

# Formosa Laboratories, Inc. Company Presentation

TWSE 4746



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# **Operation Results**

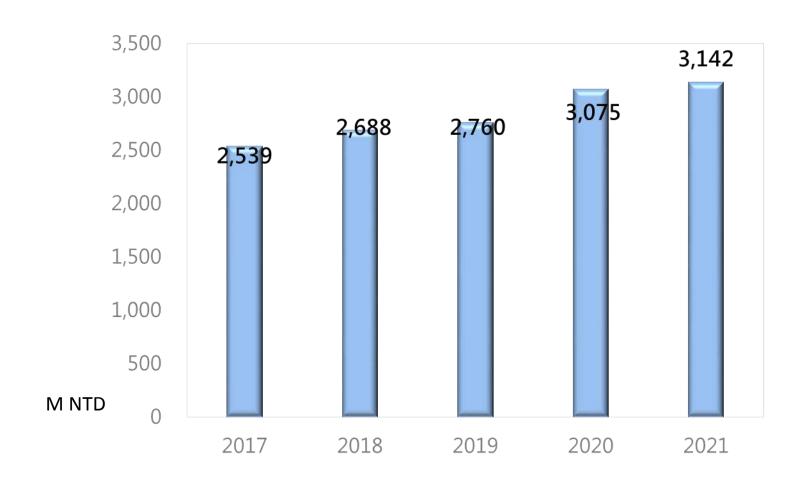


## **2021 Sales**

NTD M	2021	YoY
Polymers	1,204	0%
Vit. D Derivatives	606	3%
CDMO	140	-8%
Others	1,192	5%
Total	3,142	2%

