



# **Formosa Laboratories, Inc.**

## **Company Presentation**

TWSE 4746

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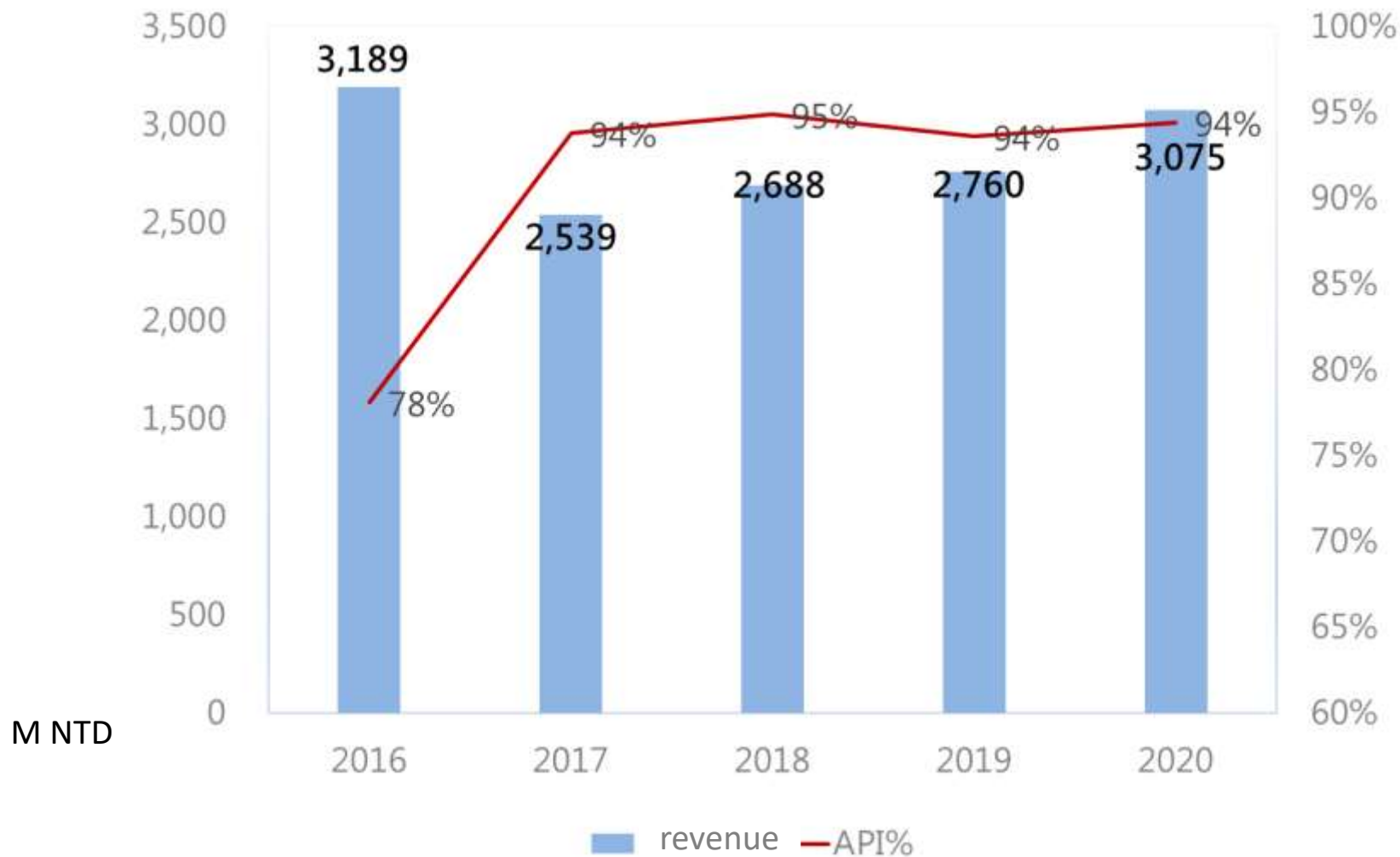
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# Operation Results

