



Formosa Laboratories, Inc.

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Company Profile

- Established Dec. 29, 1995
- SHO 120 M
- Headcount Total 809
- Business scope APIs (49 US DMFs, 15 EU DMFs, 14 JMFs)
CRAM (Contract API RD & Manufacturing)
DP Development
UV Filters
- Inspected by TFDA, US FDA, Japan PMDA, German BGV, EDQM and Mexican COFEPRIS



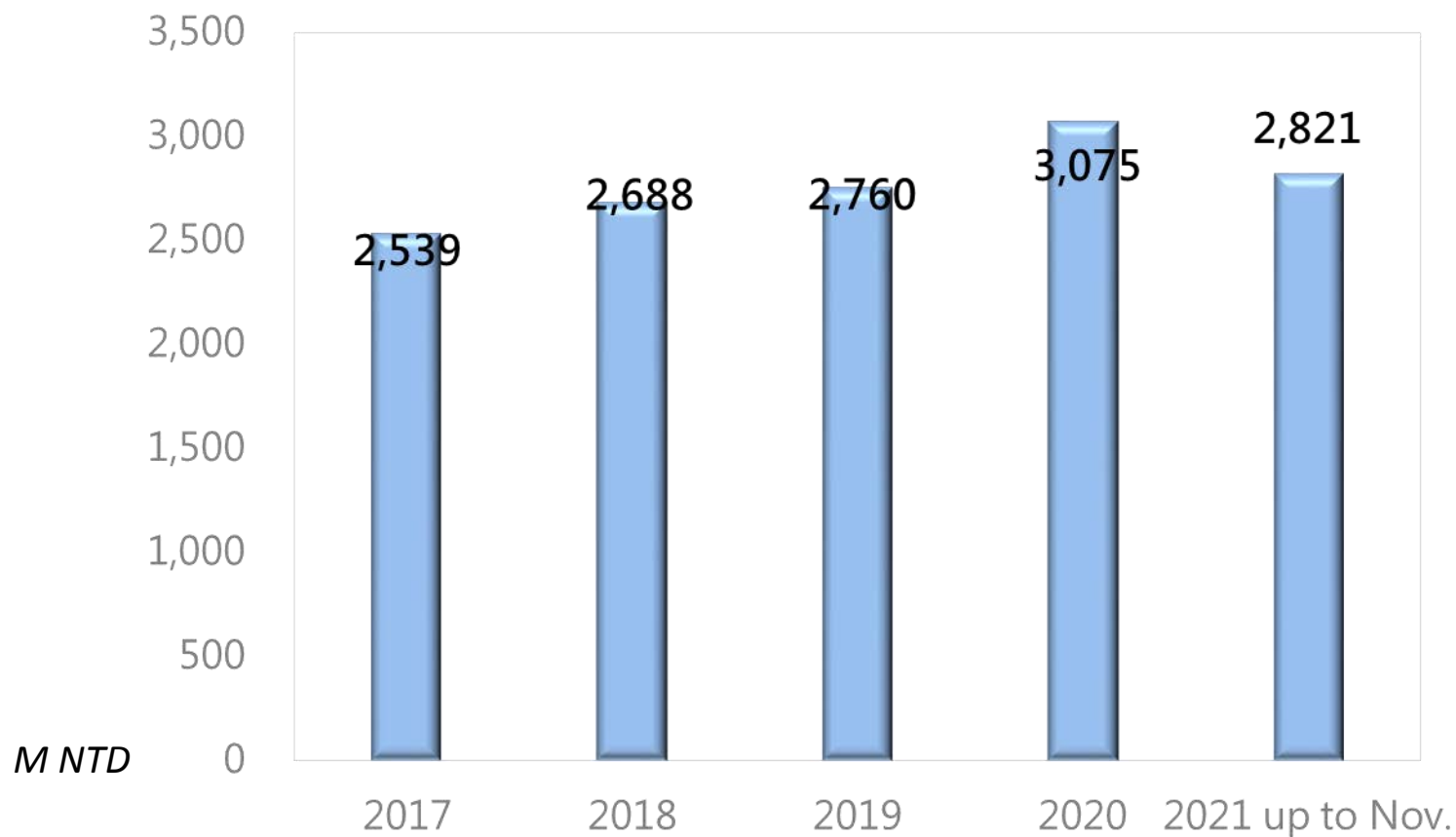


Operation Results

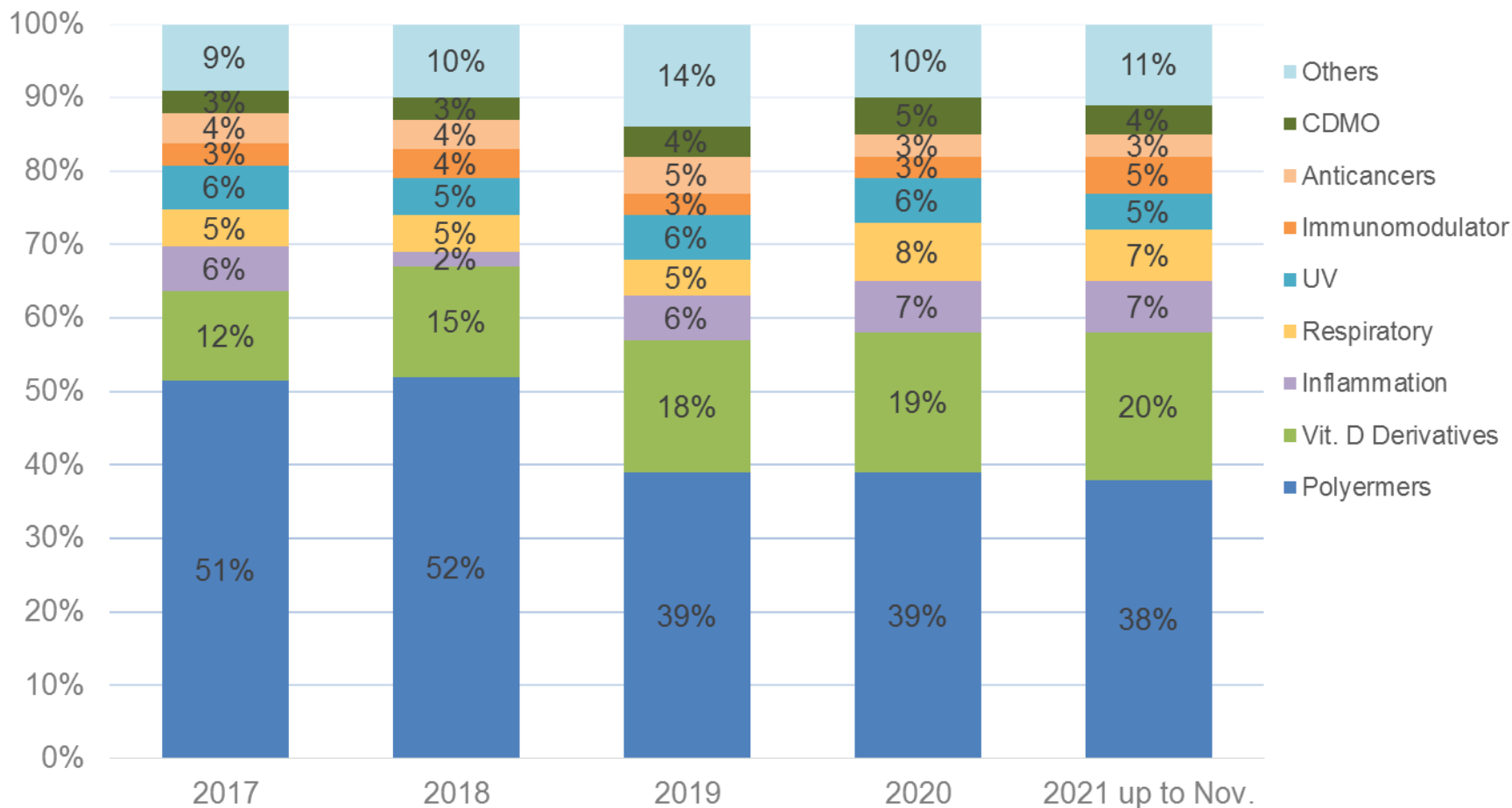
2021 up to Nov. Top Line

<i>NTD M</i>	2021	YoY
Polymers	1,068	-4%
Vit. D Derivatives	560	6%
CDMO	124	4%
Others	1,069	9%
Total	2,253	3%

