EirGenix

TPEx: 6589

YOUR RELIABLE BIOLOGICS PARTNER

Investment Forum by Cathay Securities(Virtual)
Mar. 10, 2022

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

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COMPANY PROFILE

EirGenix Profile and USPs

- Established on December 21, 2012
  - Completed acquisition of DCB's Biopharmaceutical Pilot Facility in March 2013
  - IPO on TPEx (Code: 6589) on June 28th, 2019; with market cap of $1.1 billion USD
- Back up by very strong and stable investors, i.e., the Founder of Foxconn, Terry Guo, Government and pan-government investment funds, and Formosa Laboratories as a strategic partner
- Dual business model : CDMO Services and own-product development
- Rapidly growing Contract Development & Manufacturing services business – break even in 2016; 2021 CDMO income reached up to $43.4 million USD, the total revenue in 2021 is $61.5 million USD

財團法人生物技術開發中心 Development Center for Biotechnology

COMPANY PROFILE

EirGenix Profile and USPs

- The current manufacturing capacity (Xizhi + Zhubei): mammalian cell culture capacity – 9,500 L, microbial fermentation capacity – 150 L
  - The first large scale (2 sets of 2x2000L) commercial production line in the Zhubei facility was on stream on Jan. 23, 2019; additional 1set of 2x2000L will be installed in 2022
  - Expansion of Zhubei facility to the 2nd mammalian cell culture production line (3 sets of 2x2000L) is expected to be on-stream in Q4, 2022; total capacity 25,500 L
  - Expansion of Zhubei facility Building B for microbial fermentation capacity (350 + 1000 L) with 2-3 downstream purification suites; total capacity 1500 L with 3-4 purification suites
  - A 6-8 years plan to build up a 150,000 L very large-scale mammalian cell culture facility in 3 stages (50 KL, 100 KL, and 150 KL)

COMPANY PROFILE

EirGenix Profile & USPs

- Broad and diversified product pipeline; a unique strategy of Her2 products franchise management
  - Signed the EG12014 global licensing (excluding Taiwan, Mainland China, Japan, S. Korea and Russia) agreement with Sandoz AG for the upfront and milestone payment of US$ 70 millions plus the profit sharing of the future sales on April 29, 2019
  - Completed the Global Phase III Clinical Trial for Trastuzumab Biosimilar (EG12014)
  - Submitted BLA and MAA in December of 2021
  - Initiate Phase 1 clinical trial for Pertuzumab Biosimilar (EG1206A) in Q1 of 2022
- Received multiple Best CDMO Awards
  - 2018 Asia's Best Biologics CMO Award
  - 2019 BioProcessing Excellence in Taiwan Award
  - 2020 BioProcessing Excellence in Greater China Area Award

One of the Fast-Growing Biopharmaceutical Companies In Asia!

COMPANY PROFILE

200+ years
Combined Experience in the Industry!

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***

COMPANY PROFILE

200+ years
Combined Experience in the Industry!