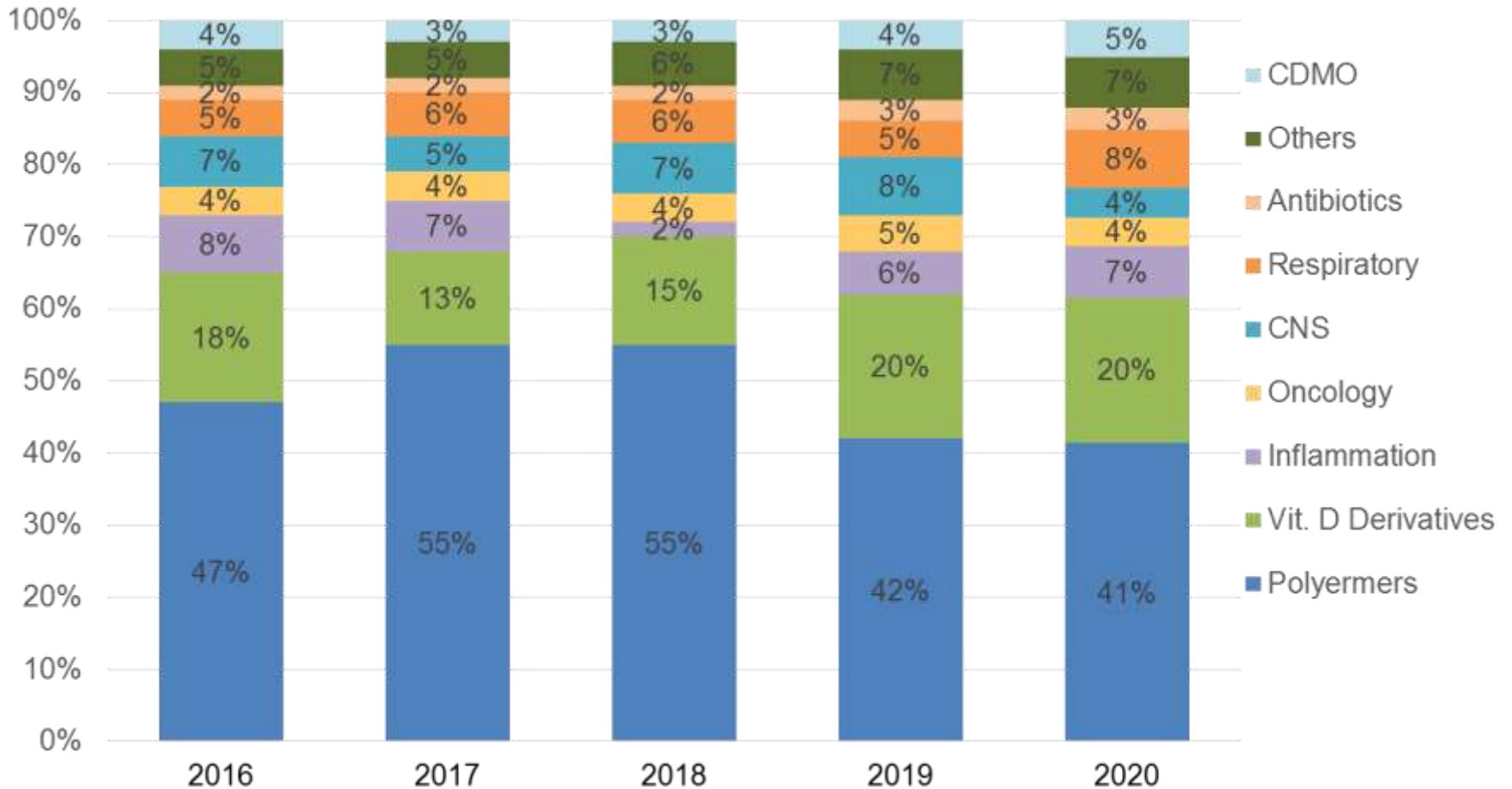
## Strong Top Line Results



## 2020 Sales Performance

<i>NTD M</i>	2020	YoY
Polymer	1,200	12%
Vitamin D Derivatives	590	16%
Other API's	1,114	12%
<b>Sub</b>	<b>2,904</b>	<b>12%</b>
UV Filter	171	-3%
<b>Total</b>	<b>3,075</b>	<b>11%</b>

