EirGenix

TPEx: 6589

YOUR RELIABLE BIOLOGICS PARTNER

Jefferies & Fubon Virtual Taiwan Corporate Day 2022
May. 17, 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.TWO) on June 28th, 2019

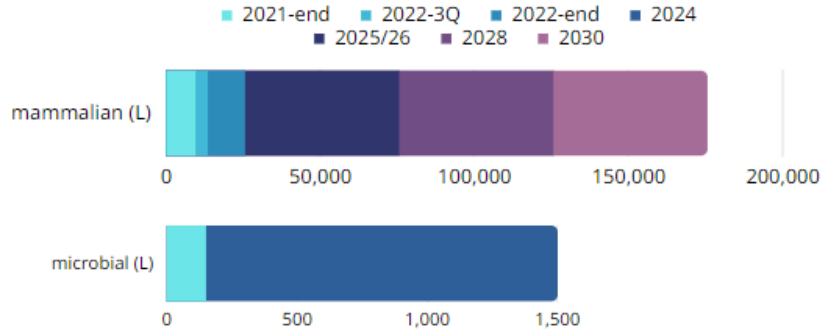
財團法人生物技術開發中心 Development Center for Biotechnology

- 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.
- Total revenue in 2021 $61.5 million USD +58%YoY, global client revenue weight 64% vs TW Domestic 36%.

COMPANY PROFILE

Capacity and Expansion Schedule

- The current manufacturing capacity (Xizhi + Zhubei): mammalian cell culture capacity – 9,500 L (**25,500L by 2022-end**), 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 3Q22
  - Expansion of Zhubei facility to the 2nd mammalian cell culture production line (3 sets of 2x2000L) is expected to be on-stream in 4Q22; **mammalian cell capacity will reach 25,500 L by 2022-end**
  - Expansion of Zhubei facility Building "B" for microbial fermentation capacity (350 + 1000 L) with 2-3 downstream purification suites; **microbial fermentation capacity to reach 1500L by 2024**
  - 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), **mammalian capacity to reach 175,500L**