2017-2021 Income



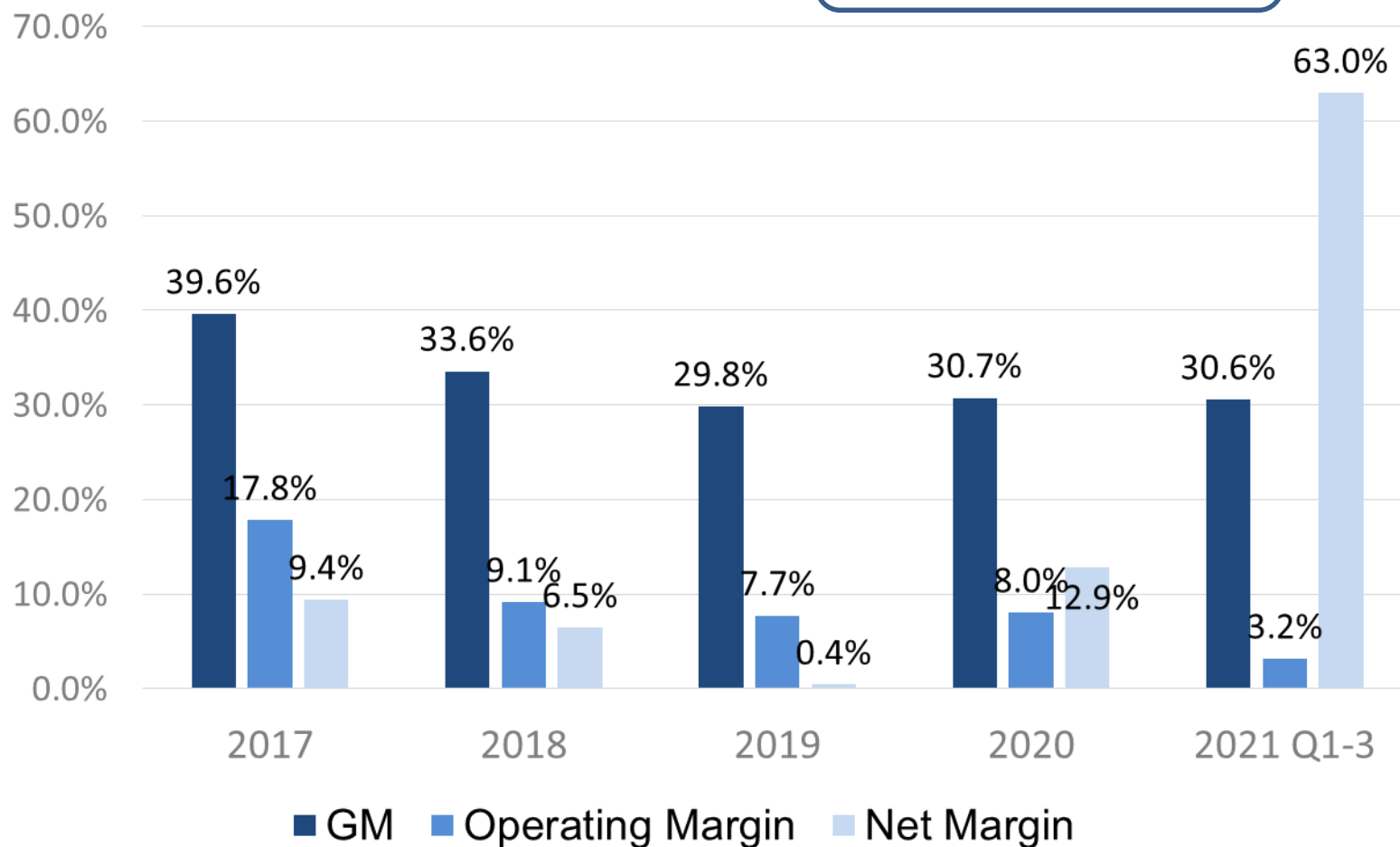
Product Mixture



Profitability (unconsolidated)