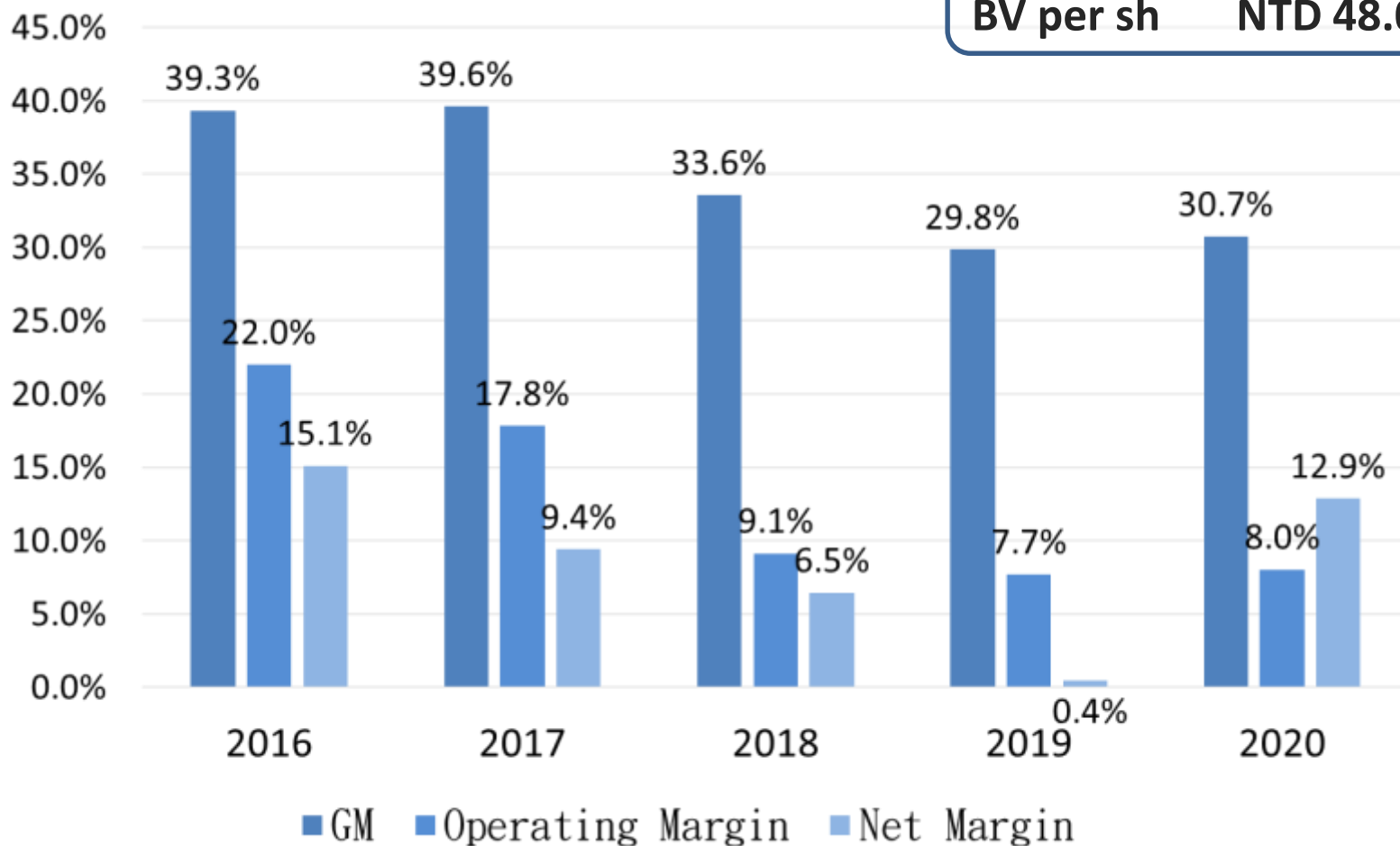
# API Product Mixture



# Profitability

2020年

EPS                    NTD 3.78  
BV per sh            NTD 48.06

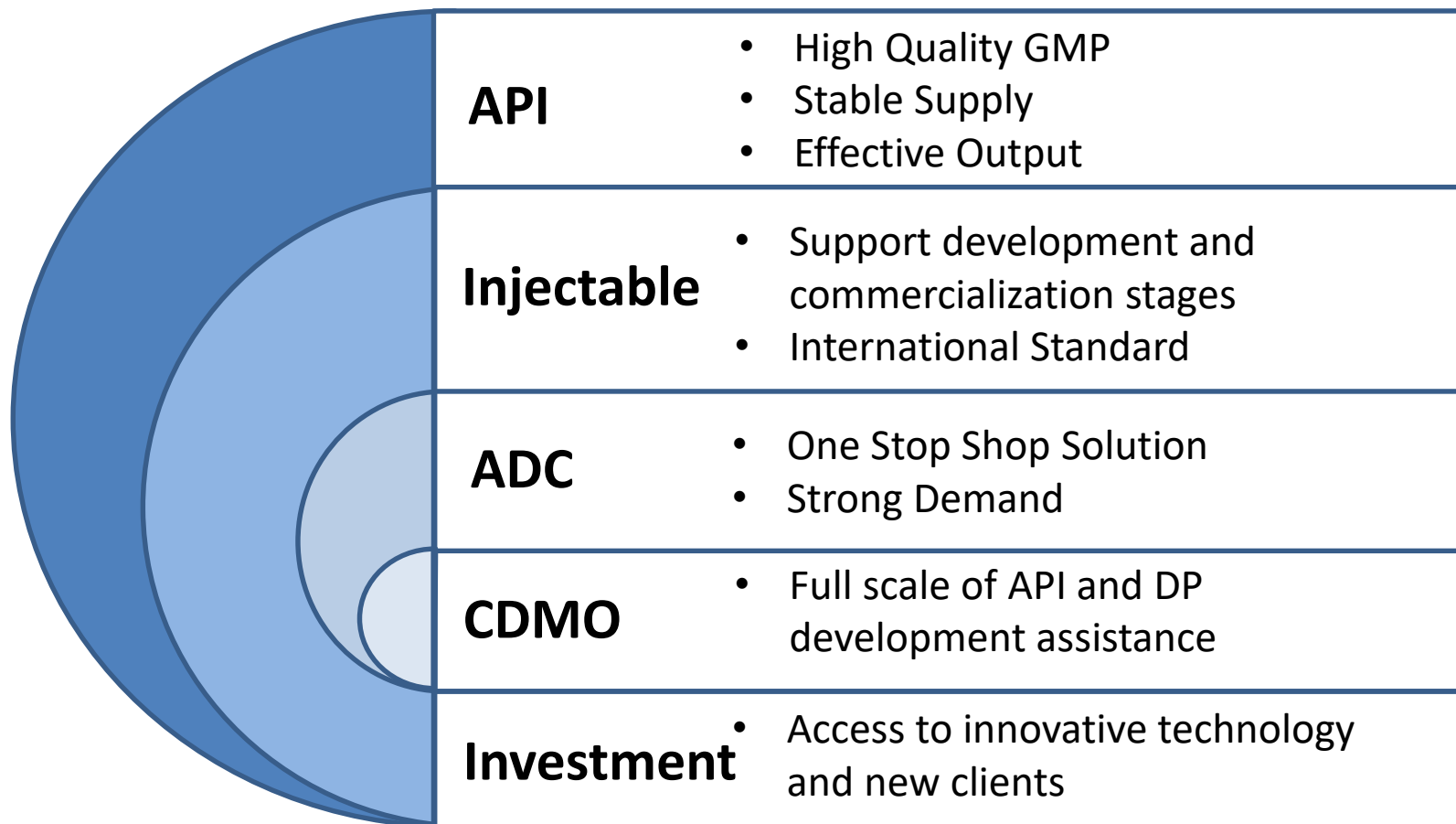




# Business Strategy



## Integrated CDMO partner



## Global Quality System

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

- GMP certificates on 41 products have been granted
- Filed 49 US DMFs, 14 European DMFs in 28 countries, 8 COS, 14 JMF

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

## High Potent Facility



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