COMPANY PROFILE

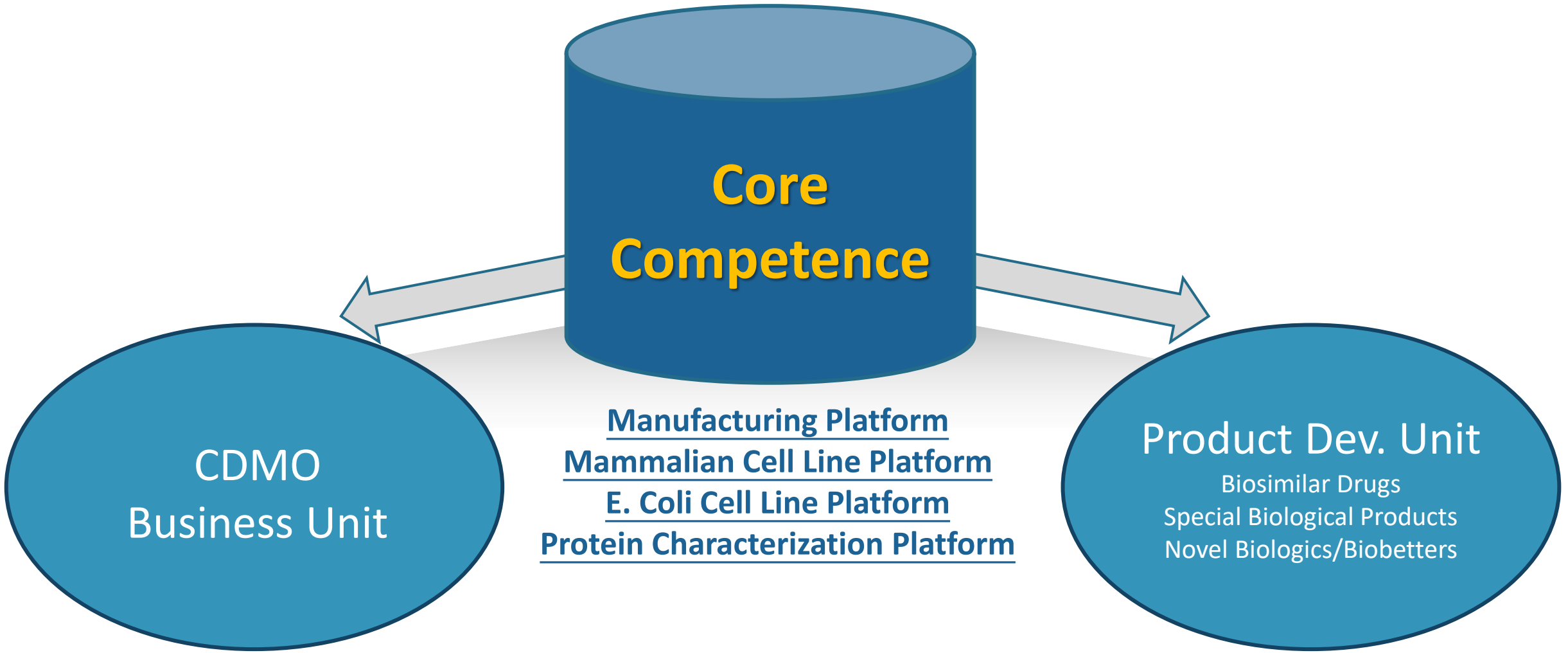
Achievements & Milestones

- **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(of the Novartis Group)** 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 (EG12014)
  - Initiate Phase 1 clinical trial for Pertuzumab Biosimilar (EG1206A) in 1Q22
- **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
- **Rated 2021 Top 5% Corporate Governance Evaluation at TPEx after second year of the IPO**

One of the Fast-Growing Biopharmaceutical Companies In Asia!

