

EirGenix, Inc.

A New Asia Development & Manufacturing Hub for Biologics



Company Introduction

2021/09/02 ICA Conference

Forward Looking Statement Disclaimer

All information and other statements contained in this presentation, other than statements of historical fact, constitute forward looking statements within the meaning of federal securities laws. These forward-looking statements involve a number of risks, uncertainties, assumptions and other factors that could affect our future results and cause actual results and events to differ materially from our historical and expected results and those expressed or implied in these forward-looking statements.

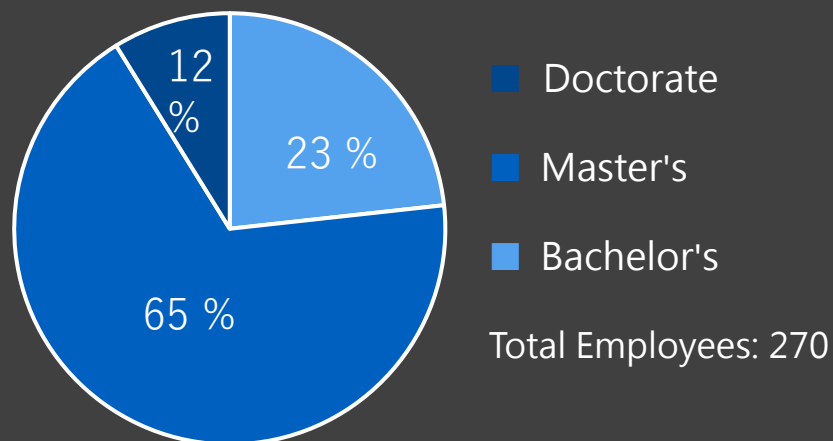
March 15, 2013

Signed agreement with DCB

~9%

Formosa Laboratories, Inc.

Employee Education Level:



Top 10 Investors

(as of 2021/04/24)

Shareholder	% Shares
Formosa Laboratories, Inc.	8.25%
National Development Fund	6.52%
Yaohua Glass CO., Ltd. Management Committee	5.58%
Taiwania Capital	4.67%
Wreker Pan	4.65%
Development Center for Biotechnology	2.61%
CTBC Venture Capital	2.16%
CTBC Capital - MOEA Small and Medium Enterprise Administration Assets	1.19%
中國信託商業銀行受託保管台康生技（股）公司	0.93%
先進國際投資股份有限公司	0.91%
TOTAL	37.47%

Note: Total of Employee Shareholders = 4.46% (2021/04/24)

> 200 years
Experience in
the industry

A Strong and Experienced Senior Management Team:



Lee-Cheng (L-C) Liu, Eng.Sci.D. | President & CEO

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



Thomas Schulze, Ph.D. | Managing Director, 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. | VP, COO

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



Ping-Yang Ye, Ph.D. | VP, CTO

Ex-Executive director of Amgen, with more than 23 years of experience of process and product development experience in Biogen-IDEC, GSK及SmithKline Beechman. He holds a doctoral degree from **University of Utah (Salt Lake City)**.



Cathy (Hsiu-Chuan) Yang | VP, CFO

Ex-General Manager of **ERS, a JV company between Fresenius and Excelsior**, overseeing the operations of 100+ kidney dialysis centers in Taiwan. She holds a Master of Science in Accounting from **University of New Haven** and has 20 years of experiences in FMCG and medical industries.



James (Chih-Dung) Teng | VP, Quality System

Ex-QA executive in Mycenax and Holly Stone Healthcare, Co., with more than 25 years of experience in GMP, quality assurance, quality control and manufacturing in pharmaceutical industry



Sheng-Chung Ju, Ph.D. | Executive Director, Engineering & Manufacturing

Ex-Head of Production at **DCB BPPF** with 25 years experience of development and production of biologics. He holds a Ph.D. from **NTU**.



