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# **ScinoPharm**

**May 26, 2021**



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# Company Overview

# ScinoPharm at a Glance

- Est. in 1997 in Taiwan (Tainan) with cGMP plants/R&D in Tainan and Changshu and marketing forces in Tainan, Shanghai and Tokyo
- Specializes in high potency (cytotoxic/steroid) API and injectable R&D and manufacturing with customers worldwide
- 74 generic APIs in portfolio with 32 referred and approved by ANDA/NDA\*
  - 872 active DMFs worldwide with 64 US DMFs\*
- 150+ contract projects with 7 approved/launched (5 NCEs) and 8 in phase 3 for NDA/MAA filing in 1-3 years\*
- Certified by key international regulators - US FDA, EMA, EDQM, Australian TGA, Japanese PMDA, Korea KFDA, Mexico COFEPRIS and German Authority

\* Data as of 2021/04/30



# Business Update

# Business Strategies

**Advancing to  
Injectables**

**Optimize  
Existing Generic  
API Portfolio**

**Expand CDMO  
Business**

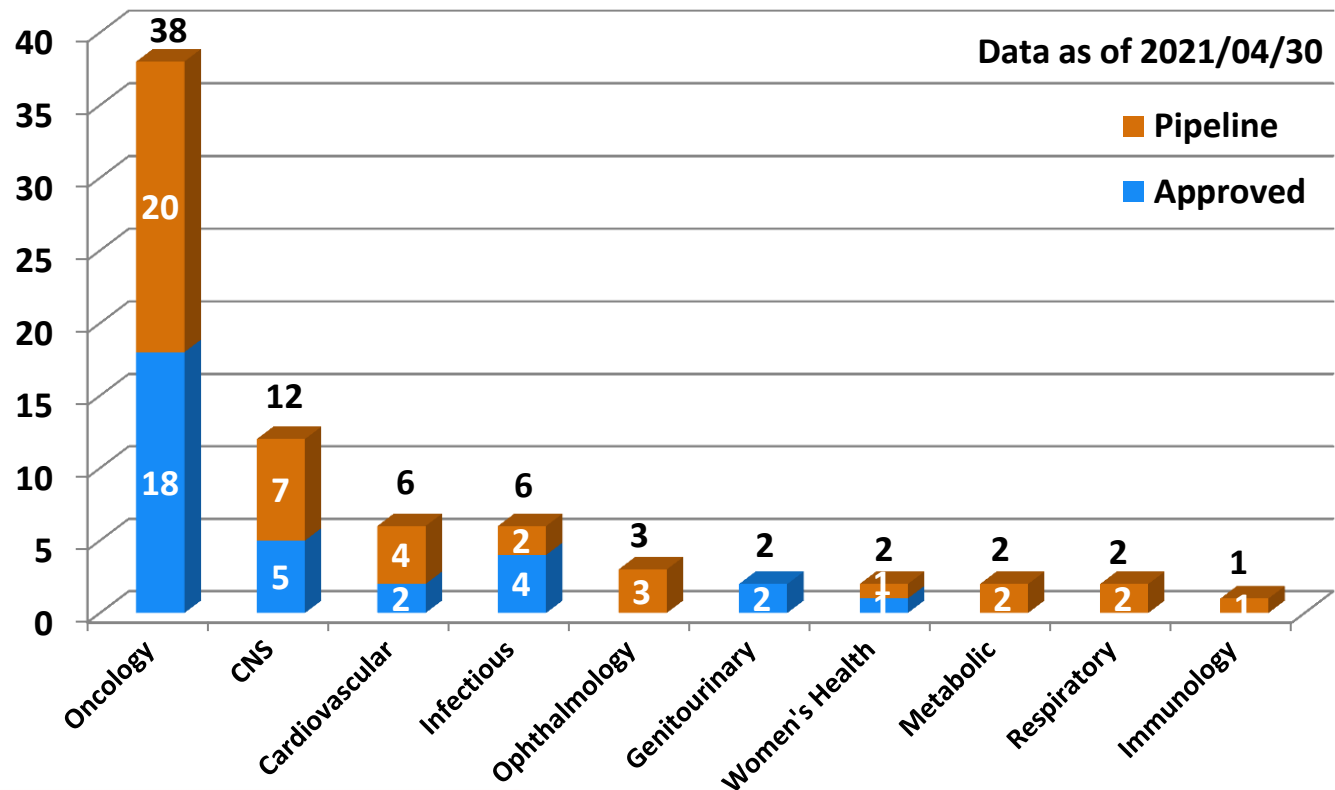
**Actively Develop Japan, China and Emerging Markets**

Optimize  
Existing  
Generic API  
Portfolio

## ■ Generic API Business

- Leverage Tainan/Changshu production advantage with better sales/production coordination to stabilize supply
- The impact of Covid-19 pandemic