# API Business

## Product Overview

### ● Polymers

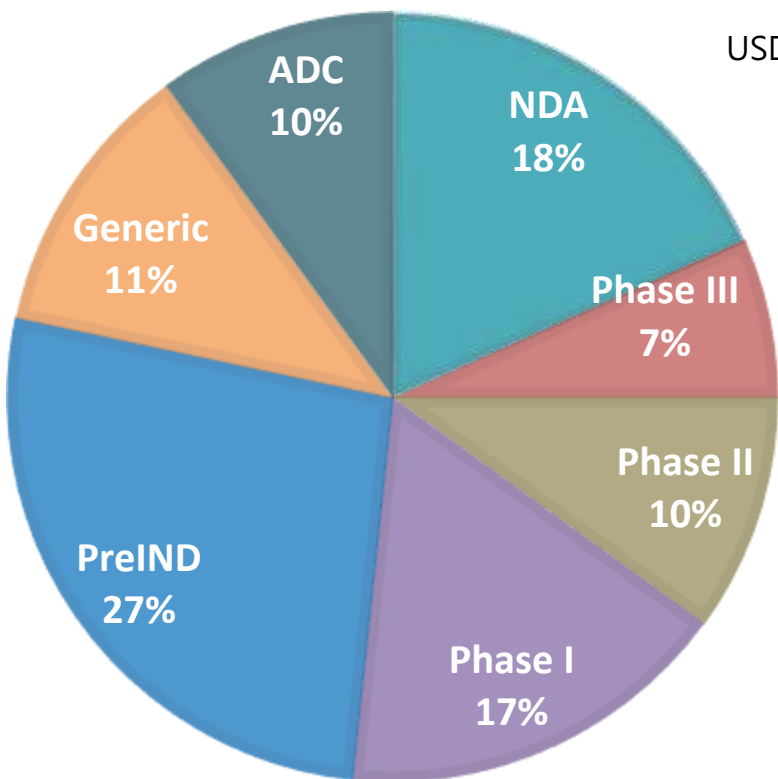
- ✓ Sevelamer Carbonate & Sevelamer HCl
  - Constant Growth in EU
  - Clients have 52% of the US generics market with 92% market share owned by generics
  - Strong demand from the emerging markets
- ✓ Colevelamer HCl
  - Exclusively supply to all approved generics companies except for AG
  - Expect to launch in Europe in 2022
- ✓ Colestipol
  - Exclusively supply to all approved generics companies except for AG, generics market share in the US ~ 99%
  - Line expansion
- ✓ Strong Market Presence