Irene (Ai-Ning) Lin | Executive Director, AS/QC

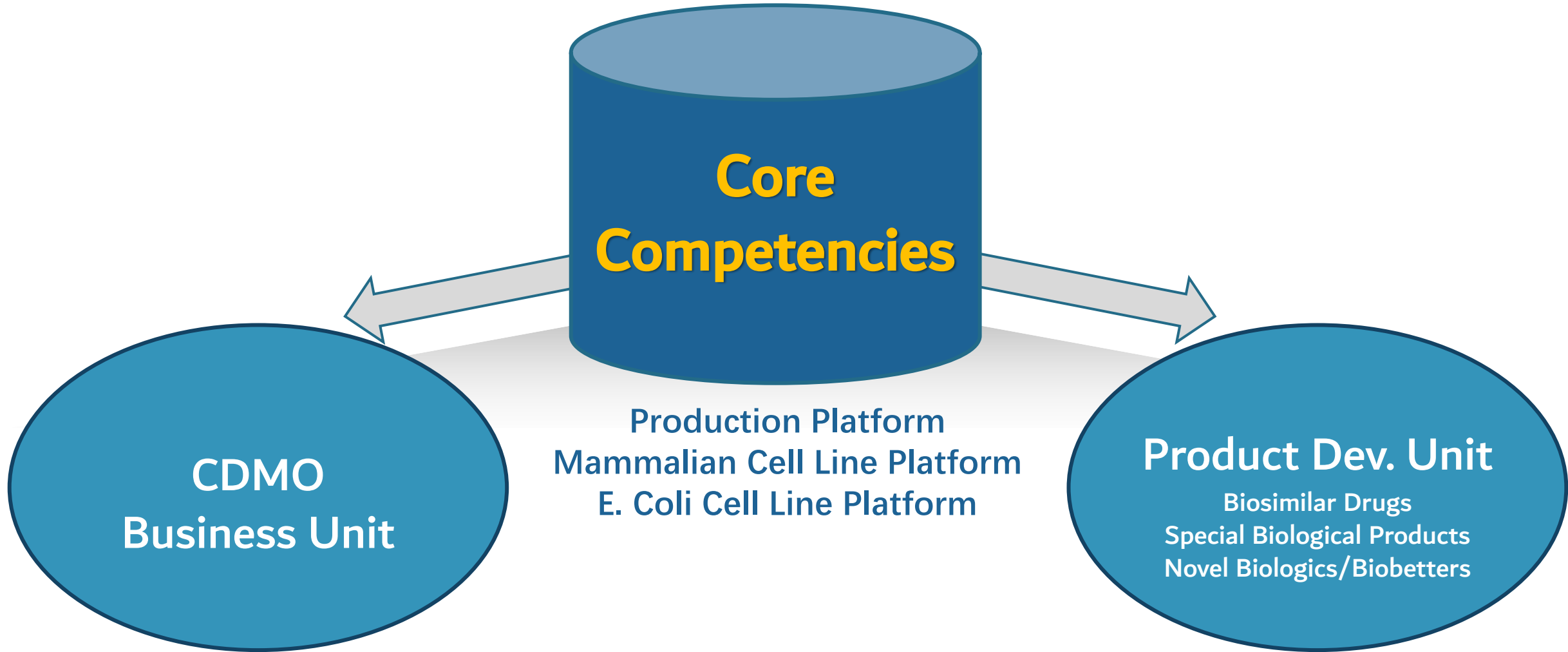
Ex-head of Purification and Protein Characterizations at **DCB BPPF** with 25 years of experience of biologic product R&D. She holds a Ph.D. from **University of Maryland College Park**.



Barbara Gromann-Izay MD | Senior Director, Medical Affairs & Clinical Operations, EirGenix Europe GmbH

Ex-AOP Clinical Development Director, with 17 years of experience in Baxter, Wyeth, Hoopkin Bio served as a Clinical Operation management position. She holds a MD degree from **University of Vienna**