## ■ Existing Generic API Portfolio





**Optimize  
Existing  
Generic API  
Portfolio**

## ■ 2021 Generic API Product Approval Plan

Type	Product	Region	Indication	Brand Marketer
Generic API	Fondaparinux Sodium	CN(✓)	Anti-thrombotic	Mylan
Generic API	Irinotecan HCl	CN	Colorectal cancer	Pfizer
Generic API	Anastrozole	CN	Breast cancer	ANI Pharmaceuticals
Generic API	Sodium Phenylbutyrate	CN(✓)	Urea cycle disorders	Horizon Therapeutics
Generic API	Azilsartan	CN	Hypertension	Arbor Pharmaceuticals
Generic API	Letrozole	CN	Breast cancer	Novartis
Generic API	Bimatoprost	CN	Glaucoma	Allergan
Generic API	Regadenovaon	US	MPI	Astellas
Generic API	* Pemetrexed Disodium 7H <sub>2</sub> O CEP	EU	Non-small cell lung cancer	Eli Lilly
Generic API	Topiramate	EU	Weight management	Vivus

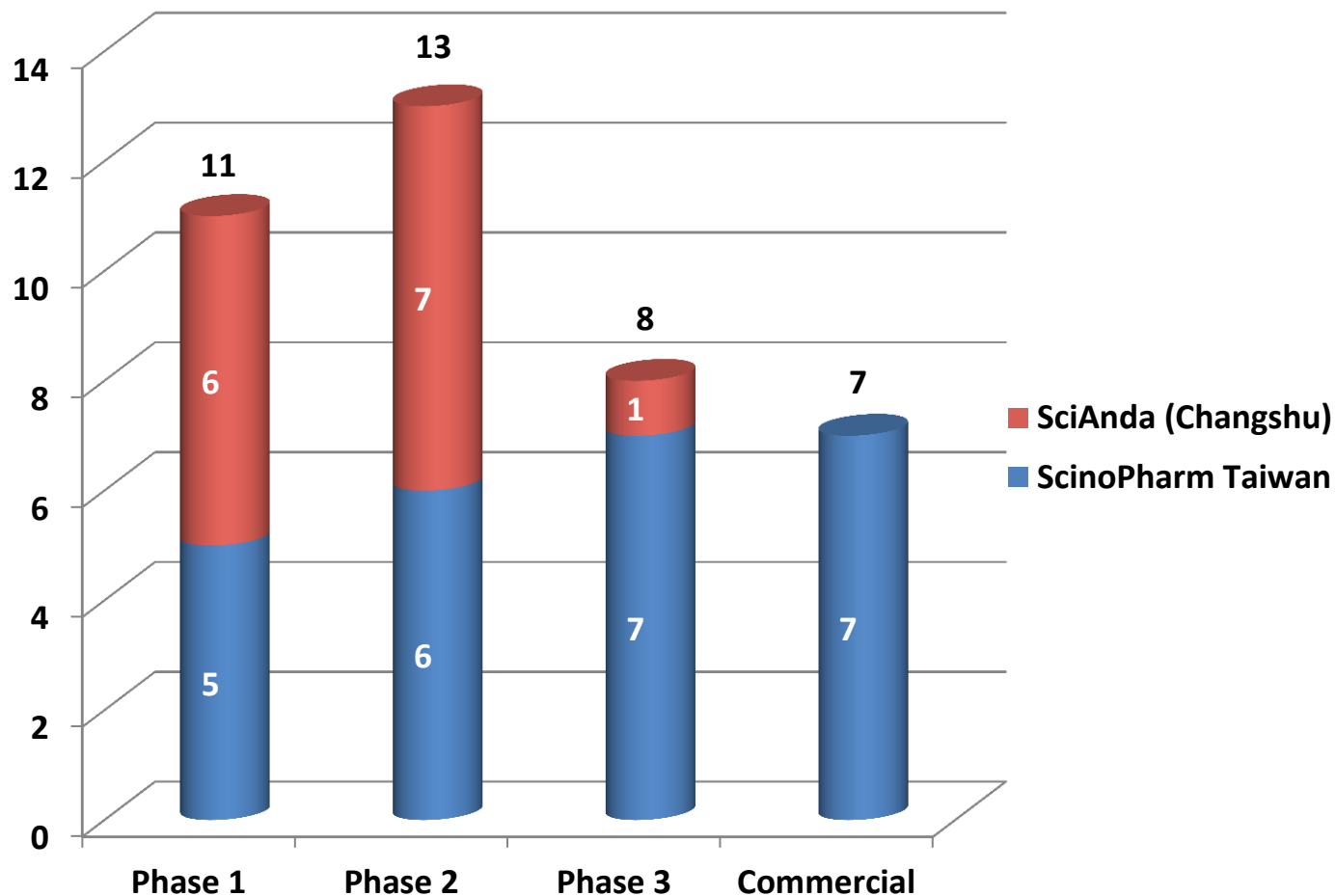
✓ : Approved

\* : Collaborative project for drug product development

Data as of 2021/04/30

**Expand  
CDMO  
Business**

## ■ CDMO Business



Data as of 2021/04/30

**Expand  
CDMO  
Business**

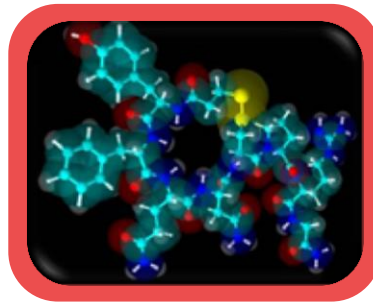
## ■ 2021 CDMO API Product Approval Plan

Type	Product	Region	Indication	Brand Marketer
CDMO API	Donafenib	CN	Cancer	Suzhou Zelgen
CDMO API	Leuprolide Mesylate	US/EU	Cancer	Foresee
CDMO API	Eflornithine	US/EU	FAP	CPP

Data as of 2021/04/30

- Donafenib, customer's NCE application, expected to be approved in China in May, 2021
- 2 CDMO products submitted to EMA and FDA by customers; one is expected to receive FDA response in mid-2021

## Advancing to Injectables



Peptides



Sterile Injectables



Pen Injectors

- Profit-sharing from 3 drug products (in-house development + outsourcing production)
