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# **ScinoPharm**

**January 19, 2022**



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# Table of Content

- **Company Overview**
- **Dual Business Development**
- **Business Update**
- **Financial Performance**
- **ESG**



# Company Overview

# ScinoPharm at a Glance

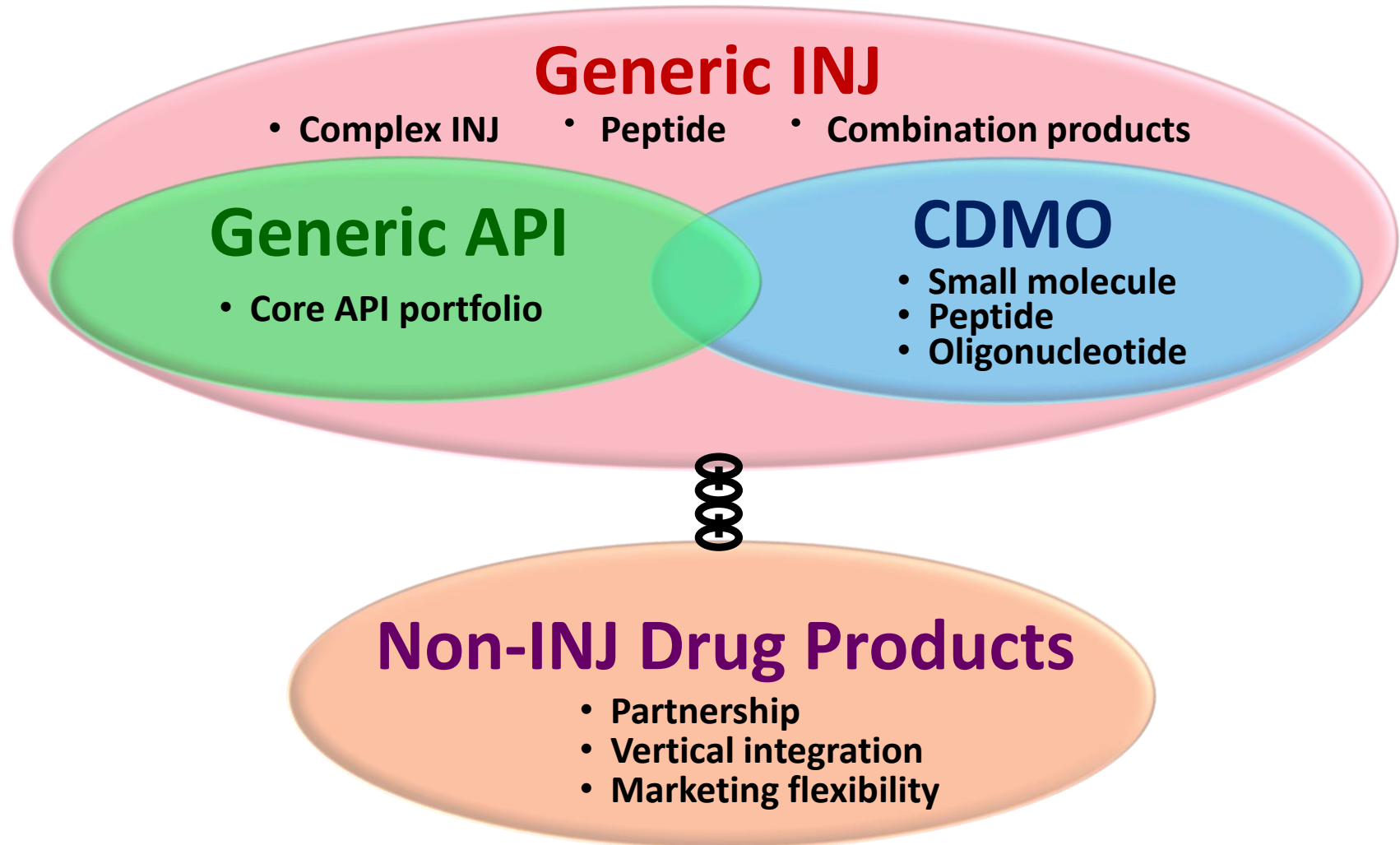
- Est. in 1997 in Taiwan (Tainan) with cGMP plants/R&D in Tainan and Changshu and marketing forces in Tainan, Shanghai and Tokyo
- Specializes in high potency (cytotoxic/steroid) API and injectable R&D and manufacturing with customers worldwide
- 74 generic APIs in portfolio with 32 referred and approved by ANDA/NDA\*
  - 879 active DMFs worldwide with 65 US DMFs\*
- 150+ contract projects with 9 approved/launched (7 NCEs) and 5 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; certified by TFDA for injectable plant