## Product Overview

### ● Market in China

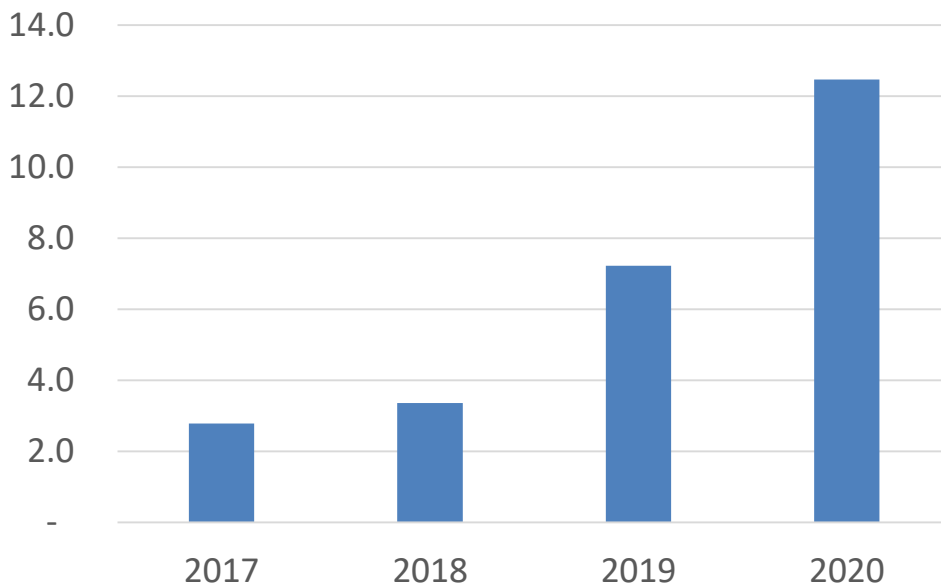
- ✓ Multiple products granted approval expected in 2021, including Sevelamer Carbonate, Temozolomide and Calcipotriol
- ✓ Montelukast 、 Paricalcitol 、 Calcipotriol cleared CN DMF
- ✓ Benzonatate commercialization in the US and China

# CDMO, new driver



USD: Million

### Revenue contribution from CDMO and Successful Commercialization

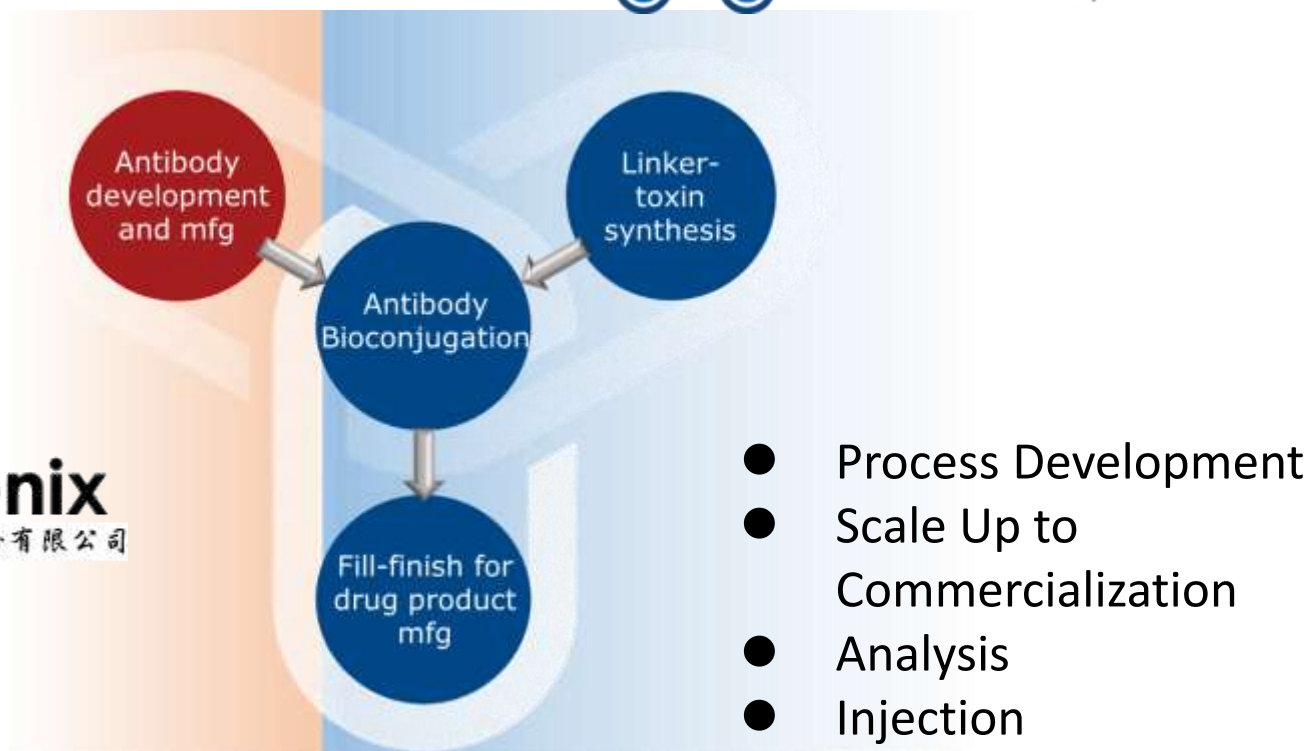


## Strong CDMO Demand

- Strong income generation capability
- Clients including Big Pharma entered into efficacy confirmation and scale up stages, boosting demands
- Well known ADC development and commercialization platform with multiple services contracts for domestic and international clients
- Generated RD and manufacturing services up to formulation development and injection for any need against COVID-19 pandemic