EirGenix

BUSINESS OVERVIEW

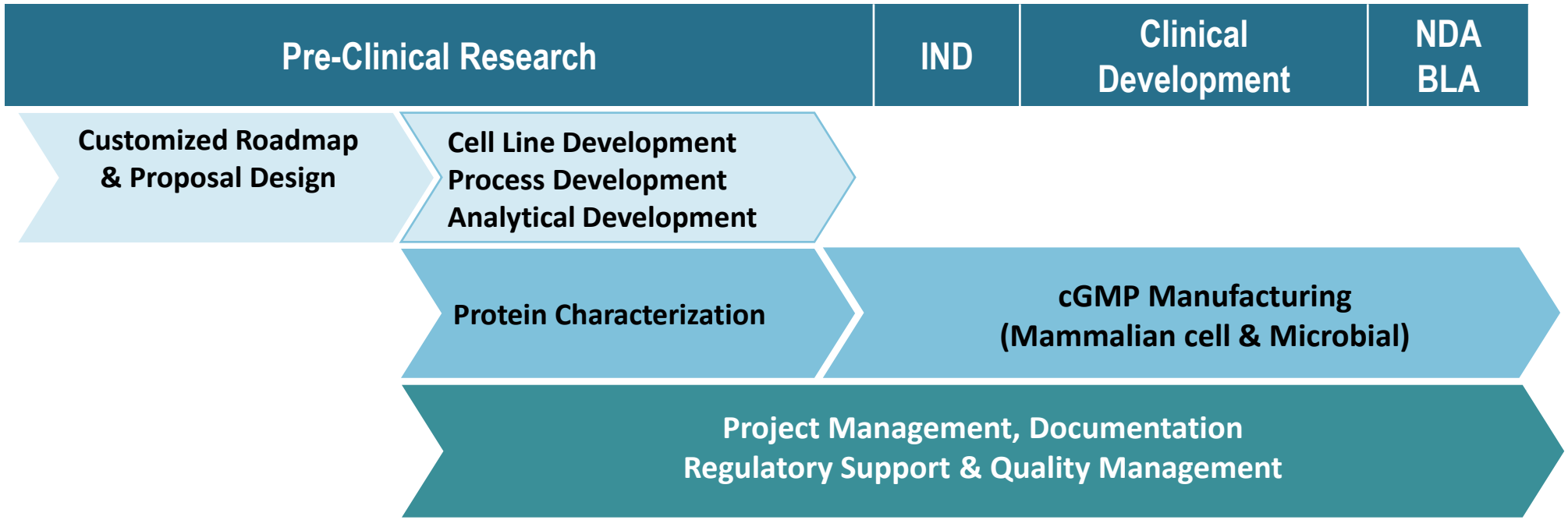


KEY STRENGTHS

Full-Service CDMO Services

One-Stop Solution from DNA to NDA/BLA

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



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

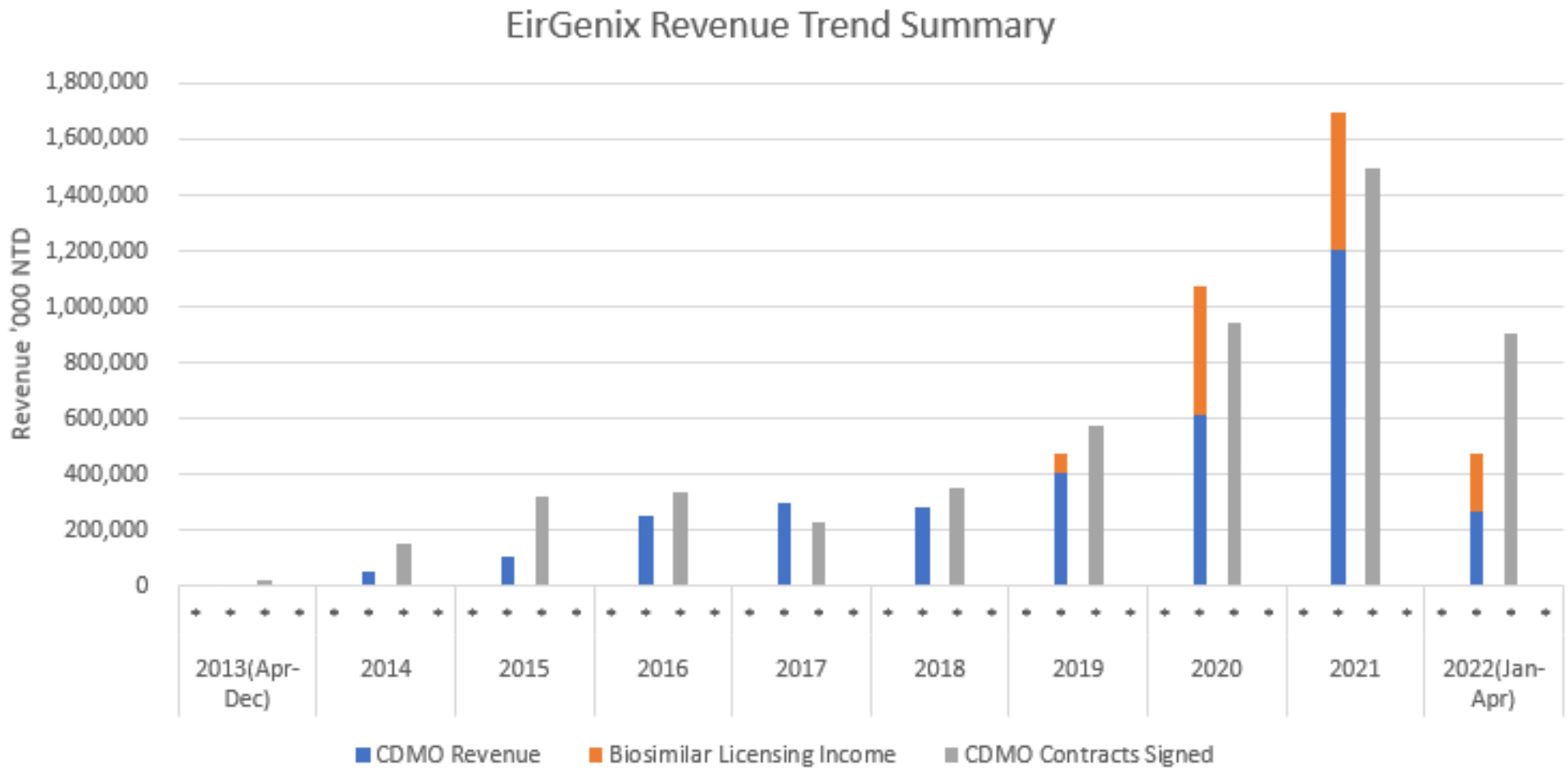
Global Compliance

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



Factors Affecting Market Value of Biosimilar Companies

	Celltrion (068270.KS)	Momenta ★	Coherus (CHRS.US)	Tanvex (6541.TW)	Formycon (FYB.DE)	EirGenix (6589.TWO)	Pfenex ※	Samsung Biologics (207940.KS)
Ongoing/Completed Phase III Clinical Results (under review)	√ (4+1)	√ (0+1)	√ (1+2)	√ (0+1)	√ (0+1)	√ (0+1)	√ (1)	√ (5+1)
Joint Development or Regional Authorized Partners	√	√	√		√	√		√
Products Under Phase III Clinical Development	√	√	√	√	√		√	√
Internal Manufacturing Capacity	√			√		√		√
Matched Items	**4**	**3**	**3**	**3**	**3**	**3**	**2**	**4**
Total Market Capital (US$ Million)	**15,376**	**NA**	**615**	**645**	**986**	**813**	**NA**	**43,580**

*Based on market data on 2022/05/13

★ Momenta was acquired by Johnson & Johnson.