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.***

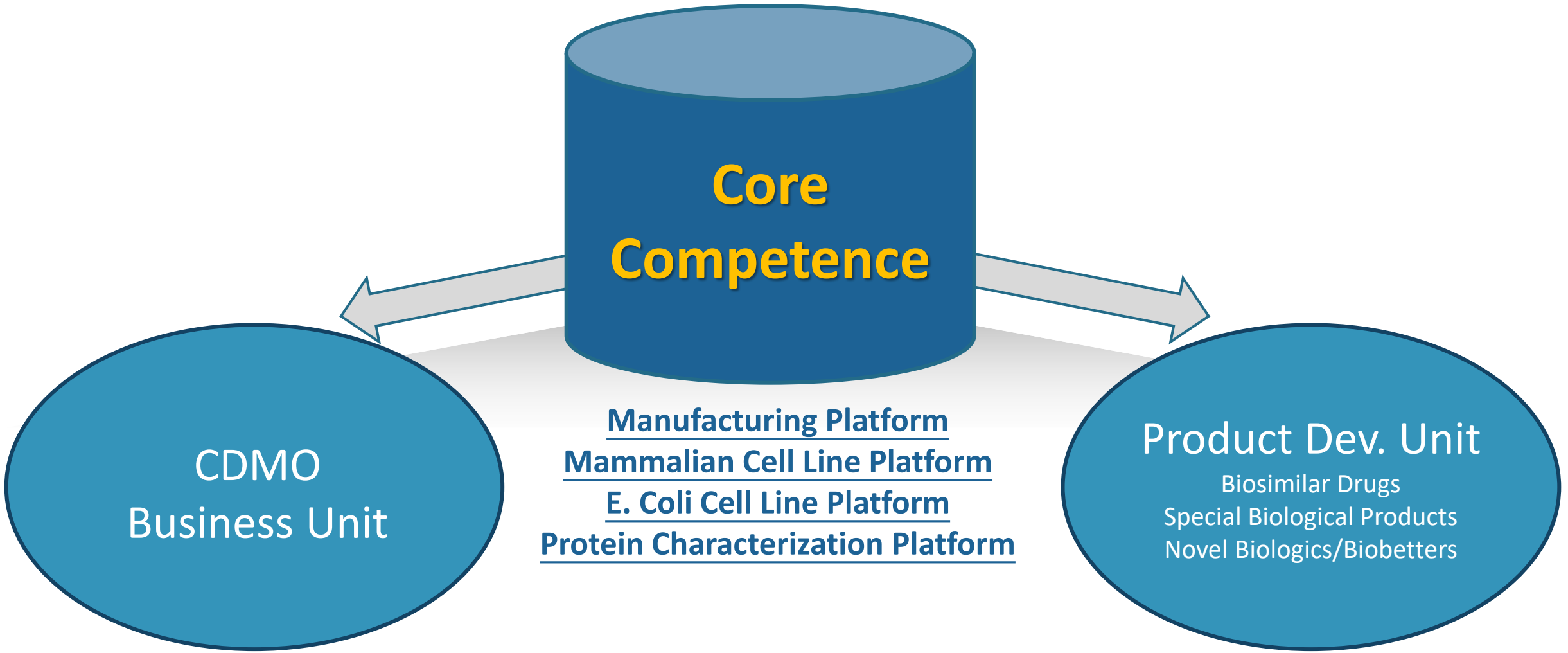
Barbara Grohmann-Izay, M.D. | Executive Director, Clinical Development & Operations