2021Q1-3

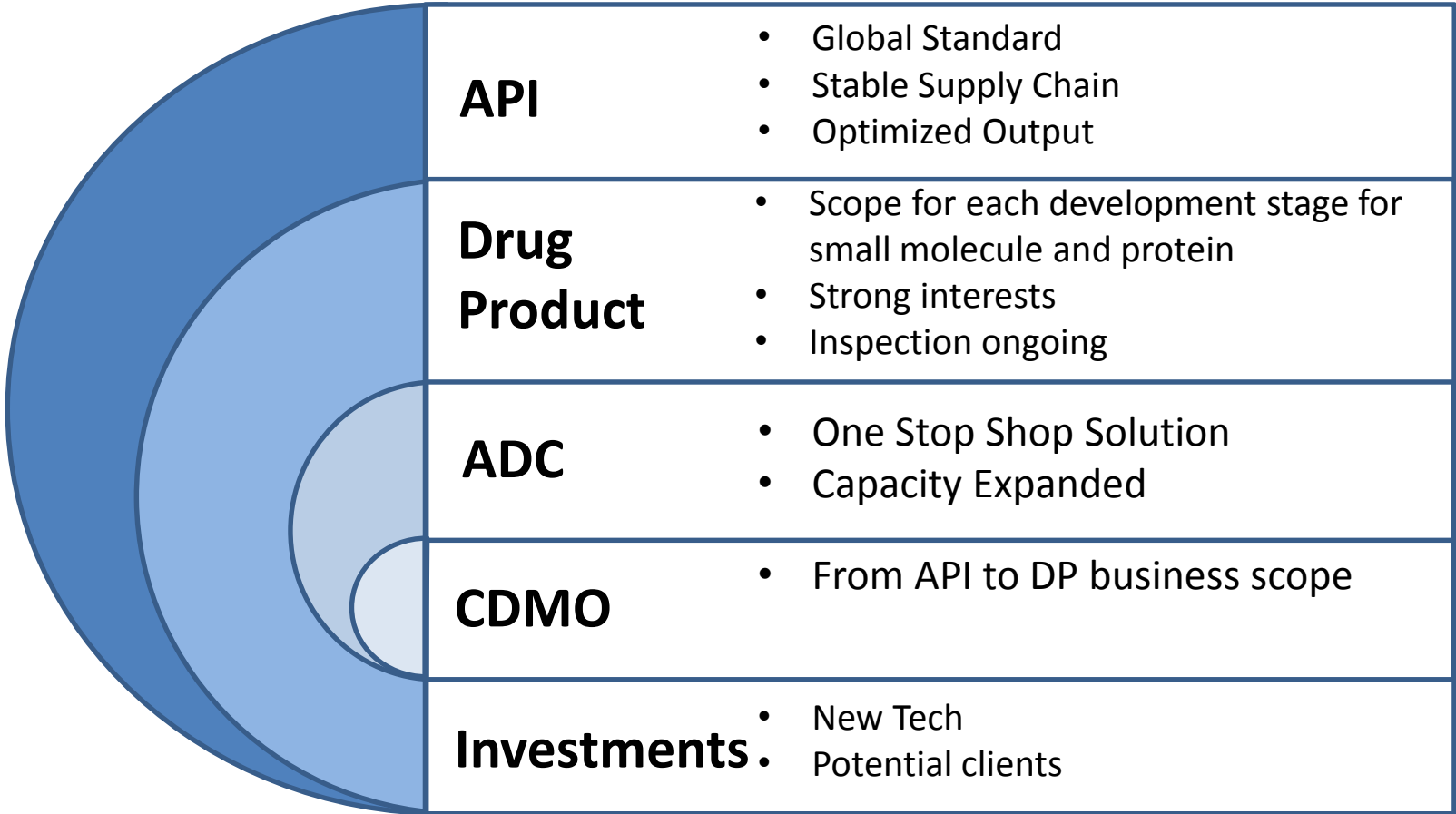
EPS 12.7元
BV per sh 62.4元





Business Update

Integrated Services



Global Quality System

Agency and country	Total inspection records	First time (year)	Last time (year)
US FDA	7	2004	2018
Germany BGV	2	2007	*
Japan PMDA	21	2009	2020
Mexico COFEPRIS	2	2010	*
Europe EDQM	1	2013	*
Taiwan TFDA	28	2002	2021

- GMP certificates on 42 products
- Granted with 49 US DMF, 15 EU DMF, 14 JMF and 8 COS

* Taiwan becomes a PIC/S member since 2013 and PIC/S members in principle will not need to inspect additionally

API products

APIs
Anticancers

Anti-inflammatory
& Analgesic Agents

MRI Enhancing
Agents

Respiratory Agents

Polymeric Drugs

CNS Agents

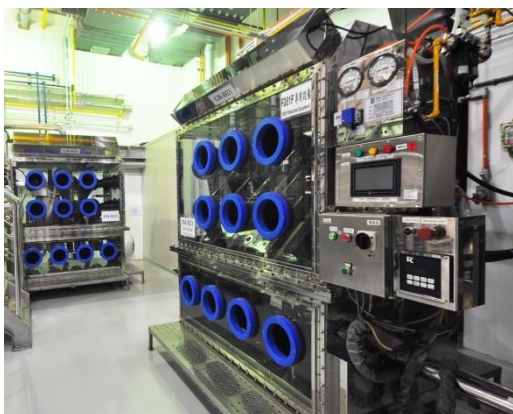
Immunomodulators

Steroids

Vit. D Derivatives

Antibiotics

High Potent Facility



- Vit D derivatives
- Steroid hormones
- Anti-cancers
- ADCs

API Line Update

- ✓ Sevelamer Carbonate / Sevelamer HCl
 - Exclusive for EU, strong demand
 - 45% US market share for the generics which occupied 99% of the total market
 - Expanded in the ROW
- ✓ Colevelamer HCl
 - 100% of US generics market share except for the authorized generic player, generics had 97% of the total market, two additional clients added soon
 - Expected to see strong demand in EU in 2022
- ✓ Colestipol
 - 100% of US generics market share except for the authorized generic player

API Line Update

● **Vitamin D. Derivatives**

Calcipotriol: Strong demand from EU with +40% YoY in 2021

Alfacalcidol: Expected to get into Japan in 2022 with aim to have 70% market share

Calcifediol: Signed an exclusive supply agreement Oct. 2021, plan to have market share of 40% in 2024

● **Cancer treatment (TMZ)**

TMZ: Stable market demand in the US and expect to see new demand in the EU in 2022