Dual Business Model



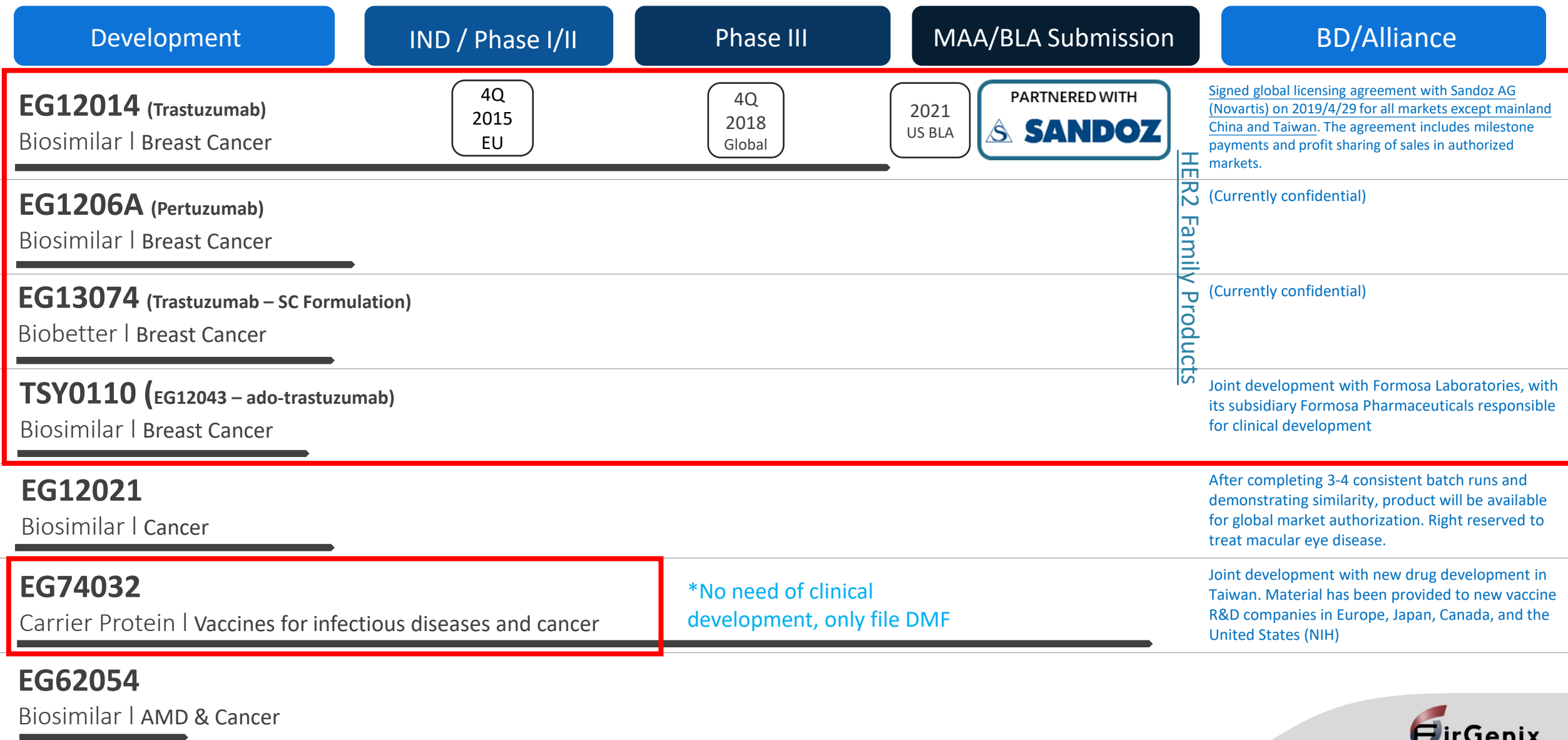
EirGenix's Profile & Current Developments

- **Dual Business Model:** CDMO Services and Internal Product Development
- Since the establishment of EirGenix, a total of NTD 8.248 billion in cash has been raised and a joint loan signed with Taiwan Enterprise Bank valued at NTD 850 million for facility construction. The joint loan has since increased to NTD 1.05 billion as of May 6, 2020. An additional NTD 300 million of convertible corporate bonds has been subscribed and guaranteed by Taichung Bank
- Broad and diversified product pipeline (total 6); **a unique strategy of HER2 products franchise management**
- Rapidly growing Contract Development & Manufacturing (CDMO) service business – break even achieved in 2016
- Newly constructed **Zhubei commercial production plant was on-line on January 23, 2019**
- On April 29, 2019, signed a global licensing agreement (excluding Taiwan and Mainland China) with Sandoz AG for EG12014 that includes upfront and milestone payments, plus profit sharing of the future sales
- Successfully completed IPO in TPEx on June 28, 2019.
- EirGenix received **PMDA's official approval on February 3rd, 2020** and was issued PMDA's "GMP compliance Inspection Result Notification", proclaiming EirGenix's compliance with relevant Japanese regulations regarding the quality, effectiveness and safety of pharmaceutical manufacturing. On March 3, 2021, EirGenix signed a long-term supply agreement with a Japanese pharmaceutical company, marking the first for a Taiwanese company to provide long-term supply of a marketed biological drug on the Japanese market. The product is a staple for cancer treatment with the Japanese market representing 30% of total market share.

EirGenix's Recent & Current Developments

- The multi-country, multi-center Phase III clinical trials for **biosimilar drug EG12014** was conducted in 91 clinical centers in 11 countries around the world where 807 patients were admitted by March 25, 2020. The pre-operative neoadjuvant therapy and tumor removal surgery for the last patient in was completed at the beginning of November 2020. **On March 23, 2021, the analysis of the Phase III clinical trials concluded that EG12014 had met its primary endpoint, showing equivalent efficacy to the originator drug and demonstrated a comparable safety profile. Submissions of Biological License Application (BLA) to U.S. FDA and Market Approval Application to EMA are now being prepared.**
- In December 2019, EirGenix's German subsidiary, EirGenix Europe GmbH was established, with its main task to manage and execute clinical development of EirGenix's biological products.
- Awards Record:
 - ✓ 2018/01/31 Asia's Best Biologics CMO Award
 - ✓ 2018/11/30 Winner of 15th Annual National Innovation Award (Biotech/Pharmaceutical)
 - ✓ 2018/12/31 Deloitte 2018 Technology Fast 500 Asia Pacific , Ranking No. 324
 - ✓ 2019/02/27 BioProcessing Excellence in Taiwan Award
 - ✓ 2019/04/10 Winner of 6th MOEA National Innovation Award (Small and Medium-Sized Enterprise)
 - ✓ 2019/07/26 Winner of 2019 Taipei Biotechnology Award (New Innovation Technology Excellence Award)
 - ✓ 2019/12/06 Winner of National Innovation Award (Enterprise Innovation Award)
 - ✓ 2020/07/08 BioProcessing Excellence in Greater China Area Award

