

# Formosa Laboratories, Inc.

TWSE 4746



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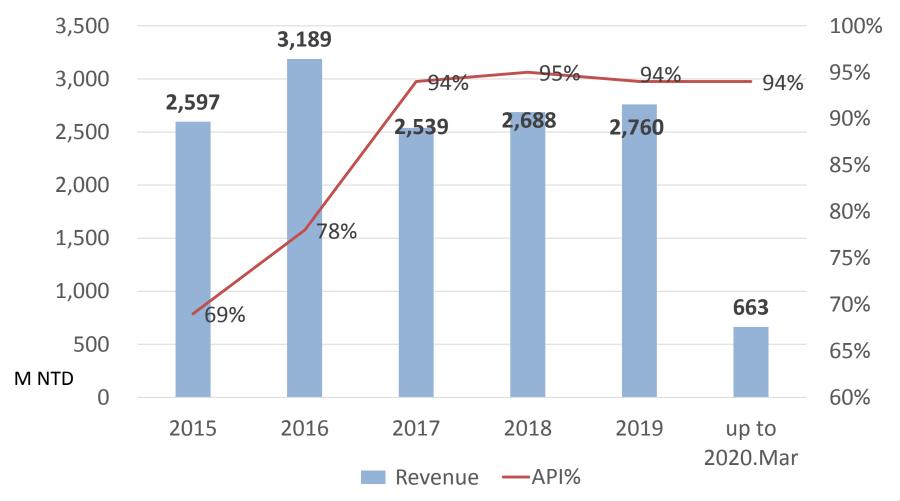
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## **Operation Results**



## **Top Line Performance**



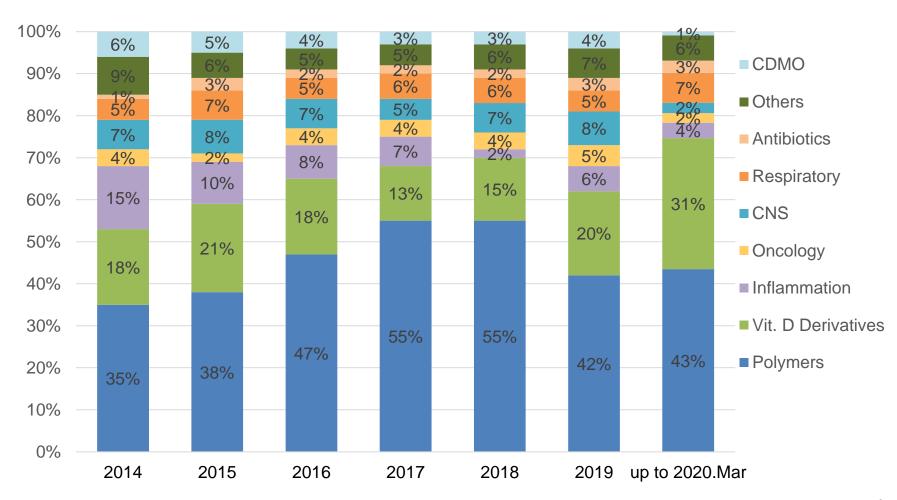


## **2020Q1** Top line

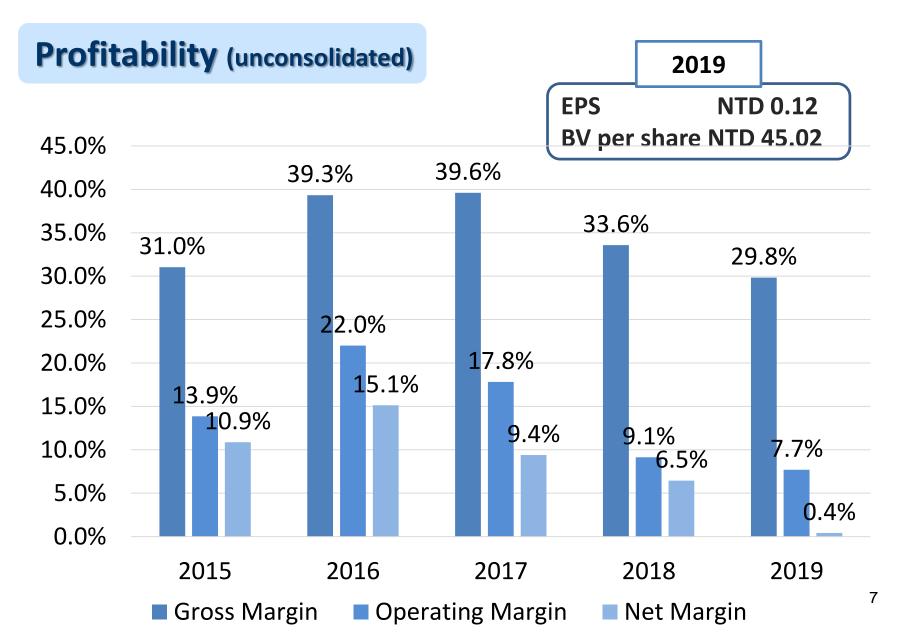
NTD M	2020Q1	YoY
Polymers	271	15.7%
Vit. D Derivatives	194	64.2%
Other API's	158	-29.8%
Subtotal	623	7.9%
UV filters	40	-48.2%
Total	663	1.3%