\* Data as of 2021/12/31



# Dual Business Development

# Dual Business Development : In-house Products and CDMO





# Business Update

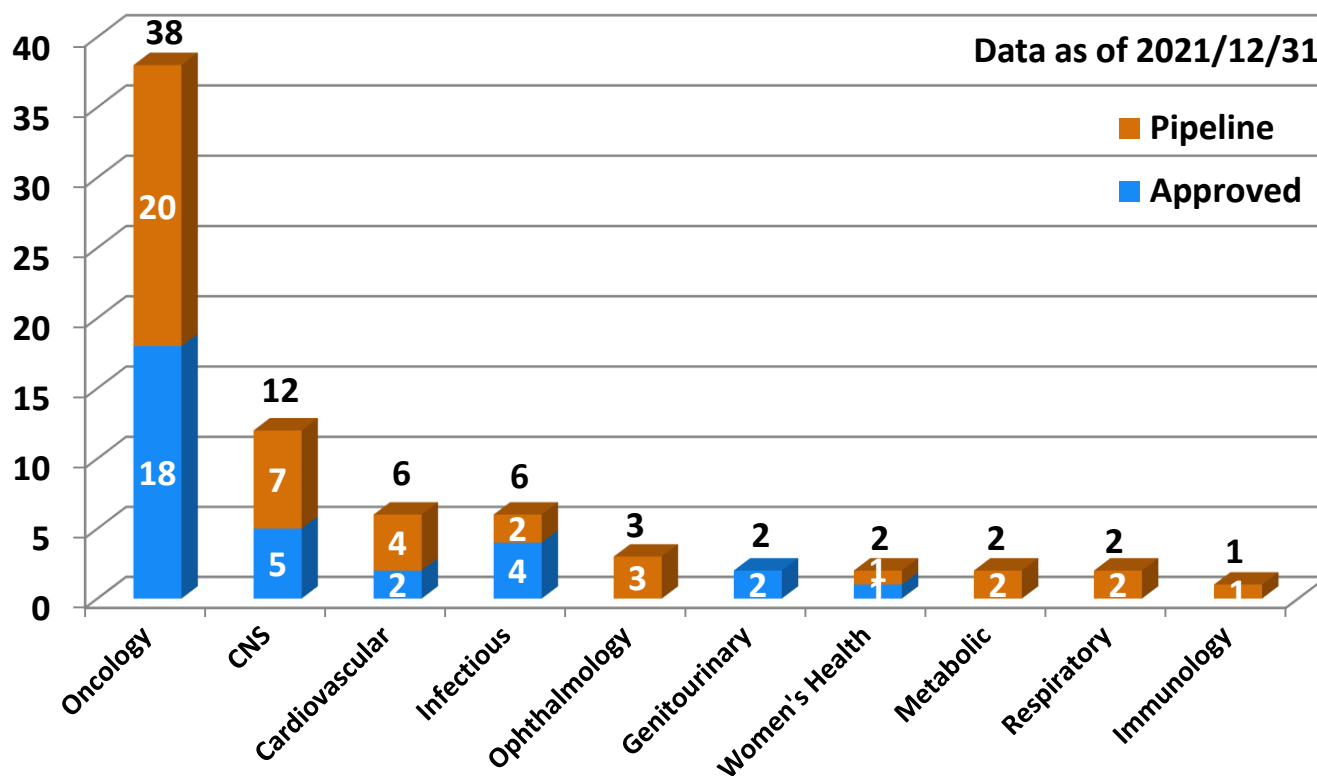


## Strengthen Core API Portfolio

### ■ API Business Priority

- Strengthen core API portfolio
- Leverage Tainan/Changshu production advantage and strengthen sales/production coordination