EirGenix's Product Pipeline

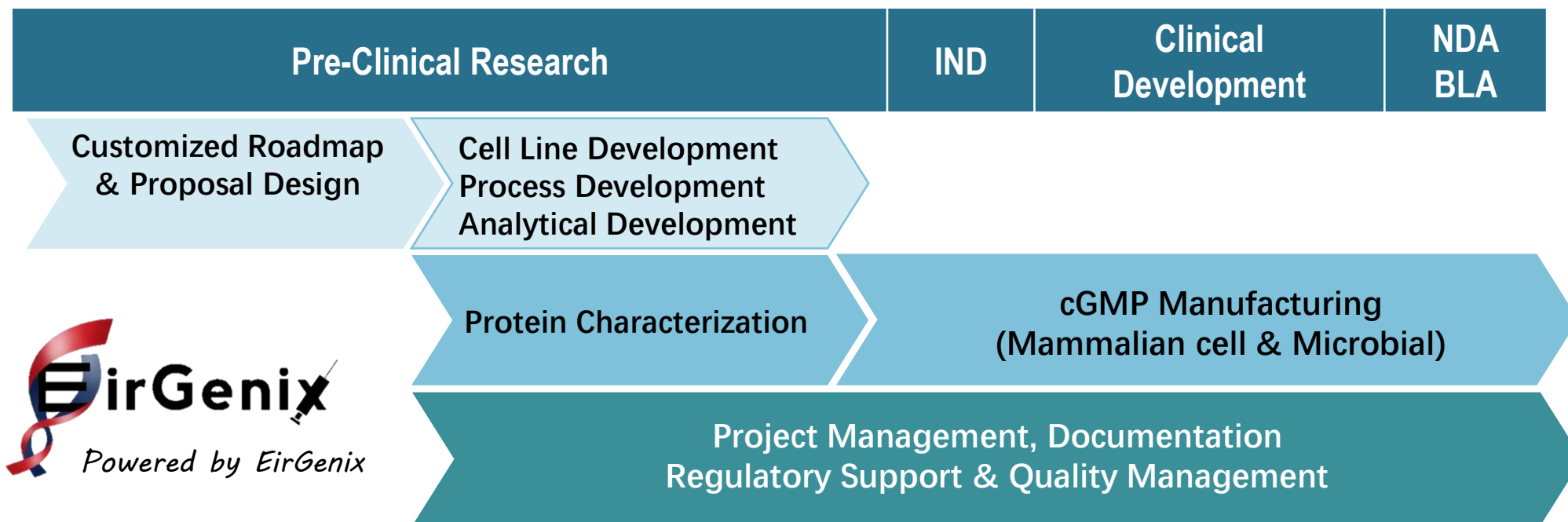


HER2 Family Products

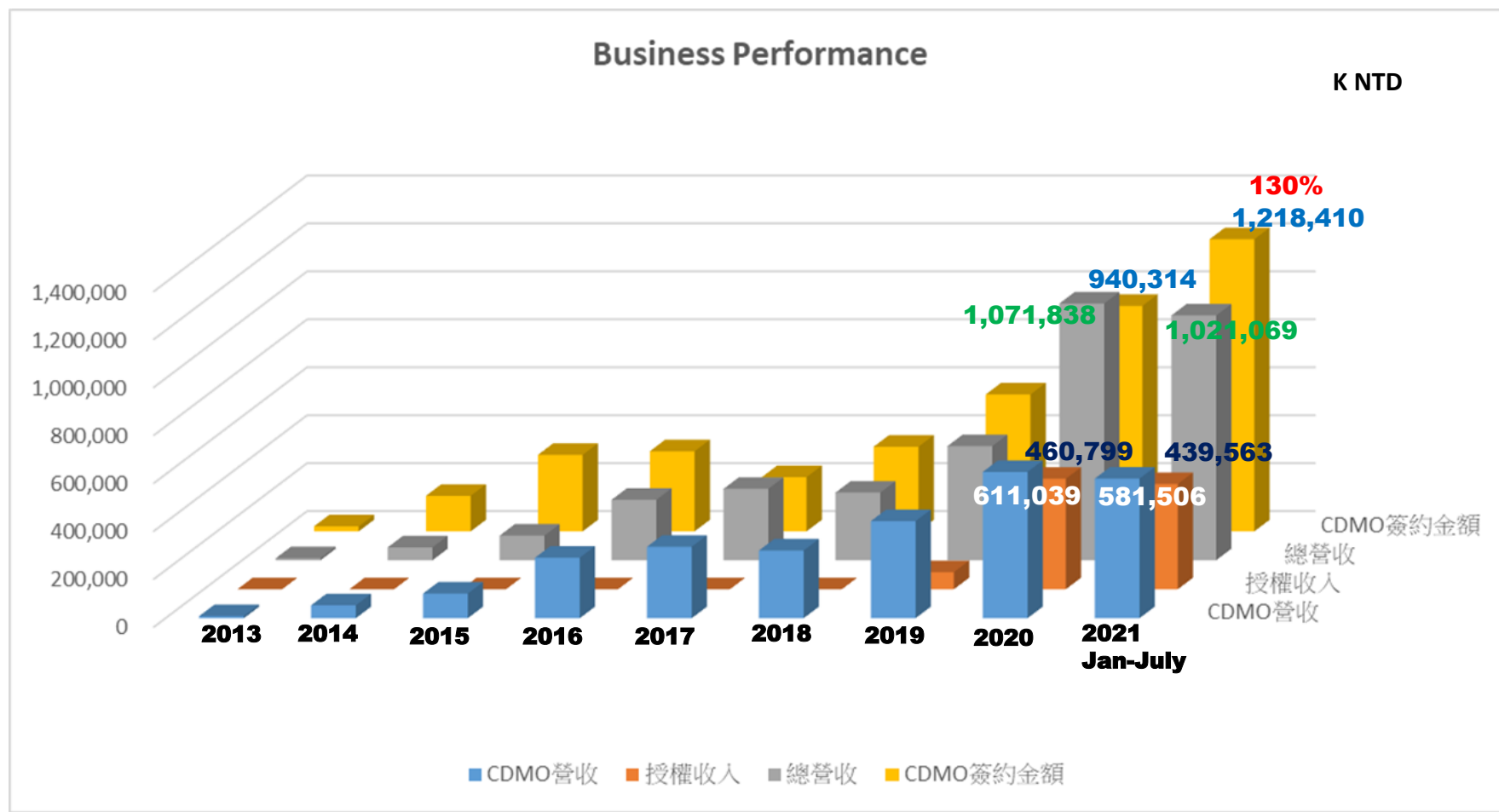
EirGenix's CDMO Services

Full-Service CDMO Services

One-Stop Solution from DNA to NDA/BLA

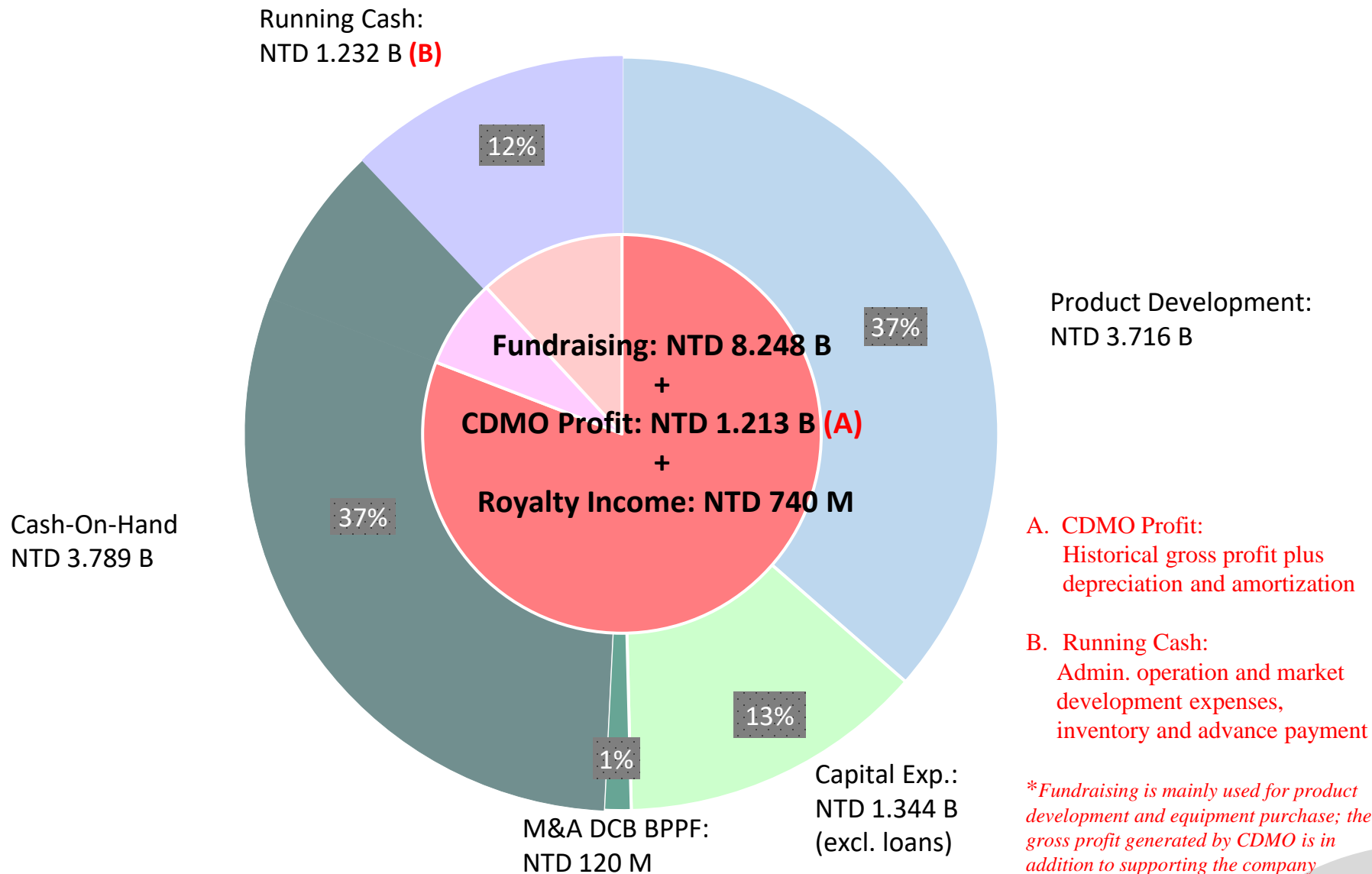


Business Performance



- CDMO Revenue
- Sales Revenue
