEMENTARY MATERIAL – EXECUTIVE TEAM

Lee-Cheng (LC) Liu, Dr.Eng.Sci. | President & CEO

*Ex-President & COO of **AnGes** with **30 years** of leadership experience in Pharma, Biotech and specialty chemical industries. He holds a Doctor of Engineering & Science from **Columbia University**.*

Thomas Schulze, Ph.D. | Managing Director of EirGenix Europe GmbH

*Ex-CEO of **Formycon** and **Avontec** with more than **25 years** of leadership experience in Pharma (Bayer AG) and Biotech. He holds a Ph.D. from **Free University Berlin** (Max-Planck Institute).*

Chih-Jung (CJ) Chang, Ph.D. | Sr. Vice President, Chief Operating Officer (COO)

*Ex-Director of PM for Oncology at **TTY** with **20 years** experience in pharmaceutical industry. He holds a Ph.D. from **National Taiwan University**.*

Hsiu-Chuan (Cathy) Yang, M.S. | Vice President, Chief Financial Officer (CFO)

*Ex-GM of **JV company of Fresenius,** oversaw ops of 100+ kidney dialysis centers. She holds a MS in Accounting from **Uni. of New Haven (CT)** with **20 years** exp. in FMCG and medical industries.*

Ren-You Forng, Ph.D. | Executive Director, Quality System

*Former Scientific Director at **Amgen,** Quality Control and Corporate Microbiologist at AstraZeneca. Has over **30 years** of exp. in biopharma facility ops and quality systems. He holds a Ph.D. from **Georgia State University***

SUPPLEMENTARY MATERIAL – EXECUTIVE TEAM

Shang-Chung (SC) Ju, Ph.D. | Executive Director, Chief Manufacturing Officer

*Ex-Head of Production at **DCB BPPF** with **25 years** experience of research and production of biologics. He holds a Ph.D. from **National Taiwan University**.*

Ae-Ning (Irene) Lin, Ph.D. | Executive Director, Analytical Sciences & Quality Control

*Ex-head of Purification and Protein Characterizations at **DCB BPPF** with **25 years** of experience of biologic product R & D. She holds a Ph.D. from **University of Maryland.***

Barbara Grohmann-Izay, M.D. | Executive Director, Clinical Development & Operations

*Studied medicine, psychology and biostatistics in **University of Vienna**, Austria, with a postgraduate program in clinical research. She has accumulated over **18 years** of experience in industrial drug development and academic research.*

Hark Chen, M.S. | Executive Director, Manufacturing & Technical Operations

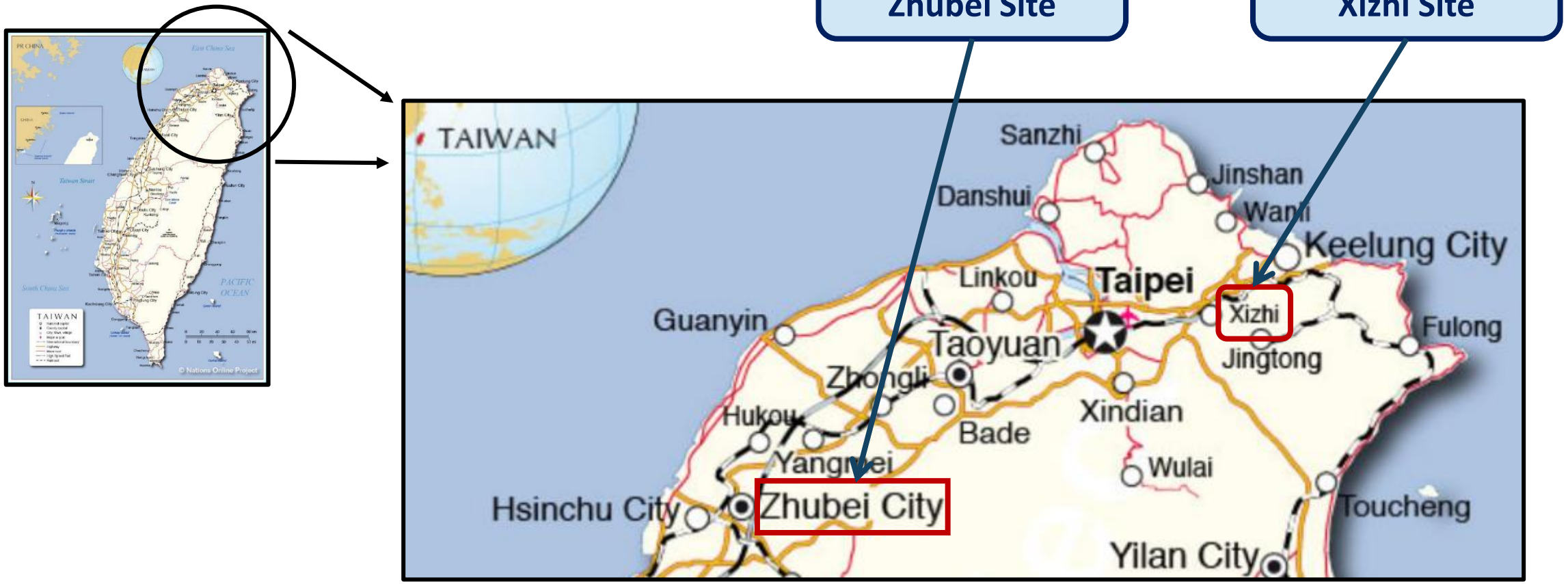
Co-founder of Mycenax Biotech Inc. and in charge of process development and manufacturing operations from 2001 to 2019. She has more than 20 years experience. She holds a MS of Chemical Engineering from National Taiwan Science & Technology University