※ Pfenex was acquired by Ligand.

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	→	→			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	→				

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

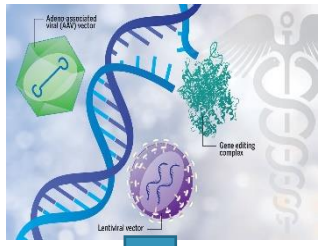
Looking Forward

EirGenix is looking forward to

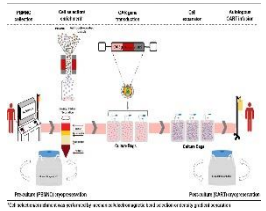
- Further increase the global presence and expand the marketing strength of its CDMO business to maintain a healthy growth rate
- Further expand its pipeline to cover immuno-oncology biosimilars by either in-licensing or form a development alliance and plan to launch 6-8 biosimilar products in the market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

Looking Forward

Cell & Gene Therapy CDMO

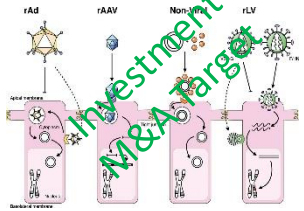


Allogenic cell processing system



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 (to resume production in late May 2022)
2. Zhubei expansion :
   a) Total mammalian cell production lines (3F & 5F) to reach 25,550 (by 2022-end)
   b) Building “B”: 350/1000 L fermenter; 2 x DSP suites (by 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

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

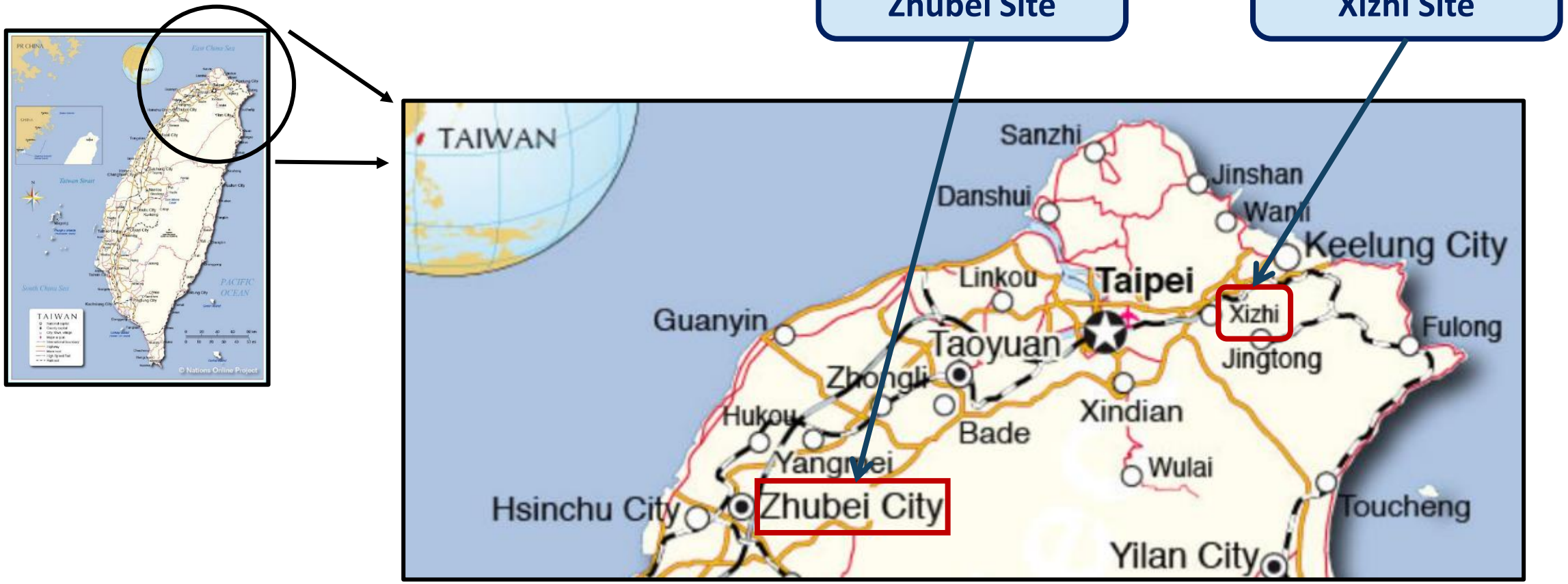
*Studied medicine, psychology and biostatistics in **University of Vienna**, Austria, with a postgraduate program in clinical research. She has accumulated over **18 years** of experience in industrial drug development and academic research.*