- Total Revenue
- CDMO Signed Contract Value

Fundraising Capital Utilization (2012/12 – 2021/06)



Factors Affecting Market Value of Biosimilar Companies

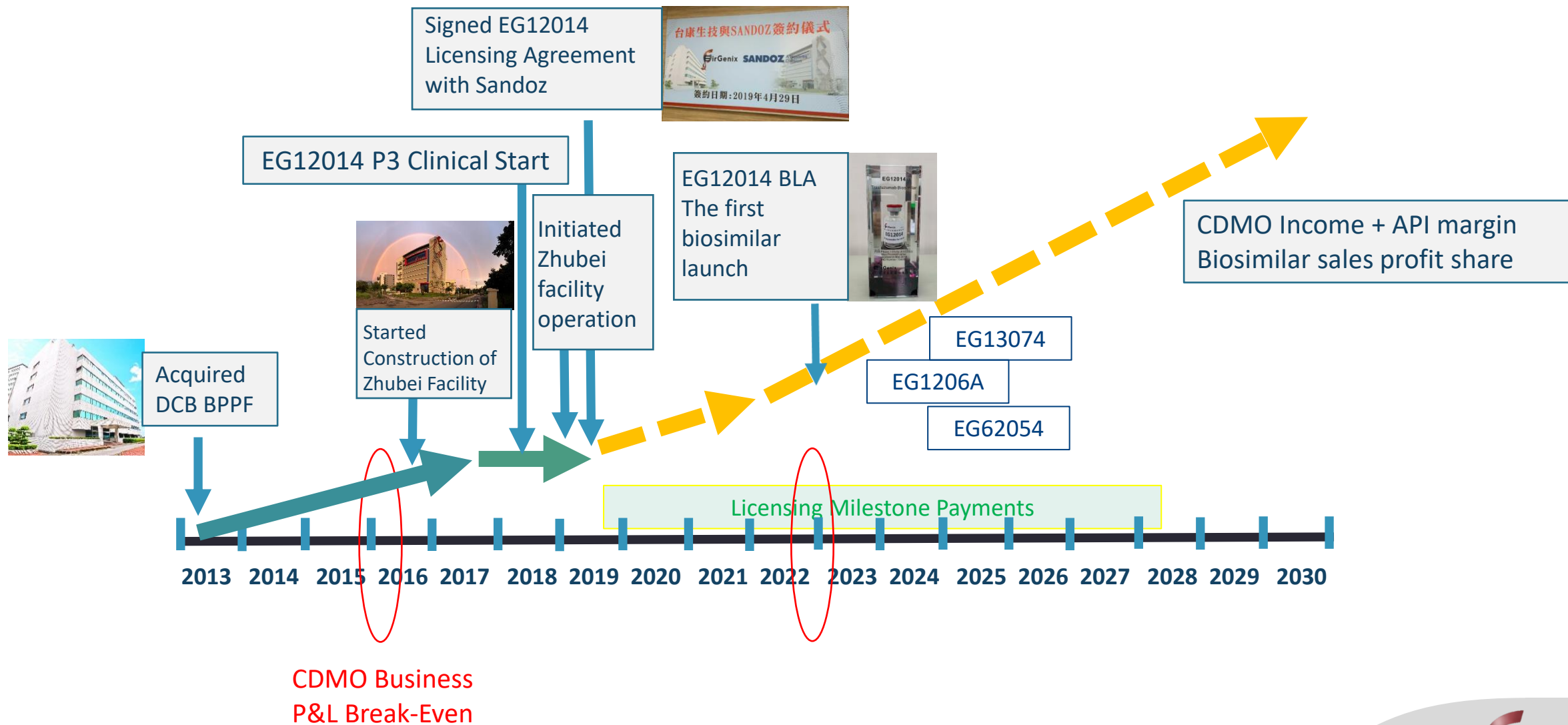
	Celltrion	Momenta [★]	Coherus	Tanvex	Formycon	EirGenix	Pfenex [✕]	Samsung Biologics
Ongoing/Completed Phase III Clinical Results (under review)	√ (4+1)	√ (0+1)	√ (1+2)	√ (0+1)	√ (0+1)		√ (1)	√ (5+1)
Joint Development or Regional Authorized Partners	√	√	√		√	√		√
Products Under Phase III Clinical Development	√	√	√	√	√	√	√	√
Internal Manufacturing Capacity	√			√		√		√
Matched Items	4	3	3	3	3	3	2	4
Total Market Capital (US\$ Million)	33,031	NA	1,147	527	635	1,147	NA	56,954

