

## **ScinoPharm Investor Conference**

**— 2024 06 11** 







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Company Overview

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# **Company Overview**



#### ScinoPharm at a Glance

- Est. 1997 in Taiwan with R&D/CGMP plants in Tainan and Changshu, China plus marketing forces in Tainan, Shanghai and Tokyo
- Specializes in providing R&D and CGMP manufacturing of APIs (cytotoxic/steroid) and injectable drug products
- 76 generic APIs in portfolio with 37 referred and approved ANDAs/NDAs\*
  - 928 active DMFs worldwide with 68 US DMFs\*
- 200+ contract projects with 12 approved/launched (10 NCEs) and 5 in phase 3 for NDA/MAA filing within 1-3 years\*
- API plant certified by key international regulators US FDA, EMA, EDQM, Australian TGA, Japanese PMDA, Korea KFDA, Mexico COFEPRIS and German Authority
- Injectable plant certified by US FDA and TFDA

# **Business Updates**



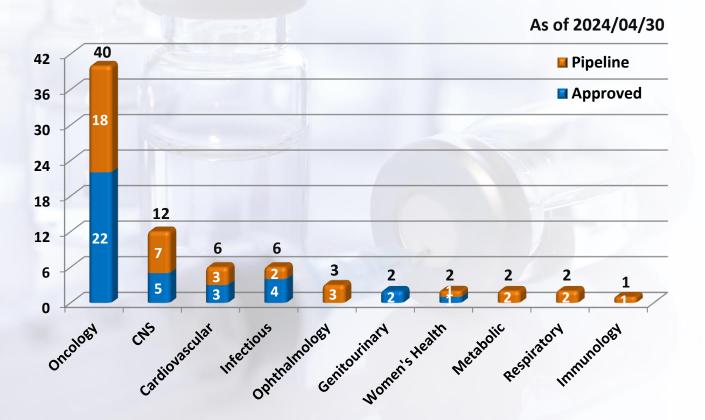
# **2024 Product Approval Plan**

Туре	Product	Region	Indication	Brand Marketer
Generic API	Cladribine	CN(*)	Multiple Sclerosis	Merck
Generic API	Olaparib	CN(√)	Cancer	AstraZeneca
Generic API	Exemestane	CN(√)	Breast Cancer	Pfizer
Generic API	Azacitidine	EU	Myelodysplastic syndromes	Celgene
Generic API	Dantrolene Na	EU	Malignant Hyperthermia	Eagles
CDMO API	Eflornithine	US/EU	Familial Adenomatous Polyposis	Post-marketing Disclosure
CDMO API	Eflornithine	EU	Neuroblastoma	Post-marketing Disclosure
Generic Drug	Clofarabine	US	Acute Lymphoblastic Leukemia	Genzyme

\* : Approved in May, 2024

Optimize Generic API Portfolio

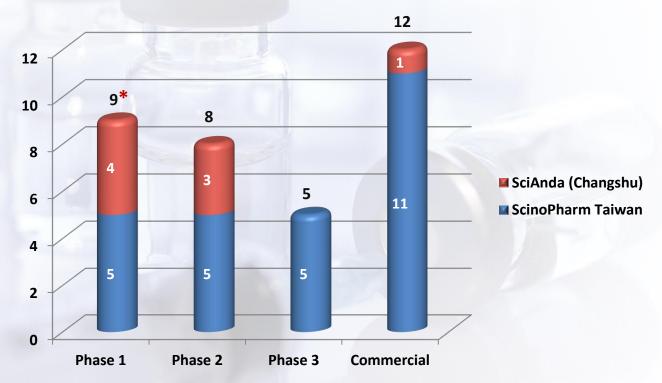
#### **Generic API Portfolio**



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Expand CDMO Business

#### **CDMO Business Status**



<sup>\*</sup>A project begins clinical trials and its status progresses from Pre-clinical to Phase I

As of 2024/04/30

Vertically Integrated Injectable

### **In-House Drug Product Status**

Registration Batches Completion US FDA ANDA Submission US FDA On-site Inspection US FDA ANDA Approval

Vial Line Lyophilized Powder

US FDA approved ANDA in Sep., 2023

Cartridge Line Prefilled Syringe

Passed Pre-Approval Inspection in May, 2022\*

Vial Line Liquid Solution

Passed Pre-Approval Inspection in May, 2022\*

Cartridge Line
Cartridge in Device

Two in-house cartridge products submitted ANDA to FDA, and another one is preparing registration batch production A product passed Pre-Approval Inspection with zero FDA-483 Form issued in Apr., 2024

\*Responded to FDA CRL

Vertically Integrated Injectable

#### **Drug Product Collaboration**



505(b)(2) Collaboration for Non-Small Cell Lung Cancer

**Launched in US by customer** 



ANDA Collaboration for Non-Small Cell Lung Cancer

Launched in US/EU by customer



ANDA Collaboration for Multiple Myeloma

Launched in the US/EU and submitted to other regions by customer



In-house Prefilled Syringe Product

Exclusive partnership in US, ANDA under US FDA review



Contract Manufacturing of Oncology Injectable

Routine dispatch for commercial supply in the US



Two In-house Cartridge Products

Exclusive partnership in US, ANDA under US FDA review

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#### **China Market**

4 CFDI on-site inspections completed in Changshu site, and more inspections are expected in 2024 to facilitate China's business growth