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

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, 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

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

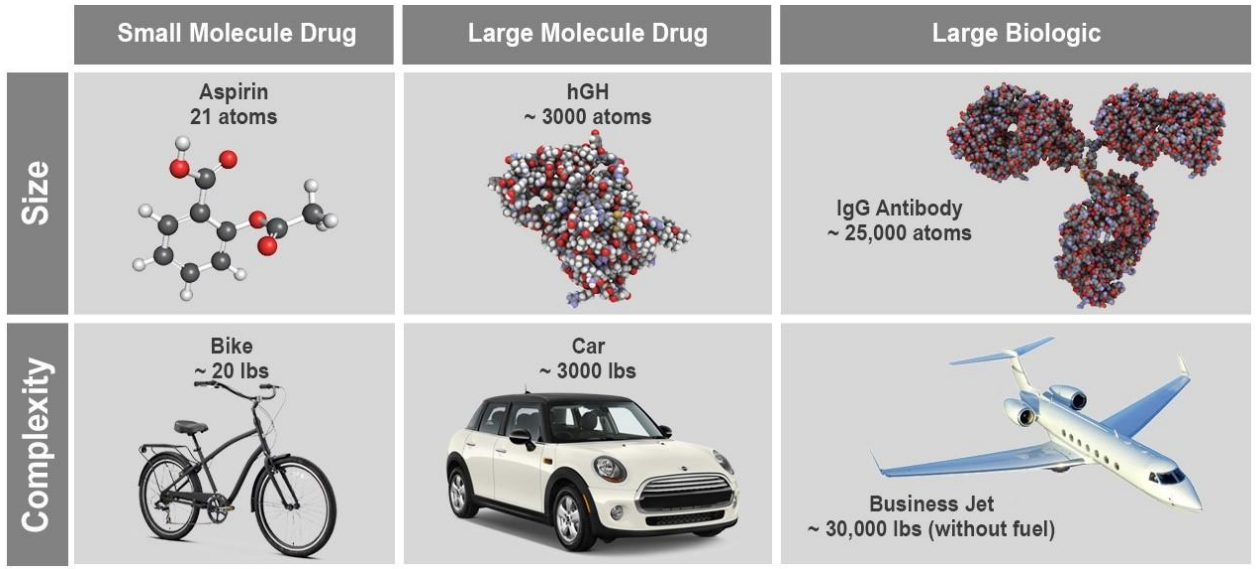
http://www.eirgenix.com/en/about/index.aspx?num=17

EirGenix

SUPPLEMENTARY MATERIAL – BIOSIMILAR VS GENERIC

- Biosimilars – 生物相似藥 vs Generics -- 學名藥
  - The regulatory pathway is different
  - Higher technical barriers and higher development cost (>$100 million USD vs a few million USD) for biosimilar development
  - Need to demonstrate no clinically meaningful differences between the biological product and the reference product through the clinical trials
  - Market penetration is relatively slower and price drop is less than generics