*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

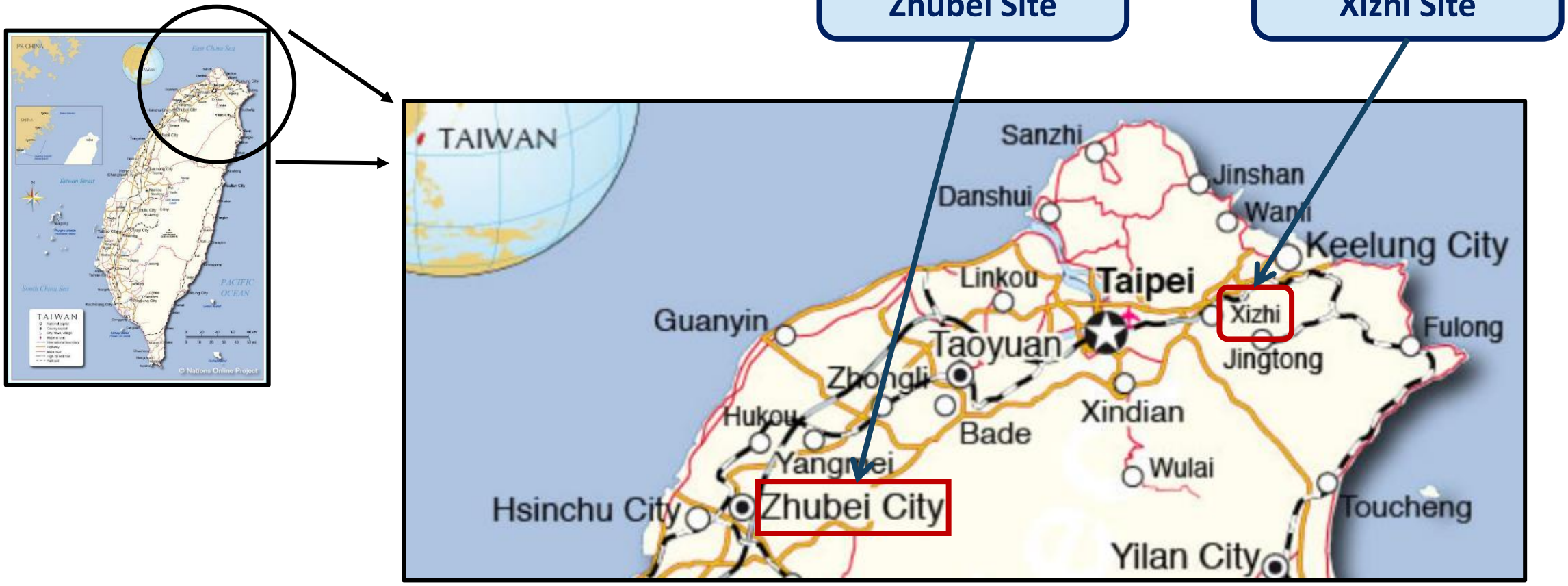
Co-founder of Mycenax Biotech Inc. and in charge of process development and manufacturing operations from 2001 to 2019. She has more than 20 years experience. She holds a MS of Chemical Engineering from National Taiwan Science & Technology University

BUSINESS OVERVIEW



BUSINESS OVERVIEW

Locations of EirGenix Facilities



BUSINESS OVERVIEW

(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

BUSINESS OVERVIEW

(2) ZhuBei Facility

ESTABLISHED: 2019 (Stage 1)

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

BUSINESS OVERVIEW

(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

BUSINESS OVERVIEW

Zhubei Facility – Mammalian Cell Culture Production Lines

CLICK HERE
360-Degree
Virtual Tour

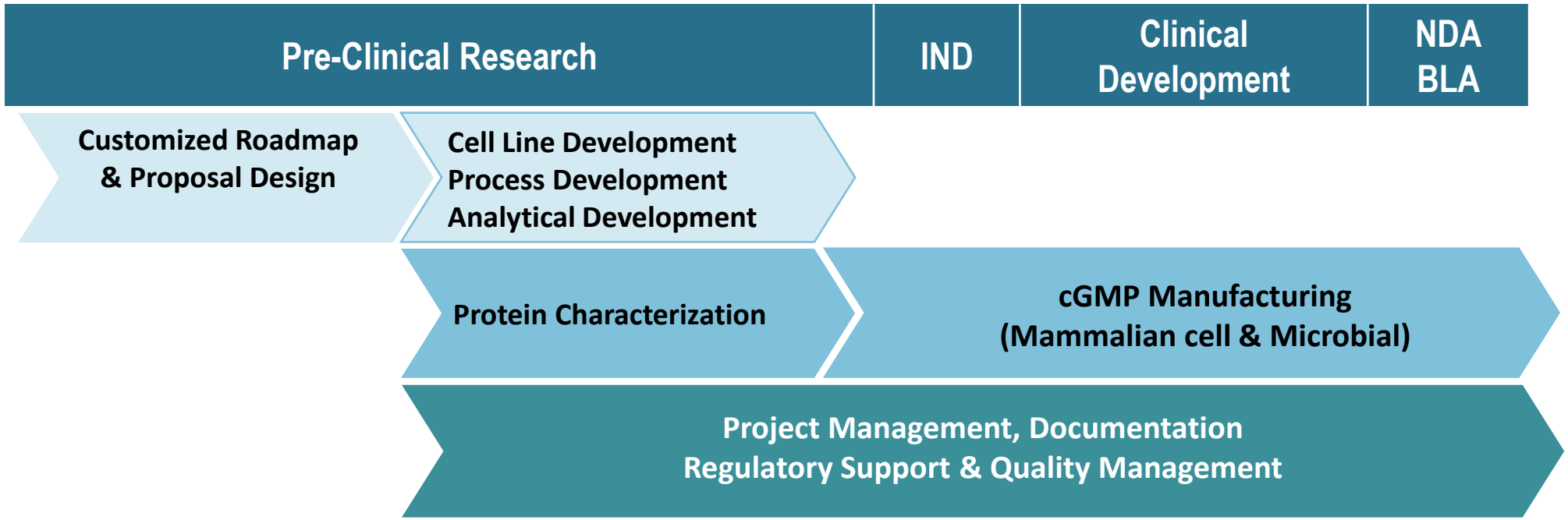
http://www.eirgenix.com/en/about/index.aspx?num=17