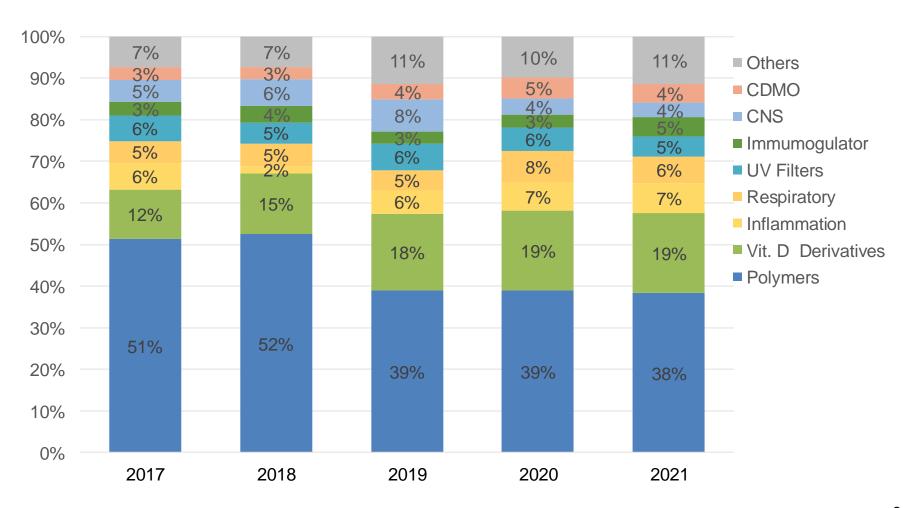


## 5 years top line results

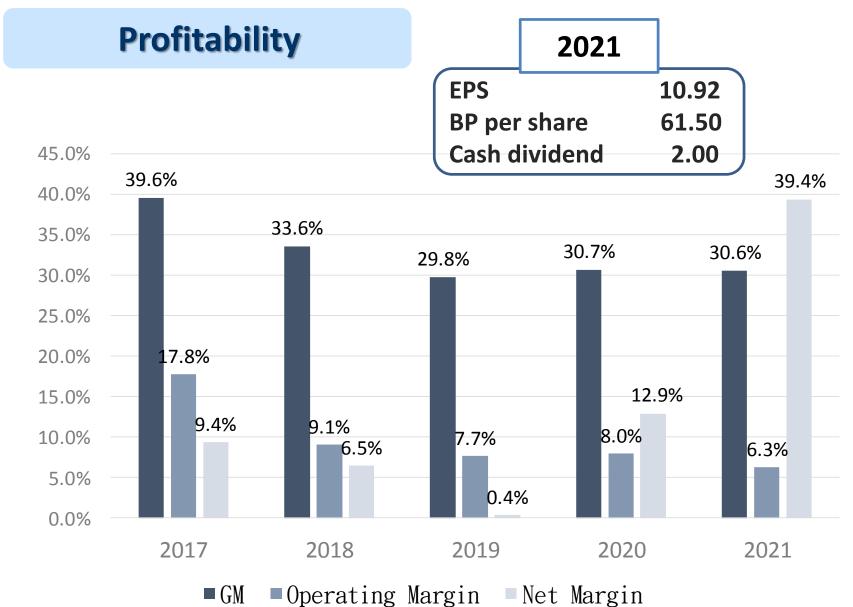




#### **Product Mixture**





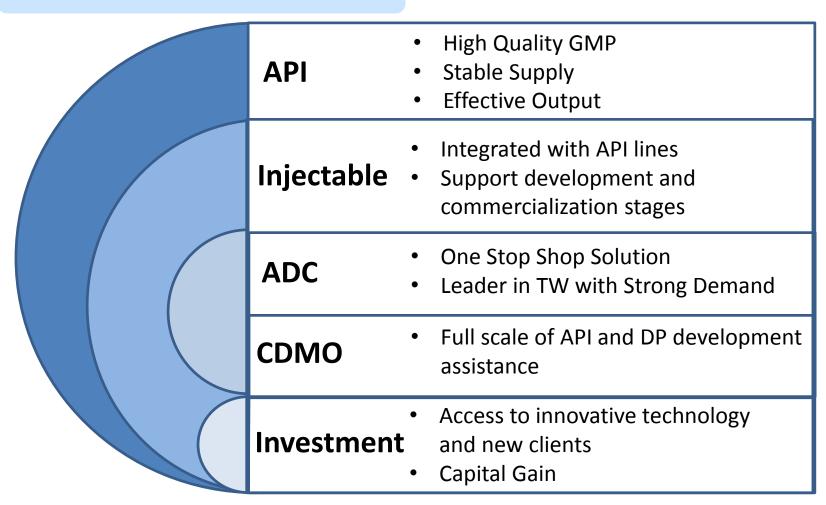




## **Business Strategy**



#### **Integrated CDMO service**





## **Partners for Key Areas**



ADC Biosimilar



Nano Tech 505(b)(2)

Protein
Drug
fill finish

API and Injectable



Nebulizer

Access to Innovative Tech with Alliances



Amino Acid Nuclide acid mRNA



#### **Global Quality System**

Country/ Agency	First Inspection	Last Inspection
US FDA	2004	2018
Germany BGV	2007	2013
Japan PMDA	2009	2020
Mexico COFEPRIS	2010	2013
Europe EDQM	2013	*
Taiwan TFDA	2002	2021











- 46 products granted with GMP certificates
- 49 US DMF, 17 EU DMF > 14 JMF , 15 CN DMF and 8 COS
- Taiwan becomes a PIC/S member since 2013 and PIC/S members in principle will not need to inspect additionally