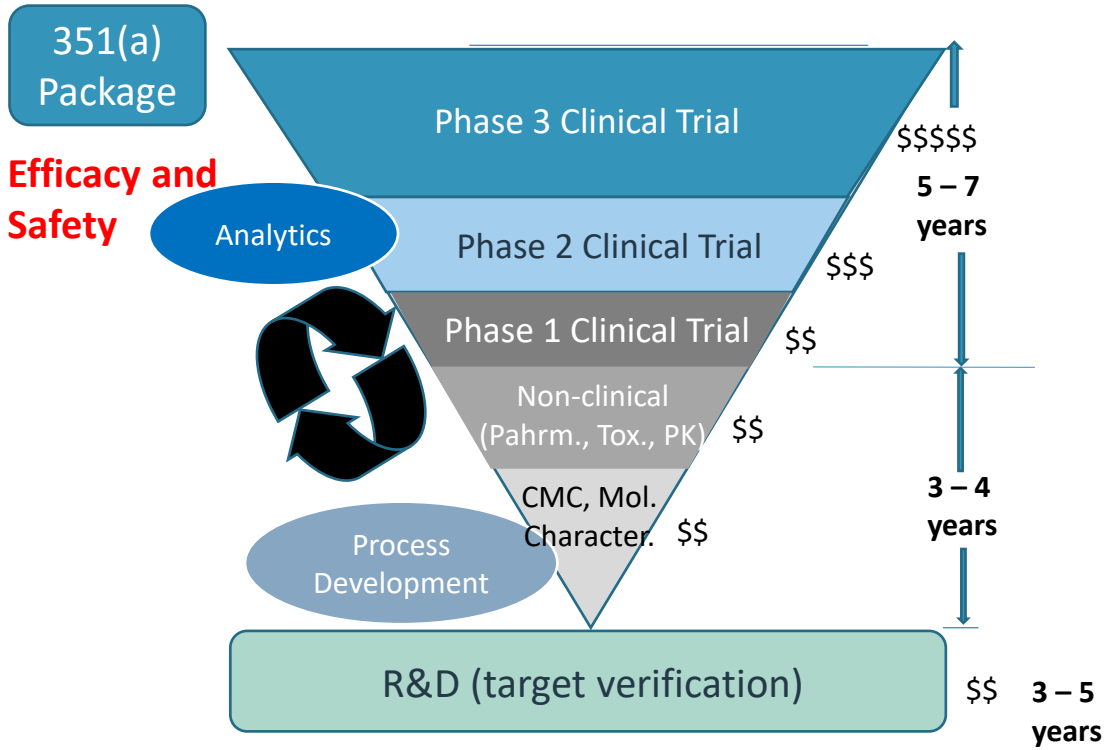
	Generic	Biologic	Biosimilar
Development cost (USD)	2-3 million	800 million	100-300 million
Time to market (years)	2-3	8-10	7-8
Clinical studies	Bioequivalence studies in healthy volunteers	Phase I- III studies efficacy and safety	Pharmacokinetic comparison studies in Phase III
Patients	20-50	800-1000	~100-500
Post-authorization activities	Pharmacovigilance	Phase IV, risk manage-ment plan including pharmacovigilance	Phase IV, risk manage-ment plan including pharmacovigilance



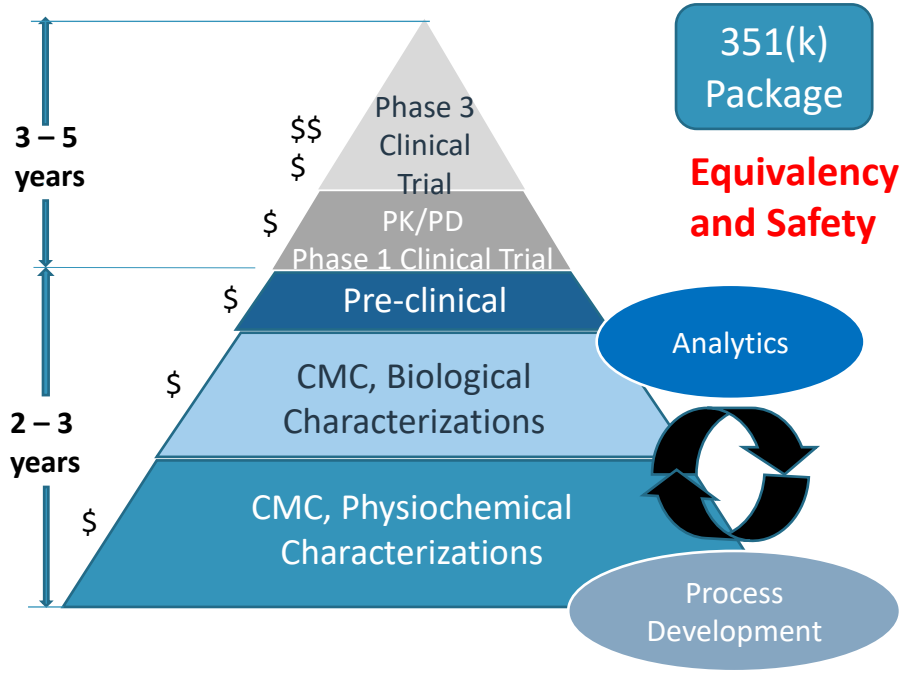
SUPPLEMENTARY MATERIAL – BIOSIMILAR VS GENERIC

Development pathways for novel biologics v.s. biosimilar

Novel biologics development pathway



Biosimilar development pathway



- Development of novel biologics requires much higher resources for conducting non-clinical studies and a series of clinical trials
- Development of biosimilar requires much higher resources to make a compound to be highly similar based on the physiochemical and biological product profiles (reverse engineering capability)