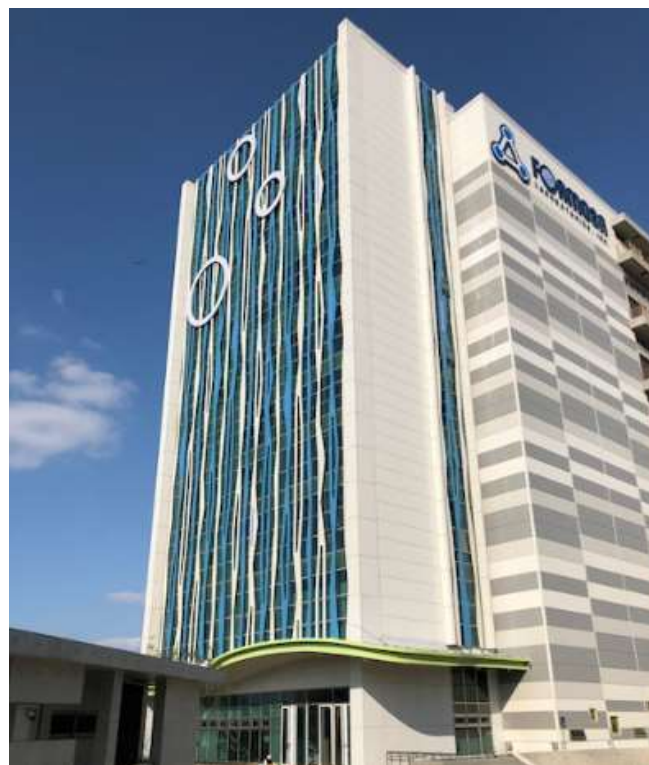
## Antibody Drug Conjugate



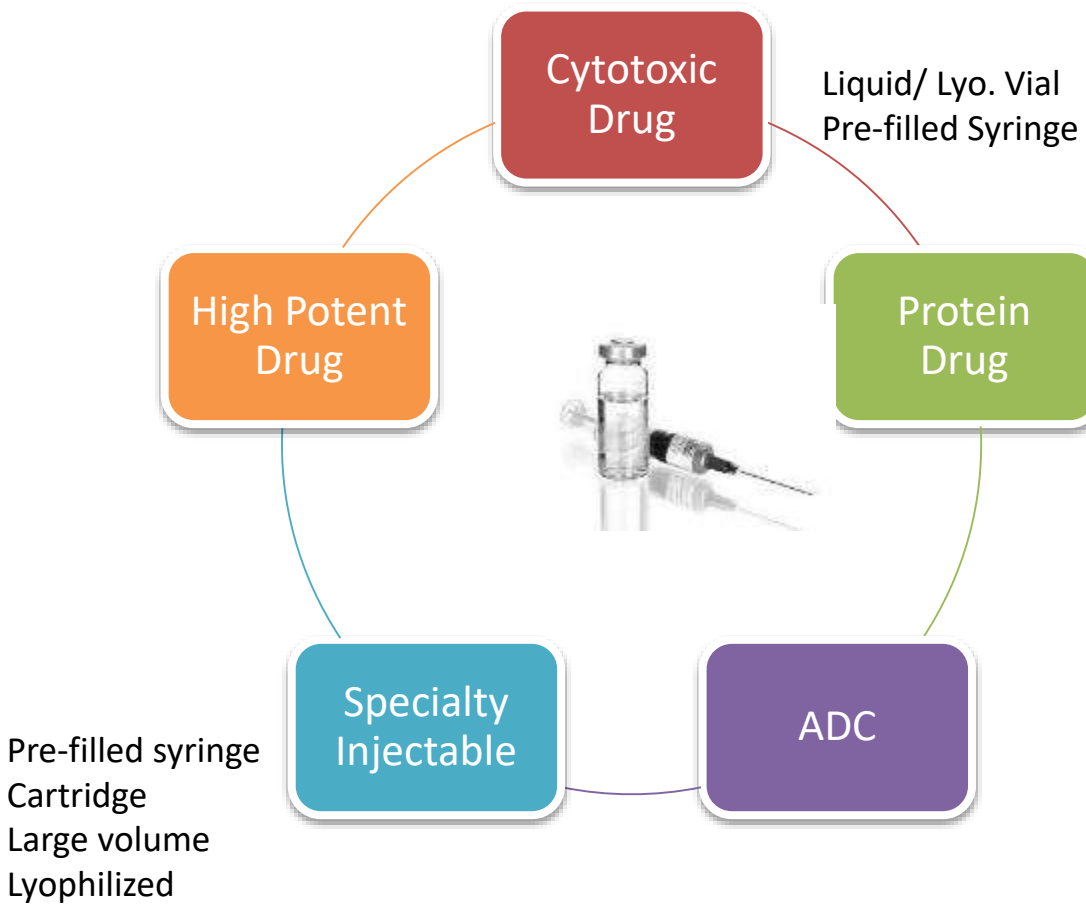
# Injectable DP

## Global Standard

- NNE design
- USA(FDA), EMA and PMDA standard
- Competence for small molecules and protein drugs
- Capacity for regular line over 100M doses per anna.
- Capacity for cytotoxic line over several dozen M doses per anna.
- Eligible to support million doses for pre-clinical demand
- Scheduled inspection by government agents from 2021Q1 to 2022Q2



# Partner from DS to DP



BLA  
Biosimilar  
Biobetter  
Vaccine



# New Drug Development



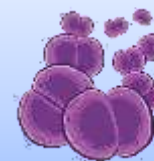
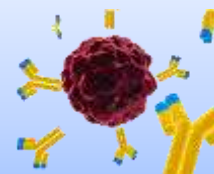
## Formosa Pharmaceutical

### Technology

- Proprietary nanoparticle formulation platform (APNT)
- Antibody-Drug Conjugate process development