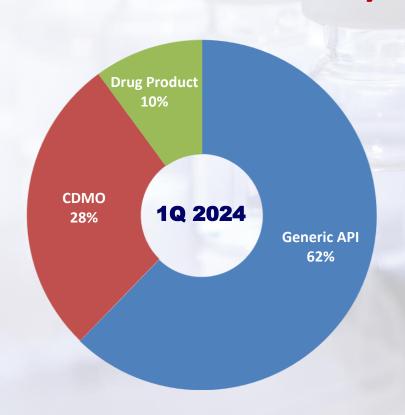
	Product	Approval	Indication	Market
2020.09	Sodium Phenylbutyrate	2021.05	Urea cycle disorders	Orphan disease medicine
2021.02	Donafenib	2021.06	Advanced liver cancer Thyroid cancer	c. RMB 600 million
2021.06	Bimatoprost	2023.02	Glaucoma	Prostaglandin drug products c. RMB 1 billion
2022.11	Azilsartan	2022.09	Hypertension	c. RMB 100 million

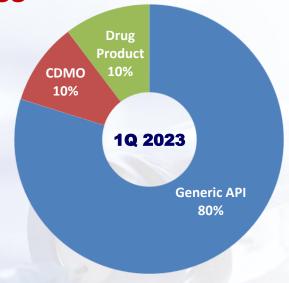
Changshu site completed inspection by US FDA with zero FDA form 483 issued in Mar., 2024

# **Financial Performance**



Sales Distribution – By Business

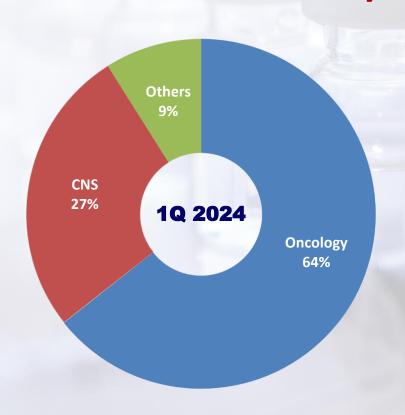


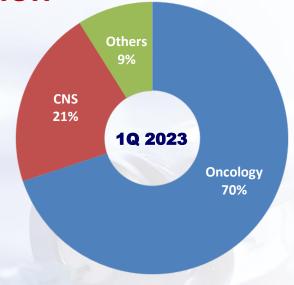


Unit: USD/M

	Generic API	CDMO	Drug Product
1Q 2024 Sales	17.5	7.8	2.8
YoY	2.6%	269.2%	29.0%

Sales Distribution – By Indication

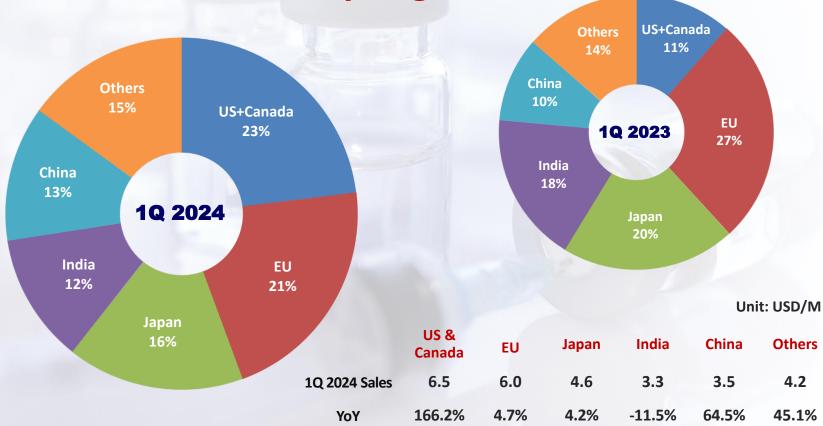




Unit: USD/M

	Oncology	CNS	Others
1Q 2024 Sales	18.1	7.5	2.5
YoY	21.2%	66.0%	31.8%

Sales Distribution – By Region



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### **Consolidated Income Statement**

NTD Million except for EPS	1Q 2024		YoY	1Q 2023	
Revenue	883	100%	36%	648	100%
<b>Gross Profit</b>	353	40%	45%	244	37%
<b>Operating Expenses</b>	(201)	-23%	3%	(195)	-30%
<b>Operating Profit</b>	152	<b>17</b> %	211%	49	7%
Net Profit before Tax	175	20%	232%	53	8%
Net Profit after Tax	140	16%	233%	42	6%
EPS (NTD)	0.18	-	-	0.05	-

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#### **Consolidated Balance Sheet**

NTD Million	2024/03/31		2023/03/31	
Cash and Cash Equivalents	4,226	35%	4,434	37%
Accounts Receivable	539	5%	406	3%
Inventories	1,667	14%	1,403	12%
Property, Plant & Equipment	3,720	31%	3,761	31%
Other Current/Non-Current Assets	1,823	15%	1,967	17%
Total Assets	11,975	100%	11,971	100%
Financial Debt	20	0%	90	1%
Other Current Liabilities	775	7%	787	7%
Other Non-Current Liabilities	655	5%	636	5%
Total Liabilities	1,450	12%	1,513	13%
Total Shareholders' Equities	10,525	88%	10,458	87%

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#### **Consolidated Cash Flow Statement**

NTD million	1Q 2024	1Q 2023	Dif.
From Operating Activities	384	197	187
Depreciation & Amortization	119	116	3
From Investing Activities	(92)	(66)	-26
Capital Expenditure	(92)	(66)	-26
From Financing Activities	(16)	10	-26
Effect of foreign exchange rate changes	7	(2)	9
Net Change in Cash	284	139	145
Beginning Balance	3,942	4,295	-353
Ending Balance	4,226	4,434	-208

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Q & A





### **Brand Quality with Asian Advantages**

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