KEY STRENGTHS

Full-Service CDMO Services

One-Stop Solution from DNA to NDA/BLA

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



BUSINESS OVERVIEW

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

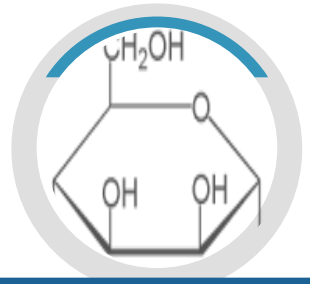
- CD (Circular Dichroism)
- DSC (Differential Scanning Calorimetry)
- Fluorescence Spectrometer

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

BUSINESS OVERVIEW

Additional Service Offerings

Antibody Drug Conjugate (ADC) Development

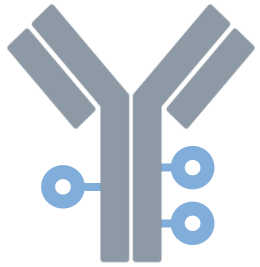
- Integrated expertise in ADC Development with strategic partner, Formosa Laboratories

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.

KEY STRENGTHS

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

KEY STRENGTHS

65+

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

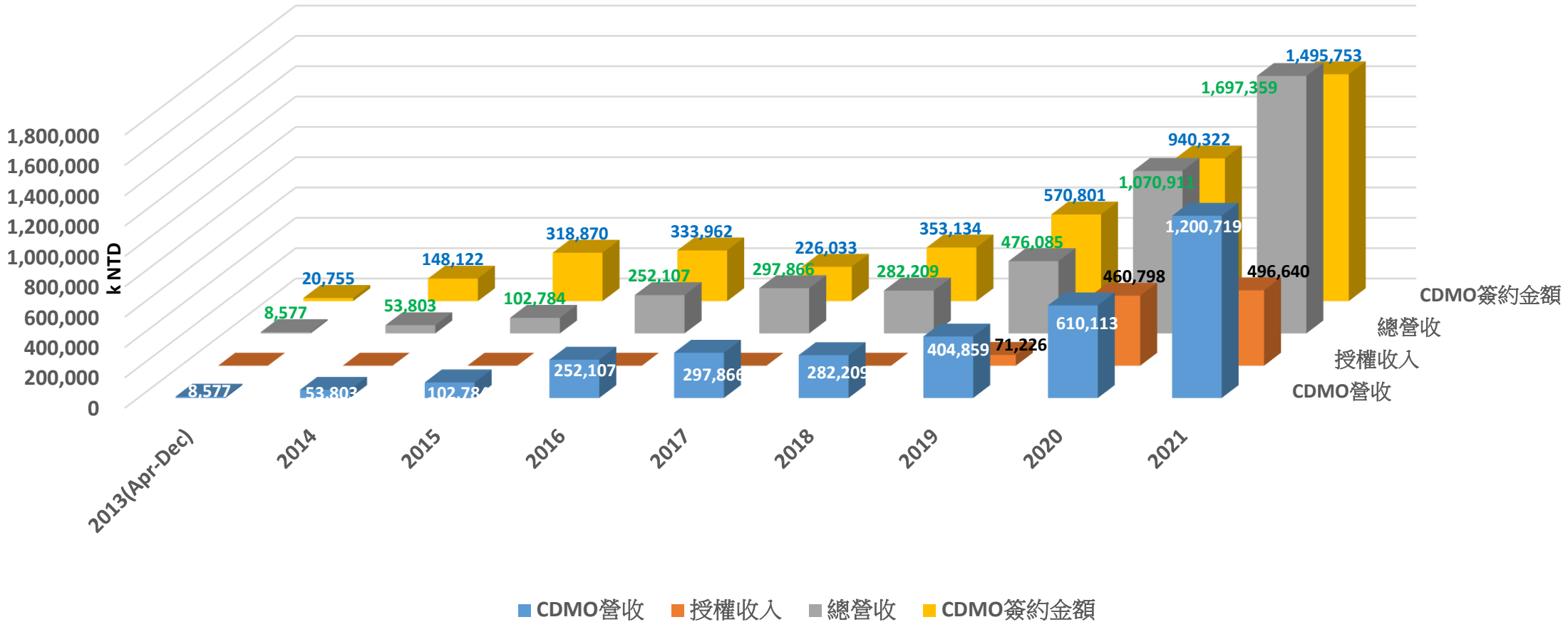
Global Compliance

Compliance and Certification – Key Highlights

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

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**

Business Performance



PRODUCT PIPELINE OUTLOOK

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					In negotiations
EG13074 TRZ (SC formulation)	Monoclonal Antibody	Cancer	HER2					PARTNERED WITH SANDOZ A Novartis Division
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					

Her 2 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 EG's own pertuzumab (EG1206A) and be the top 2 to launch the product would have the complimentary effect to enhance the market penetration of EG'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

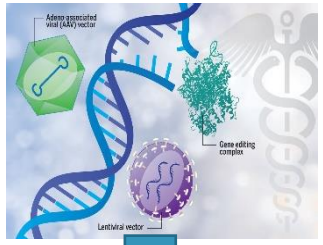