- Small-molecule and Fermentation production

### Therapeutic Areas

- Ophthalmology
- Oncology
- Anti-infectives



### Development Strategy

- Cost effective and time manageable development route including 505(b)(2), Biosimilar and NCE

# API Nanolization

Columnar  
Shape  
~40,000  
nm



SEM: 20,000x  
magnification

APNT  
nanolization

Spherical  
Shape  
~140 nm



APP13007  
drug product

API  
Formulation  
without APNT

API only in water  
(API  
precipitation)

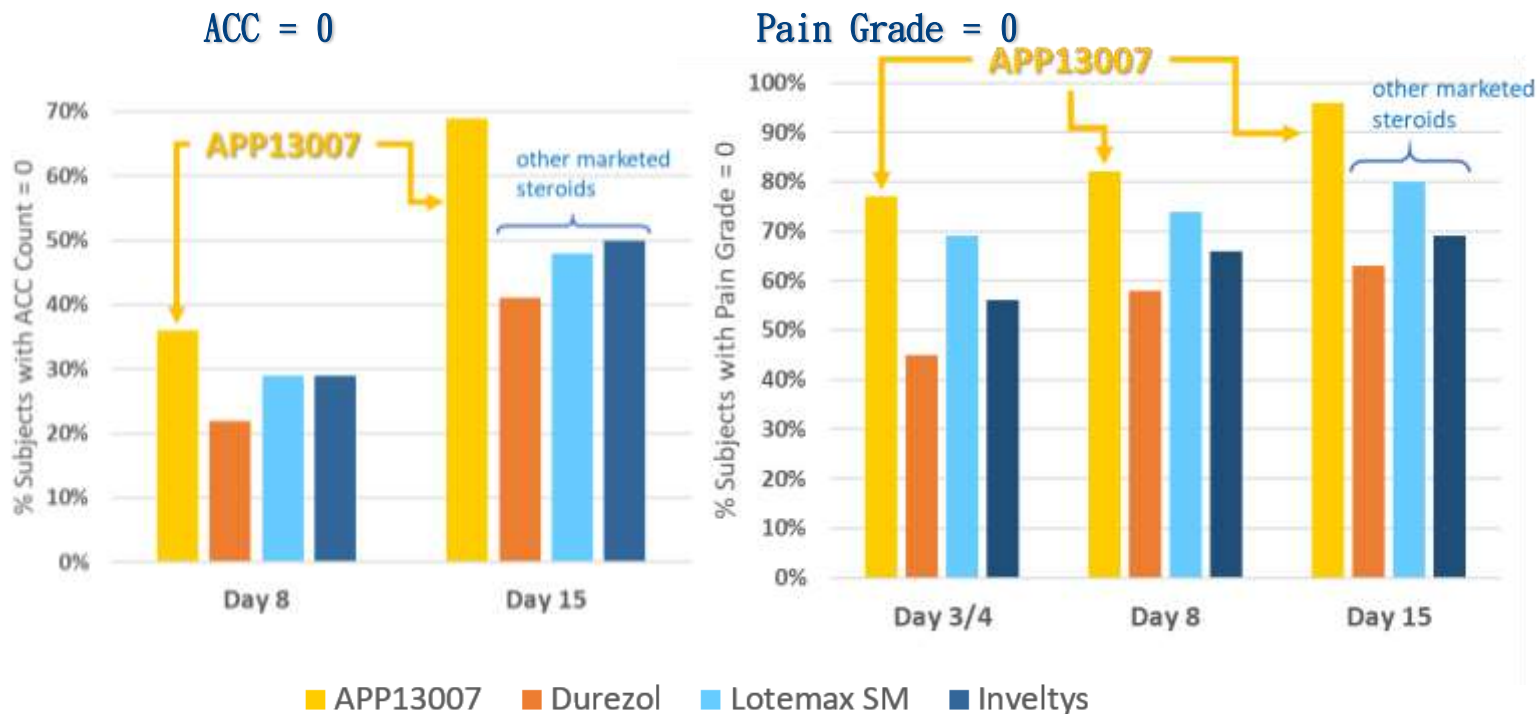
- APNT Formulation Platform enhances the dissolution and distribution of poorly soluble compounds, thereby improving bioavailability.
- Reliable and tunable particle reduction
- Chemical integrity and purity are conserved
- Strong patent protection in multiple countries/regions