### ■ Generic API Products



**Strengthen  
Core API  
Portfolio**

## ■ 2021 Approved Generic API Product

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 2021/12/31

**Expand  
CDMO  
Business**

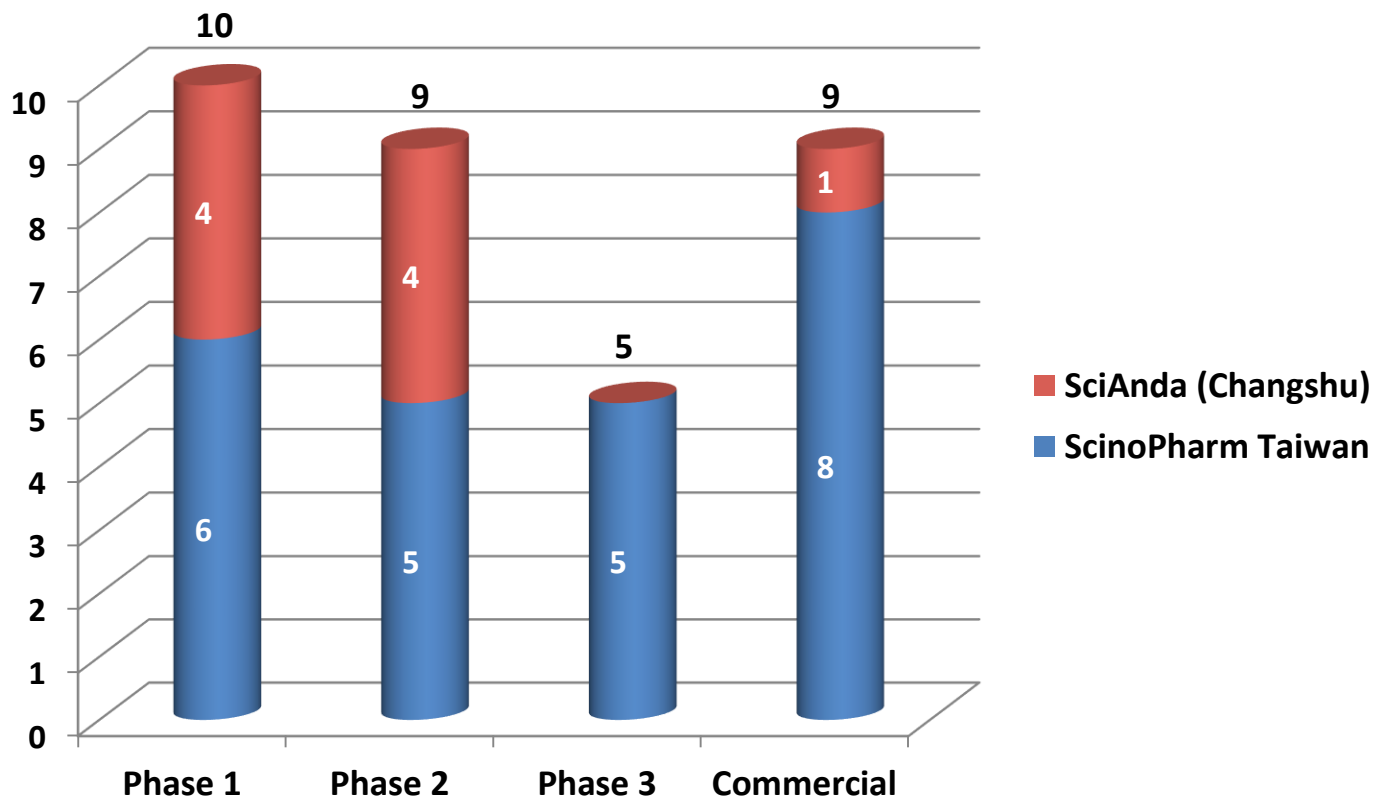
## ■ CDMO Business Priority

■ Small molecule

■ Peptide

■ Oligonucleotide

## ■ CDMO Business Status



Data as of 2021/12/31

**Expand  
CDMO  
Business**

## ■ 2021 Approved CDMO API Product

Type	Product	Region	Indication	Brand Marketer
CDMO API	Donafenib	CN(✓)	Cancer	Suzhou Zelgen
CDMO API	Camcevi	US(✓) EU	Cancer	Foresee
CDMO API	Eflornithine	US/EU	FAP	CPP

### ■ Donafenib:

Data as of 2021/12/31

- Approved and launched in China in June, 2021 (Indication: Advanced liver cancer)
- Submitted to NMPA in Oct. 2021 (Indication: Thyroid cancer)