● **Leflunomide**

Leflunomide: 70% market share in the US, Canada and EU

Mycophenolate Sodium: granted with US DMF

API Line Update

● China

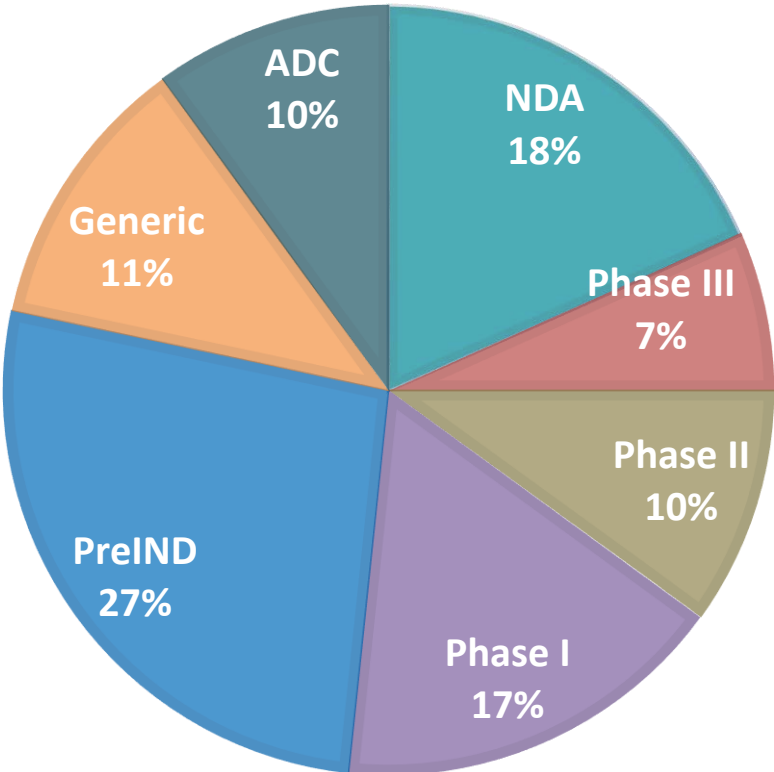
- ✓ Driven by BE and China/ US dual filing
- ✓ Benzonatate: commercialization in the US
- ✓ Sevelamer Carbonate: Expected to market in 2022
- ✓ Temozolomide/ Calcipotriol: Approved and marketed in 2021
- ✓ Alfacalcidol/ Montelukast/ Paricalcitol: Approved by NMDA
- ✓ Gadoterate Meglumine: Expected to market in 2022
- ✓ Mycophenolate Sodium: Clients filed in the US
- ✓ More than 10 products are in the process of registration in China

Strong CDMO Demand

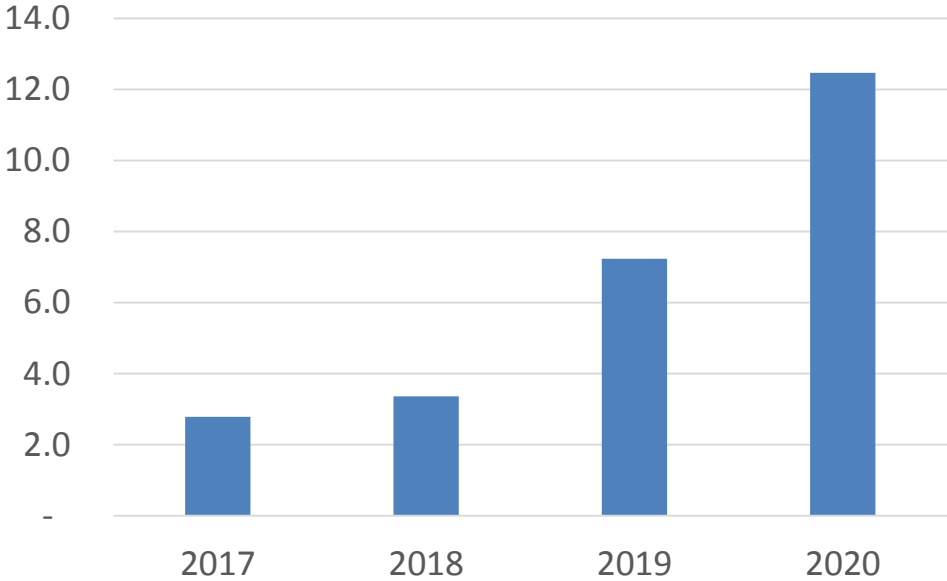
- Provided services for domestic and international clients at all development stage from R to D and commercialization
- Well know ADC development service
- To see demand for drug product development