★ Momenta was acquired by Johnson & Johnson.

✕ Pfenex was acquired by Ligand.

*Based on market data on 2021/08/23

EirGenix's Past Performance & Future Vision



EirGenix's COVID-19 Anti-Epidemic Activities

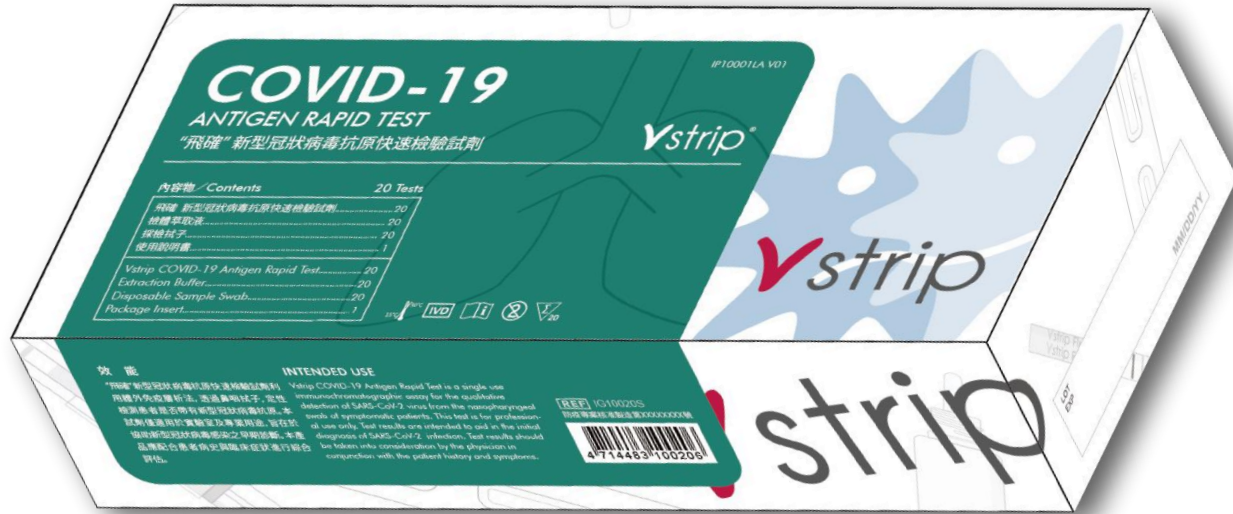
Cooperative Units: Domestic and foreign academic and research circles and hospitals, etc.

Cooperators: Domestic and foreign antibody development and vaccine companies, etc.



EirGenix, Inc.

AEP Alliance – Vstrip® COVID-19 Antigen Rapid Test



PRODUCT HIGHLIGHTS

1. Rapid test results within 10 minutes.
2. Functional for early-stage infections.
3. Utilizes nasal mucus from the nasopharyngeal cavity.
4. No equipment required.