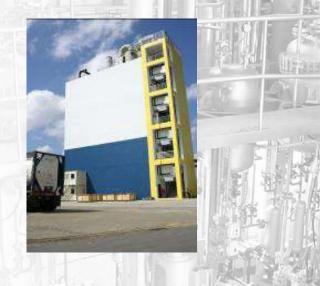
## **High Potent Facility**







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







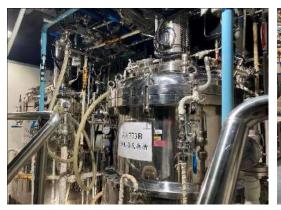
## **Fermentation Facility**















## **API Business**



#### **API Product Lines**

**Anticancers Anti-inflammatory &**Analgesic Agents **MRI Enhancing Agents Respiratory Agents Polymeric Drugs** 

**CNS Agents Immunomodulators Steroids** Vit. D Derivatives **Antibiotics** 



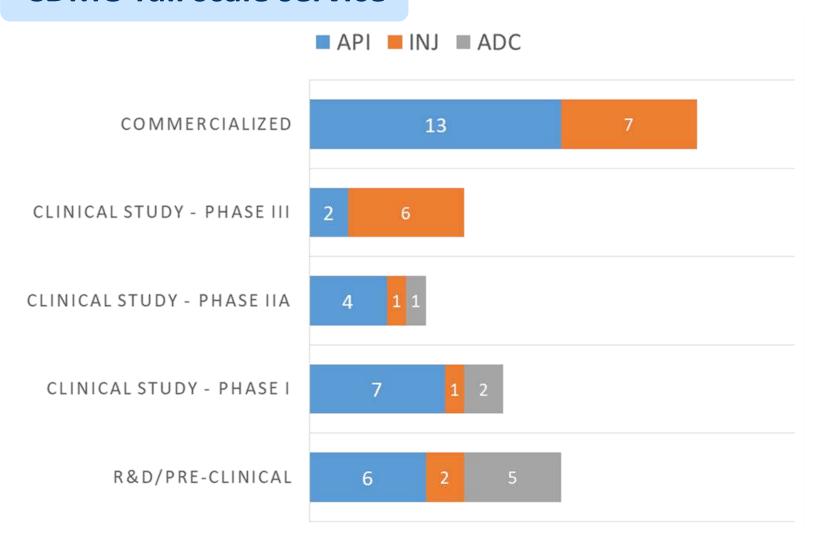
#### **Key Product Update**

#### Polymers

- ✓ Sevelamer Carbonate & Sevelamer HCl
  - 20-30% Growth for 2022 in EU
  - 40-50% market share in the US
- ✓ Colesevelam
  - 80% of the US market
  - Product launch in EU in 2022Q2
- ✓ Colestipol
  - Exclusively supply to all approved generics companies except for AG, generics market share in the US ~ 99%
- ✓ Strong market position with 40-70% share for all product lines in the world
- ✓ Expansion to fit demand
- Chinese Market
  - ✓ Positive view with new product launches



#### **CDMO** full scale service



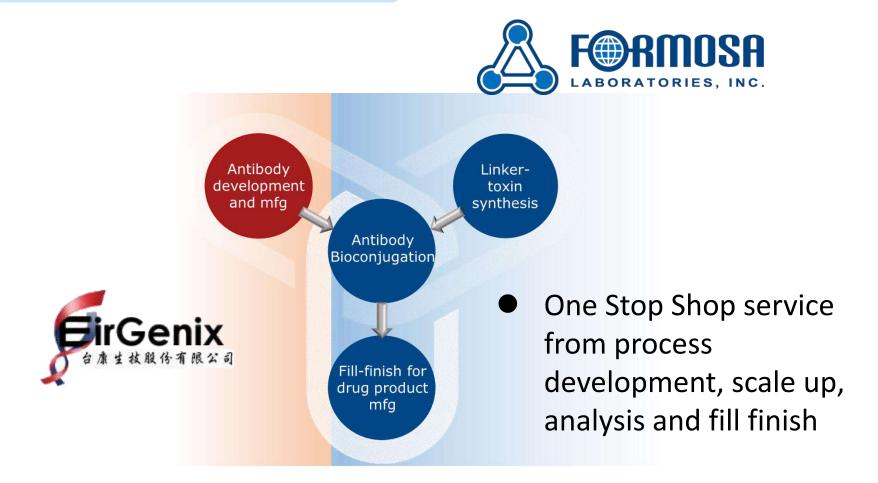


#### **Strong CDMO Demand**

- Strong income generation capability
- Clients including Big Pharma entered into efficacy confirmation and scale up stages, boosting demands
- Well developed ADC service platform for domestic and international clients with milestone supporting human trial and passing QP inspection
- Generated RD and manufacturing services up to formulation development and injection for any need against COVID-19 pandemic



#### **ADC** service





## **Strong ADC Demand**

- Domestic and International Request
- Leading position in Taiwan for capability and capacity
- Line Expansion to meet demands

Batch Size	Client Region	Clinical Stage
00's g	APAC	Phase 2
00's g	Europe	Pre-clinical->Phase 1
00's mg	APAC	Pre-clinical
00's g	APAC	Phase 1
0's g	APAC	Pre-clinical
0's g	APAC	Pre-clinical



# **Injectable DP**



#### **Global Standard Line**

- NNE design
- USA(FDA), EMA and PMDA standard
- Serve small molecules and protein needs
- Regular line over 100M doses per anna.
- Cytotoxic line over several dozen M doses per anna.
- Eligible to support million doses for preclinical demand
- Scheduled inspection by government agents from 2021Q1 to 2022Q2
  - 2021Q3 cytotoxic line inspected by TFDA
  - 2021 granted with PICs GMP and PICs GDP certificates

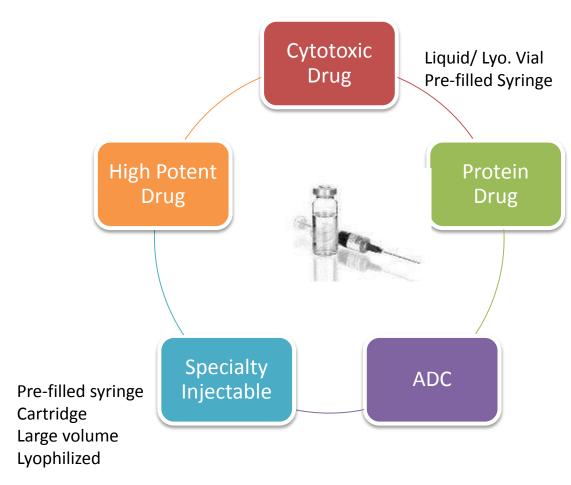








#### Partner from DS to DP





BLA Biosimilar Biobetter Vaccine



#### 台耀化學股份有限公司