- ANDA of 1<sup>st</sup> in-house prefilled-syringe product was submitted to FDA in May, 2020 – Response to FDA in progress
- Registration batches of Vial line (prefilled-syringed /pen device) and Cartridge line (liquid solution/ lyophilized powder) products were completed
- Completed the 1<sup>st</sup> TFDA on-site inspection in Apr. 2021, pending for official inspection report
- Target to submit the 2<sup>nd</sup> in-house produced ANDA in Q2, 2021 and 1<sup>st</sup> NDA (505(b)(2)) in Q4, 2021

# Actively Develop Japan, China and Emerging Markets

## Japan Market

- Japan office will upgrade to a branch to facilitate business
- The impact of Covid-19 pandemic
- The largest generic API supplier for Galantamine HBr and Capecitabine in Japan
  - Indication : Alzheimer's disease / Various cancers
  - Japan market size : c. USD 200 million / over USD 100 million
- Leverage Japan's late patent expiration and our new injectables capacity to explore opportunities for generic APIs + CDMO projects

# Actively Develop Japan, China and Emerging Markets

## China Market

- Customer's Fondaparinux Sodium PFS launched in Feb. 2021
  - Indication : Anti-thrombotic
  - Market Size : c. RMB 200 million
- Changshu site completed CFDI's 1<sup>st</sup> on-site inspection for Sodium Phenylbutyrate in Sep. 2020. Customer obtained approval in May, 2021 and will launch in China as orphan drug
  - Indication : Urea cycle disorders
- Changshu site, in Feb. 2021, completed CFDI's on-site inspection for NCE - Donafenib
  - Customer approval expected in May, 2021
    - Indication : Advanced liver cancer first-line treatment
    - 1<sup>st</sup> year sales projected by research report : c. RMB 220 million
- Changshu site to activate another 3 on-site inspections in 2021