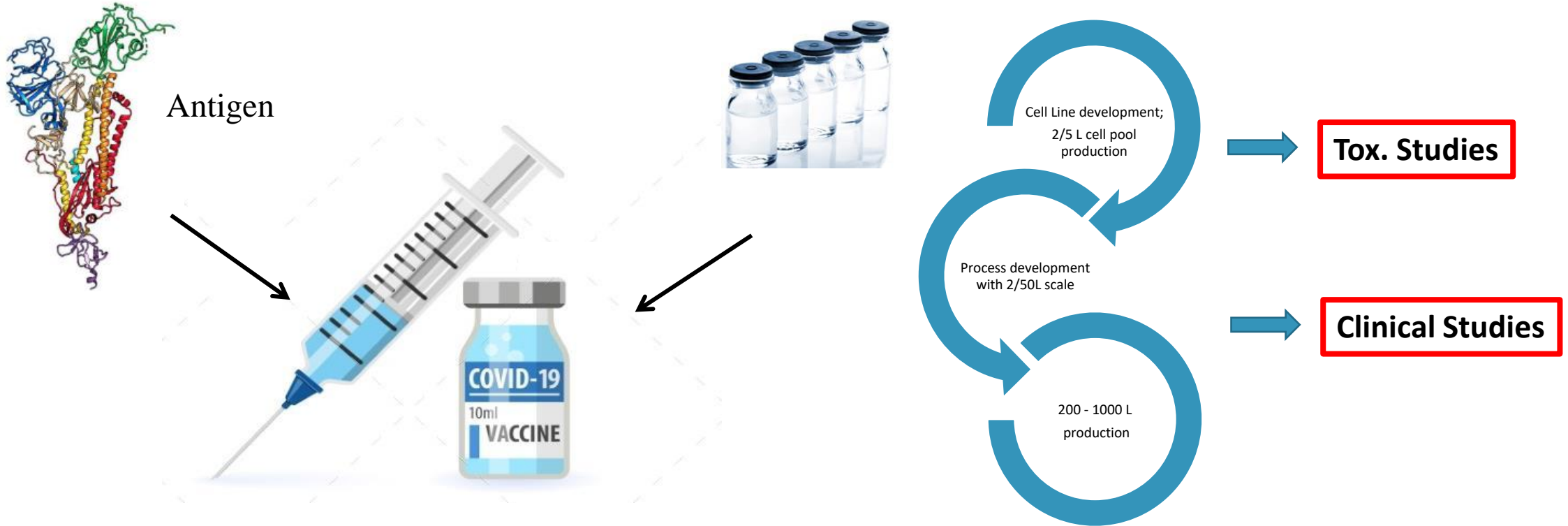
- ◆ 2020/08/27 Vstrip® Antigen Rapid Test obtains TFDA Emergency Use Authorization (EUA), the first in Taiwan for antigen rapid tests; 2021/05/03: Cassette version receives EUA.
- ◆ 2020/09/25 Received approved validation from Indian Council of Medical Research (ICMR) and sales license; 2021/03/09: Received official import license in India
- ◆ 2020/12/02 Obtained EU's CE-IVD Authorization (Reference Number: BS0266-2020)
- ◆ 2020/12/24 Obtained Temporary Authorization from Singapore's Health Sciences Authority
- ◆ 2021/02/02 Acquired Belgian Free Sales Certificate (Free Sales Certificate No.: 000003 26-01-21)

EirGenix & Medigen Vaccine Biologics (MVC)

Provide full services from early process development to large scale production for MVC's COVID-19 vaccine MVC-COV1901

COVID-19 S-2P Protein

Well-established adjuvant



This is a warp speed development project to assist the client (MVC) developing a vaccine candidate from cell line development to be ready for clinical trial within 6 months. With a satisfactory phase 1 result, MVC got the approval from TFDA to start the large phase 2 (total more than 3,700 subjects) clinical trial. Upon completion of Phase 2 trial with satisfactory results, the NHCC may grant an EUA as part of the vaccination program. EirGenix has already produced enough drug substance of S2P antigen for MVC to prepare for more than 4 million doses of MVC-COV1901



感謝狀

茲感謝 台康生技股份有限公司

熱心參與國家衛生研究院感染症與疫苗
研究所執行之[開發新型冠狀病毒疫苗]
計畫，並無償提供自有產品強化疫苗能
力的載體蛋白(CRM197)供應疫苗開發。

謹致此狀 敬表謝忱

院長梁廣義



中華民國一零九年五月四日

Appreciation letter from NHRI-Taiwan for providing them free carrier protein (CRM197) for their vaccine development programs.

Taiwan & EirGenix can Help!

Clients' Success Is Our Priority



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