### ■ Camcevi:

- Approved by FDA in May, 2021; MAA review in progress
- Approved by Canada Healthcare in Nov. 2021
- Clinical trial application accepted by China NMPA for substantial review in year-end of 2021

### ■ Eflornithine:

- Submitted to FDA and EMA by customer

## ■ **INJ Business: In-house Products and CDMO**

- **Focus on Complex INJ 、 Peptide & Combination products**
- **Registration batches of cartridge, prefilled-syringe, liquid solution and lyophilized powder products were completed**
  - **ANDA of 1<sup>st</sup> in-house prefilled-syringe product was submitted to FDA in May, 2020 - Responded to FDA's review in Sep. 2021**
  - **ANDA of 1<sup>st</sup> in-house liquid solution product was submitted to FDA in June, 2021 - Responded to FDA's review in Jan. 2022**
  - **ANDA of 1<sup>st</sup> in-house lyophilized powder product was submitted to FDA in Dec. 2021**
  - **Registration batches of 1<sup>st</sup> cartridge product were completed**
- **Injectable plant certified by TFDA in Dec. 2021**

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

## ■ **Japan Market**

- **Completed the establishment of Japan branch in Q3, 2021 to cultivate Japan market**
- **20 generic customers with 7 from top 10 drug firms**
- **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
- **Completed 3 CFDI on-site inspections in Changshu site; China market continues to grow**

Inspection	Product	Approval	Indication	Market
2020.09	Sodium Phenylbutyrate	2021.05	Urea cycle disorders	Orphan disease medicine
2021.02	Donafenib	2021.06	Advanced liver cancer first-line treatment	2022 sales projected by research report : c. RMB 400 million
2021.06	Bimatoprost	Expected 2022 Q2	Glaucoma	Prostaglandin drug products c. RMB 1 billion

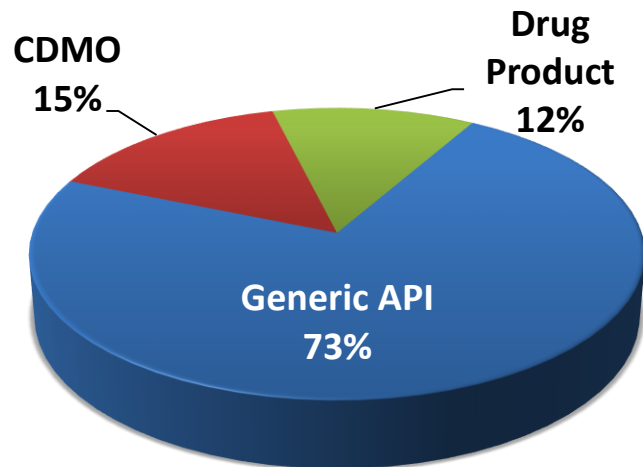
- Clinic trial of customer's Sodium Phenylbutyrate for new indication in progress
- Customer's Donafenib submitted to NMPA in Oct. 2021 for new indication - Thyroid cancer