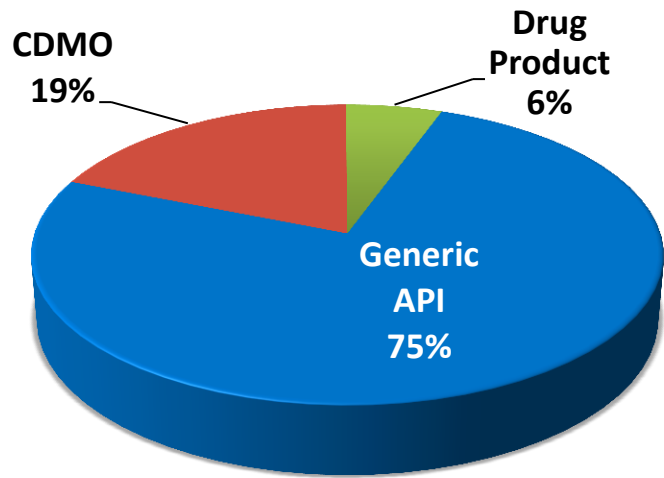
# Financial Performance

# Consolidated Income Statement

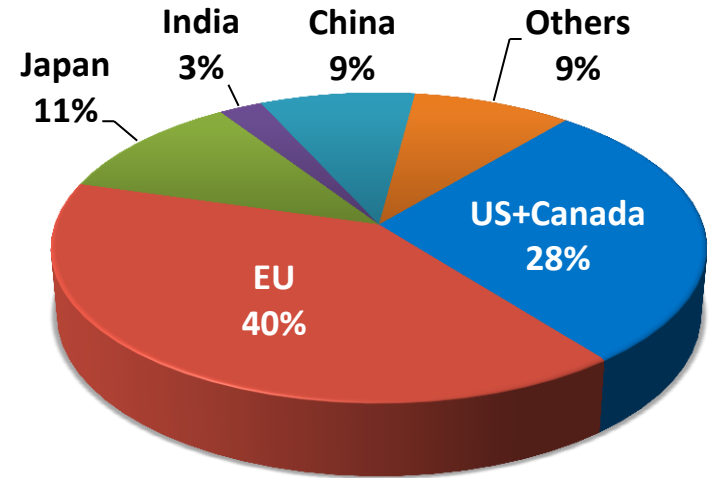
In NTD Million, except for EPS	1Q 2021 (Reviewed)		YoY	1Q 2020 (Reviewed)	
Revenue	641	100%	18%	543	100%
Gross Profit	365	57%	49%	244	45%
Operating Profit	110	17%	147%	45	8%
Net Profit before Tax	113	18%	131%	49	9%
Net Profit after Tax	90	14%	155%	35	7%
EPS (NTD)	0.11	-	-	0.04	-



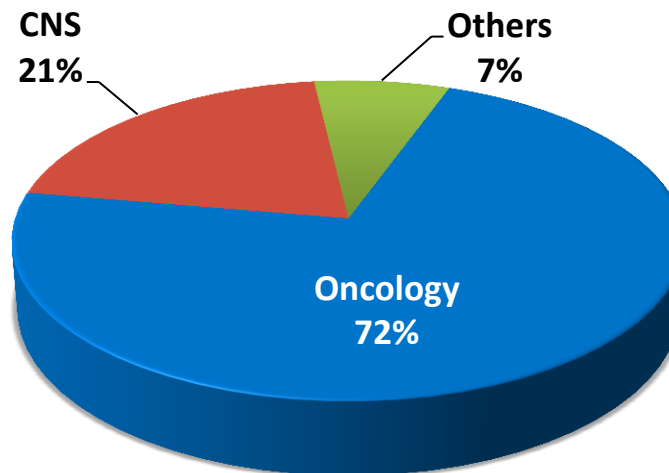
# 1Q 2021 Sales Distribution



**by Business**



**by Region**



**by Indication**

# Sales Distribution – YoY

## By Business

Unit: USD

	Generic API	CDMO	Drug Product
1Q 2021 Sales	17.0M	4.3M	1.3M
YoY	4.8%	178.9%	669.3%

## By Indication

	Oncology	CNS	Others
1Q 2021 Sales	16.3M	4.6M	1.7M
YoY	22.7%	38.4%	24.5%

## By Region

	EU	US & Canada	Japan	India	China	Others
1Q 2021 Sales	9.1M	6.4M	2.5M	0.6M	2.0M	2.0M
YoY	5.5%	80.9%	-28.3%	78.2%	545.1%	21.1%

# Consolidated Balance Sheet

In NTD Million	2021/3/31 (Reviewed)		2020/3/31 (Reviewed)	
Cash and Cash Equivalents	4,040	33%	3,691	32%
Accounts Receivable	321	3%	398	3%
Inventories	1,423	12%	1,276	11%
Property, Plant & Equipment	4,164	34%	4,351	37%
Other Current/Non-Current Assets	2,230	18%	1,936	17%
<b>Total Assets</b>	<b>12,178</b>	<b>100%</b>	<b>11,652</b>	<b>100%</b>
Financial Debt	43	0%	232	2%
Other Current Liabilities	696	6%	575	5%
Other Non-Current Liabilities	628	5%	706	6%
<b>Total Liabilities</b>	<b>1,367</b>	<b>11%</b>	<b>1,513</b>	<b>13%</b>
<b>Total Shareholders' Equities</b>	<b>10,811</b>	<b>89%</b>	<b>10,139</b>	<b>87%</b>

# Consolidated Cash Flow Statement

In NTD million	1Q 2021 (Reviewed)	1Q 2020 (Reviewed)
From Operating Activities	117	264
From Investing Activities	(162)	144
From Financing Activities	31	(3)
Effect of foreign exchange rate changes	(1)	(19)
Net Change in Cash	(15)	386
Beginning Balance	4,055	3,305
Ending Balance	4,040	3,691



# Q & A



## Brand Quality with Asian Advantages

[www.scinopharm.com](http://www.scinopharm.com)

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