CDMO in spot

RD and Commercialization stage Income

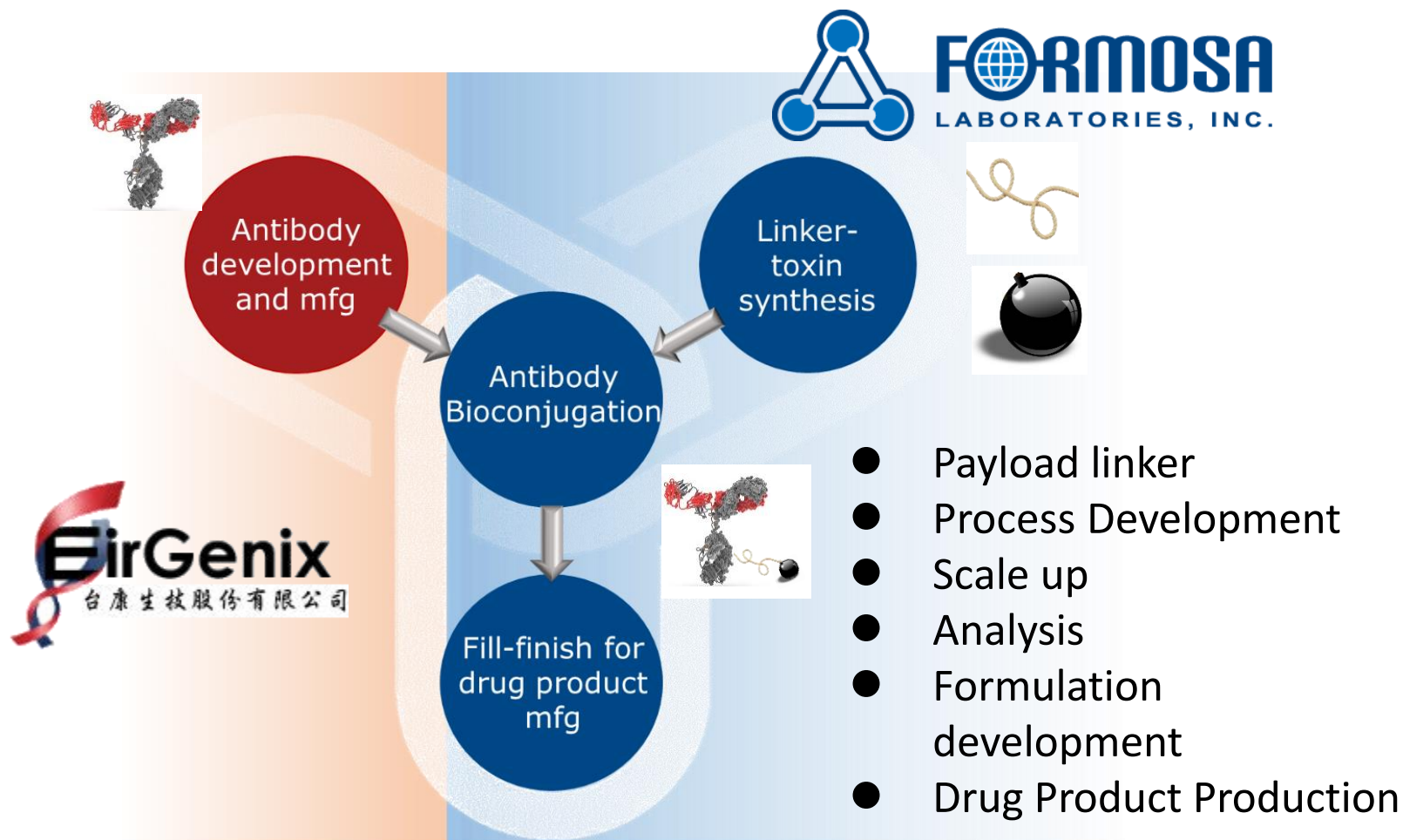


USD: Million



- R&D process development → process validation
- pre-IND scale → commercial scale
- chemical sourcing → CMC documentation
- drug substance → drug product