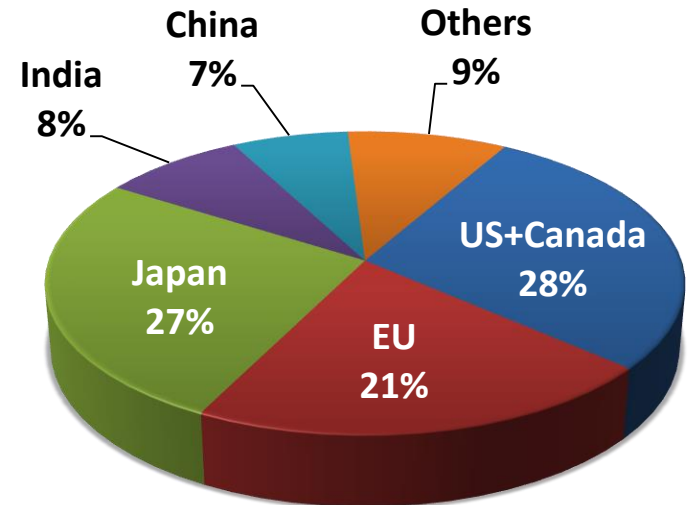
# Financial Performance



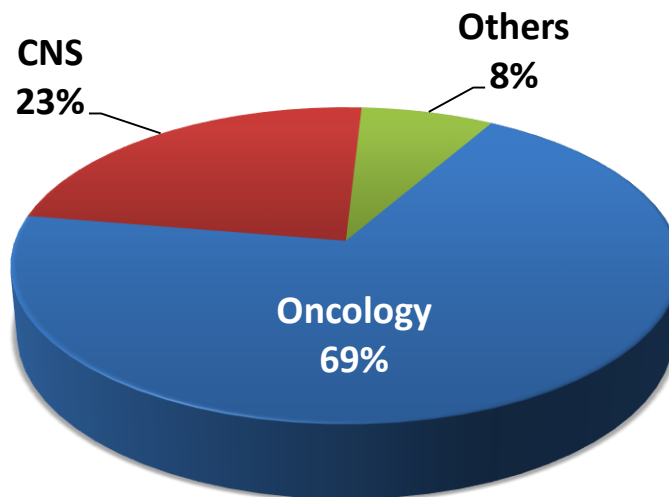
# 2021 Sales Distribution



**by Business**



**by Region**



**by Indication**

# Sales Distribution – YoY

## By Business

Unit: USD

	Generic API	CDMO	Drug Product
2021 Sales	71.9M	14.7M	12.1M
YoY	0.2%	-41.8%	61.0%

## By Indication

	Oncology	CNS	Others
2021 Sales	68.4M	22.9M	7.4M
YoY	13.0%	-23.7%	-47.2%

## By Region

	US & Canada	EU	Japan	India	China	Others
2021 Sales	27.7M	20.8M	26.1M	8.2M	6.7M	9.2M
YoY	35.8%	-48.6%	33.3%	-32.2%	117.7%	2.6%

# Consolidated Income Statement

In NTD Million, except for EPS	3Q 2021 (Reviewed)		YoY	3Q 2020 (Reviewed)	
Revenue	2,043	100%	-8%	2,209	100%
Gross Profit	945	46%	-11%	1,058	48%
Operating Profit	227	11%	-36%	354	16%
Net Profit before Tax	235	11%	-32%	346	16%
Net Profit after Tax	190	9%	-31%	274	12%
EPS (NTD)	0.24	-	-	0.35	-

# Consolidated Balance Sheet

In NTD Million	2021/9/30 (Reviewed)		2020/9/30 (Reviewed)	
Cash and Cash Equivalents	3,732	33%	3,759	31%
Accounts Receivable	284	2%	468	4%
Inventories	1,373	12%	1,350	11%
Property, Plant & Equipment	4,066	36%	4,211	35%
Other Current/Non-Current Assets	1,994	17%	2,212	19%
<b>Total Assets</b>	<b>11,449</b>	<b>100%</b>	<b>12,000</b>	<b>100%</b>
Financial Debt	0	0%	244	2%
Other Current Liabilities	503	4%	638	6%
Other Non-Current Liabilities	624	6%	633	5%
<b>Total Liabilities</b>	<b>1,127</b>	<b>10%</b>	<b>1,515</b>	<b>13%</b>
<b>Total Shareholders' Equities</b>	<b>10,322</b>	<b>90%</b>	<b>10,485</b>	<b>87%</b>

# Consolidated Cash Flow Statement

In NTD million	3Q 2021 (Reviewed)	3Q 2020 (Reviewed)
From Operating Activities	331	616
From Investing Activities	(238)	51
From Financing Activities	(411)	(210)
Effect of foreign exchange rate changes	(5)	(3)
Net Change in Cash	(323)	454
Beginning Balance	4,055	3,305
Ending Balance	3,732	3,759



# ESG

# ESG

2021



## Environment

**593 tons**

Reduction in CO2 emissions by reducing 4.4% of electricity usage

**c. 136,000 kWh**

Green energy generated by in-house solar panels



## Social Responsibility

**NTD1.65mn**

Employee epidemic prevention and health management expenditure

**c. 26,000 viewers**

ScinoPharm Art Forum to advocate the UN's Sustainable Development Goals (SDGs)



## Corporate Governance

**20%**

Female members % in the Board  
(higher than the average of TWSE listed companies)

**4 : 5**

Ratio of male to female senior management



# Q & A





## Brand Quality with Asian Advantages

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

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