Looking Forward

EirGenix is looking forward to

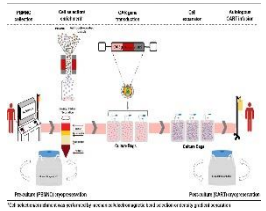
- Further increase the global presence and expand the marketing strength of its CDMO business to maintain a healthy growth rate
- Further expand its pipeline to cover immuno-oncology biosimilars by either in-licensing or form a development alliance and plan to launch 6-8 biosimilar products in the market by 2030

Looking Forward

Cell & Gene Therapy CDMO

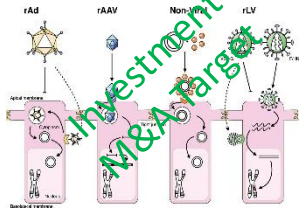


Allogenic cell processing system



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

1. Xizhi facility improvement: 1x200/1000L (SUB) adding 1x200L (SUB) and removing 500 L SS (2022)
2. Zhubei expansion :
   a) Add 1 set of 2x2000L to the existing mammalian production line (3rd floor) (2022)
   b) 2nd mammalian cell production plant (5th floor) – 3 sets of 2x2000L, 2x1000L, 2x200L (2022)
   c) Building B: 350/1000 L fermenter; 2 x DSP suites (2024)
3. Very Large Scale fully automated hybrid production plant : 150,000 L constructed in 3 stages to reach the scale of 50 KL in 2025, 100KL in 2028 and 150 KL in 2030
4. Total capacity: mammalian cell culture – 176,000 L; microbial fermentation – 1500 L
5. Regional small-mid CDMO target for investment or M&A

Looking Forward

Biosimilars

Her 2 Family

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

New List :
To be in-house developed, or in-licensed or a 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

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 would share the high development cost and the risks


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