#### **API Product Mixture**





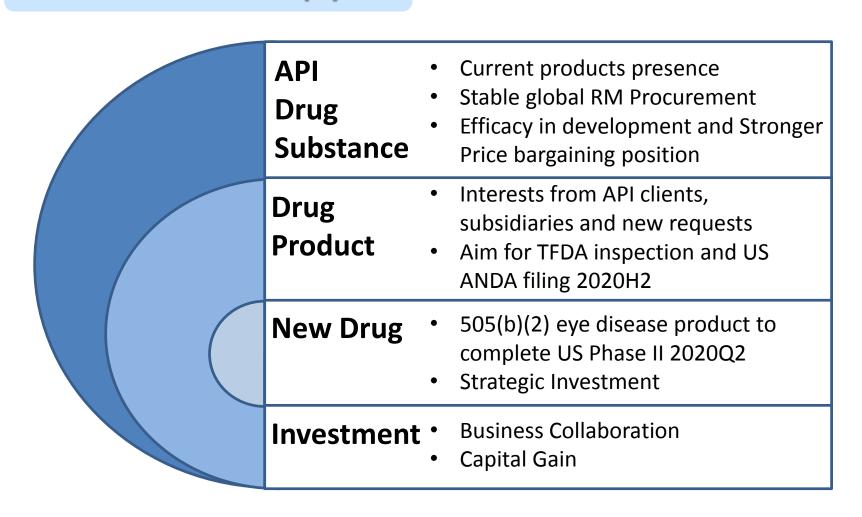




## **Business Strategy**



## **DS-DP-NCE-505(b)2**





## **Global Quality System**

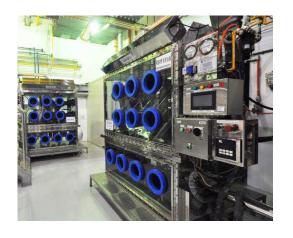
Agency and country	Total inspection records	First time (year)	Last time (year)
US FDA	7	2004	2018
Germany BGV	2	2007	*
Japan PMDA	8	2009	2018
Mexico COFEPRIS	2	2010	*
Europe EDQM	1	2013	*
Taiwan TFDA	15	2002	2019

- GMP certificates on 41 products have been granted
- Filed 45 US DMFs, 11 European DMFs in 28 countries, 6 COS, 12 JMF
- 36 GMP audits by global pharmaceutical companies in 2019
- Taiwan becomes a PIC/S member since 2013 and PIC/S members in principle will not need to inspect additionally



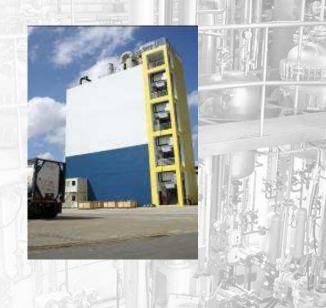
## **High Potent Facility**







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







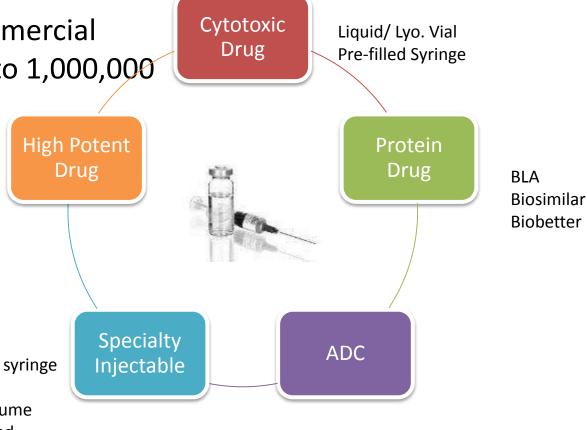
## **One-Stop DS-DP Partner**

From IND to NDA/ANDA/BLA filing

From Lab to Commercial

• From 100 doses to 1,000,000

doses per batch



Pre-filled syringe Cartridge Large volume Lyophilized



## **DP development Team**

#### Formulation R&D

- 3 PhD
- 5 MSs

## Analytical R&D

- 3 PhD
- 27 MS
- 8 BS
- 2 Associate





Pharmaceutical
Development Report
(PDR) ready for
manufacturing





## **API Business**



#### **Product Overview**

### Polymers

- ✓ Sevelamer Carbonate
  - Gained 100% European generics market, demand strong
  - Clients have 51% of the US generics market with 92.3% market share owned by generics
  - Strong demand from the emerging markets