# APP13007

- Phase 3 start in US in Feb., 2021
- Expected Launch in 2023

## Phase 2 Summary

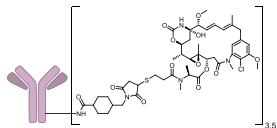
Response rate of APP13007 strongly suggests superiority over competitors in reducing inflammation and pain for critical Phase 3 endpoints



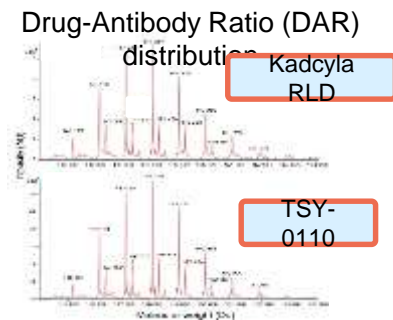
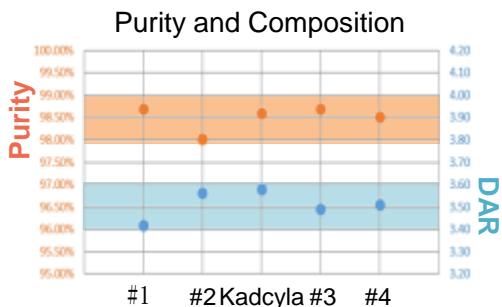
\* Graphs are a comparison of published clinical data; These data are not from a head-to-head clinical study.



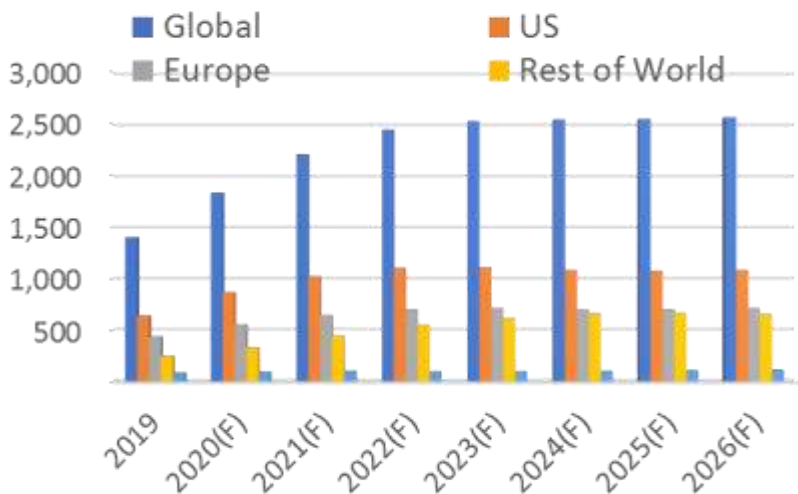
# TSY0110



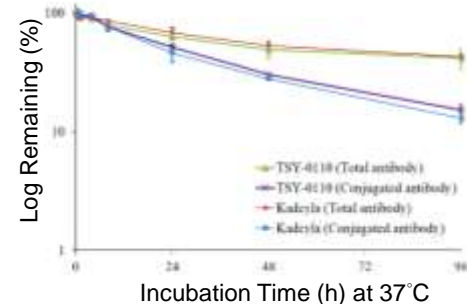
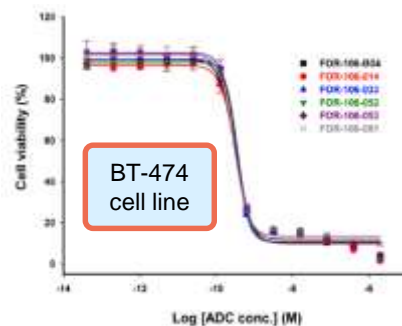
- Approved in 2013 as second-line treatment for metastatic breast cancer
- Early Breast Cancer indication added in 2019
- Additional HER2-related indications being explored in clinical trials > 30 combination trials ongoing



### Sales Forecast (\$MM USD)



## Similarity





台耀化學股份有限公司

Q&A