ADC



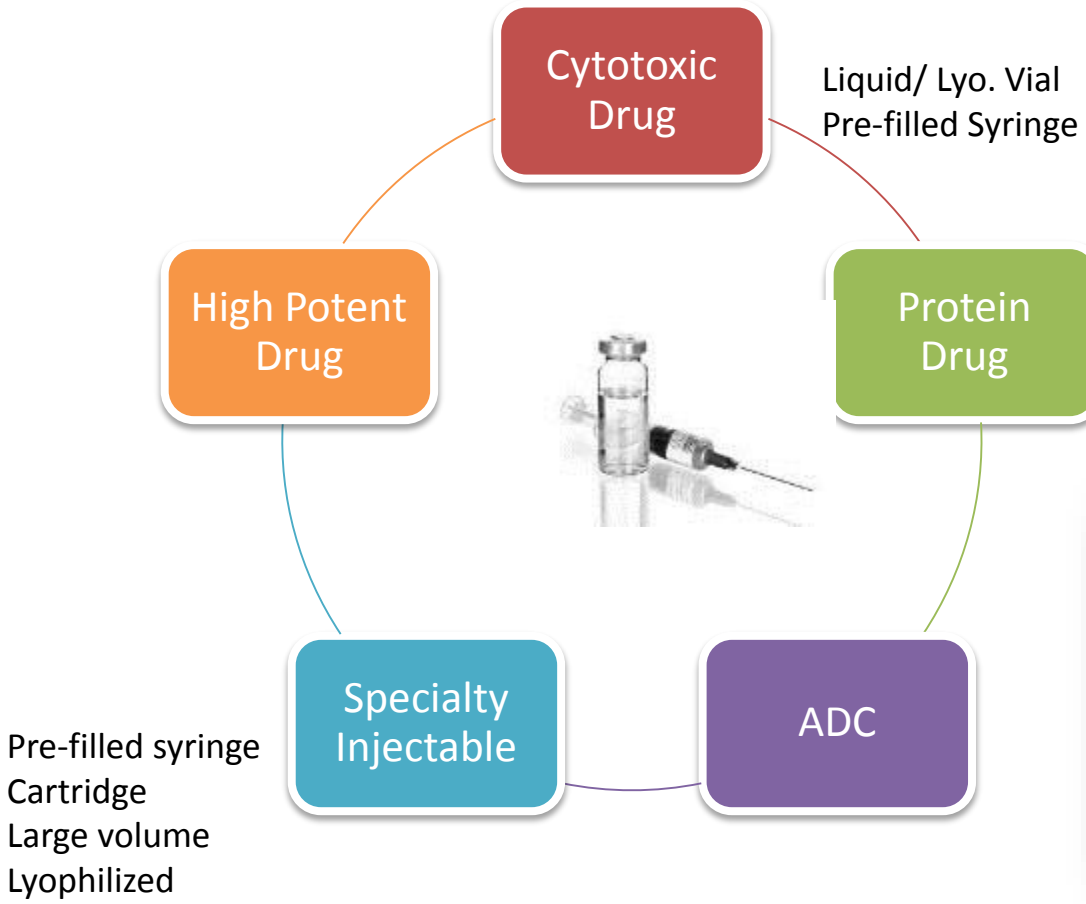
Injection Plant

International Standard

- Designed by NNE
- USA(FDA), EU(EMA) and Japan (PMDA) standard
- Able to provide services for small molecule and protein drugs
- Capacity over 100M p.a., for regular line, cytotoxic line and pre-clinical stage clients
- In the process of facility inspection



Designed for all



Multiple Scale/ Score

Plant	Filling Line	INJ Type	Filling Quantity	Compounding Volume	Batch Size (vials)	Lyophilizer
V	V1 (Non-cytotoxic)	Vial	2mL~100mL	10L~1000L	10,000~250,000	30 m ² x 2
		Lyophilized	2mL~100mL			
	V2 (Non-cytotoxic)	Vial	2mL~20mL	1L~60L	100~24,000	2.3 m ²
		Lyophilized	2mL~ 20mL			
		Pre-filled	0.5mL~3mL			N/A
	D	D1 (Cytotoxic/ High Potent)	Vial	2mL~100mL	1L~100L	1,000~40,000
Lyophilized			2mL~ 50mL			
Pre-filled*			0.5mL~3mL	N/A		

* Long term expansion plan



台耀化學股份有限公司

Q&A