#### ✓ Colevelamer HCl

- Exclusively supply to all approved generics companies except for AG, generics market share in the US ~ 64%
- Two new US clients end of 2020
- 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%



#### **Product Overview**

- Vit. D Derivatives
- Oncology (TMZ)
- Inflammation (Leflunomide)



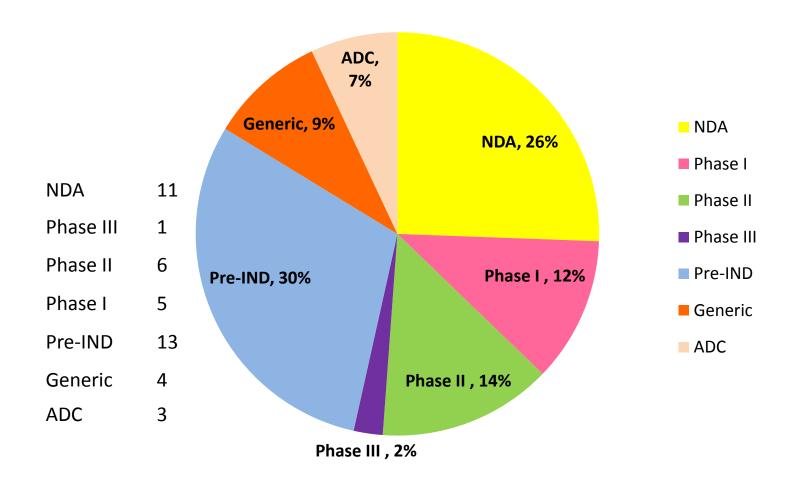
#### **Product Overview**

#### China Market

- ✓ BioEquivalance and US-China green channel
- ✓ Client gained 1<sup>st</sup> approval for Montelukast
- ✓ Several clients initiated Benzonatate commercialization in the US and Chian
- ✓ Expected to get approval for Sevelamer Carbonate, Temozolomide and Calcipotriol in 2020



### **CDMO Overview**





## **Strong CDMO Demand**

- Expect to see a strong YoY growth
- Clients entering into efficacy confirmation or scale up stages, boosting demands in 2021 to 2022
- Well known ADC development platform to provide services domestically and internationally



#### COVID-19

 Collaborated with Taipei Veterans General Hospital, National Yang-Ming University and National Chiao Tung University for drug development

Photo from Taoyuan City Government







# Injection



## **Overview**





#### **International Standard**

- Designed by NNE
- USA(FDA), EMA and PMDA standard
- Competence for small molecules and protein drugs



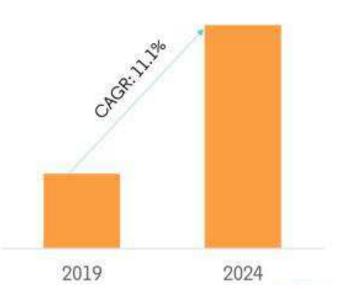




## **Injectable DP Service**

- Business models include Licensing,
   Co-Development and CDMO
- Invested companies and subsidiaries are potential partners
- Unique and strong API portfolio attract new customers
- More than 10 projects in discussion
- Deal structure includes fees and milestones for development and commercialization

#### Injectable Drugs Market Summary



Source: Mordor Intelligence and future market insights

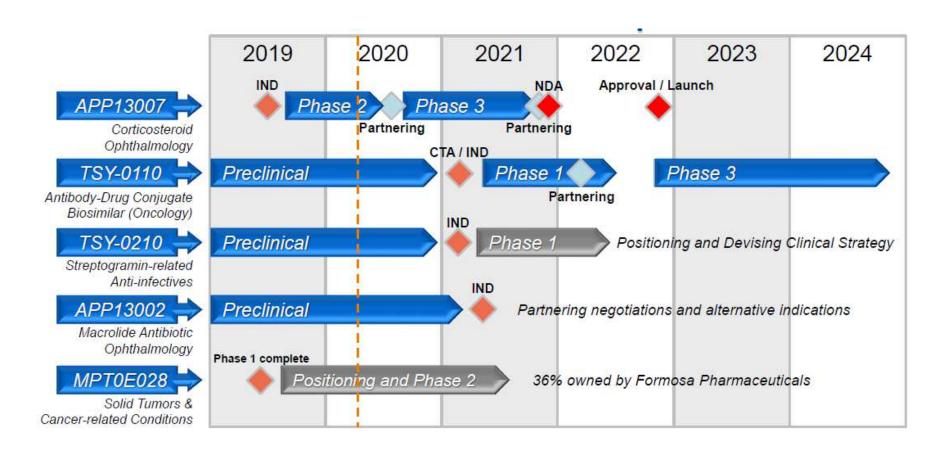


# New Drug Development Formosa Pharmaceuticals.





## **Pipeline Update**





Q&A