Ywan-Feng Li, Ph.D. | Executive Director, Global Regulatory Affairs

*Former director of the Pharmaceutical Science Division at the Center for Drug Evaluation-Taiwan (CDE), Vice President of United Biopharma with **over 20 years** experience of pharmaceutical technology . She holds a Ph.D. from **University of North Carolina.***

SUPPLEMENTARY MATERIAL – FACILITY LOCATION

Locations of EirGenix Facilities



SUPPLEMENTARY MATERIAL – FACILITY LOCATION

(1) XiZhi Facility

ESTABLISHED: 1984

ADDRESS: No. 101, Lane 169, KangNing Road,
XiZhi District, New Taipei City

FACILITIES:

6F: Microbial Process Development Lab
5F: Microbial PIC/S GMP Plant
4F: Analytical Lab / Cell Line Development Lab
3F: QC Lab / Process Development Lab
2F: Cell Banking Area / PIC/S GMP Warehouse
1F: Cell Culture PIC/S GMP Plant / PIC/S GMP Warehouse
B1: Support Areas / Utilities

XiZhi

SUPPLEMENTARY MATERIAL – FACILITY DETAIL

(2) ZhuBei Facility

ESTABLISHED: 2019 (Stage 1)

ADDRESS: No. 168, Sec. 1, ShengYi Rd.,
ZhuBei City, Hsinchu County

FACILITIES: 8 Floors + Lower Floor (Stage 1, completed 2019)

- Offices
- Mammalian PIC/S GMP Mfg.
- Process Dev. Labs, Quality Control Labs
- PIC/S GMP Warehousing

SUPPLEMENTARY MATERIAL – FACILITY DETAIL

(2) ZhuBei Facility

One Microbial Cell Culture Production Line

- 350 + 1,000L USP fermenters & 2-3 suites of DSP

Two Mammalian Cell Culture Production Lines

- Each production line: USP with max. 3 sets of 2x2,000L & One DSP facility
- One DSP can handle up to 16 Kg Mab/lot, use SU design can run up to 60 lots/year. With 3 sets of 2x2,000L SUBs in USP, the maximum production capacity up to 500 Kg Mab /Year

Capacity for Mammalian Cell

- **Stage 1 (2016-2019)**
  - Line 1: (50/200/2x1,000L SUB) 2 sets of 2x2,000L; QC Lab.
  - Max. capacity ~ 42 Lots/yr
- **Stage 2 (2020-2022)**
  - Expand Line 1: Adding one more set of 2x2,000L; PS Lab.
  - Build up the 2nd production line (5th fl): 3 sets of 2x2,000L
  - Max. capacity ~ 120 Lots/yr
- **Stage 3 (2022-2024)**
  - Build up the Building B with 1x350L, and 1x1000 L fermenters, one harvest zone and 2 downstream purification suites

SUPPLEMENTARY MATERIAL – FACILITY DETAIL

Zhubei Facility – Mammalian Cell Culture Production Lines

CLICK HERE
360-Degree
Virtual Tour

http://www.eirgenix.com/en/about/index.aspx?num=17

EirGenix