

# ScinoPharm Investor Conference

January, 2024







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Company Overview

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# **Company Overview**



#### ScinoPharm at a Glance

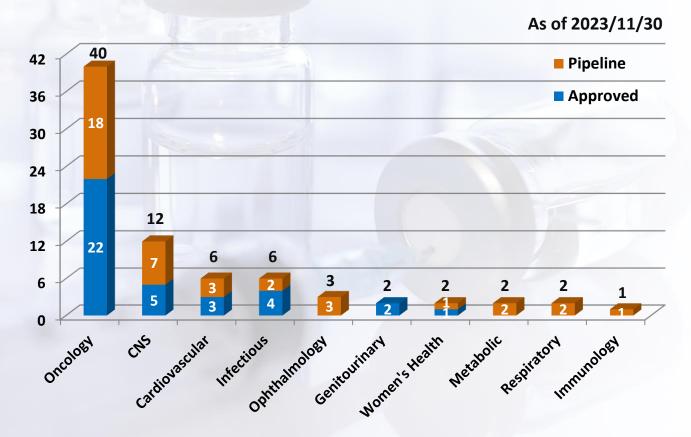
- Est. 1997 in Taiwan with R&D/CGMP plants in Tainan and Changshu, China plus marketing forces in Tainan, Shanghai and Tokyo
- Specializes in providing R&D and CGMP manufacturing of APIs (cytotoxic/steroid) and injectable drug products
- 76 generic APIs in portfolio with 37 referred and approved ANDAs/NDAs\*
  - 923 active DMFs worldwide with 68 US DMFs\*
- 200+ contract projects with 11 approved/launched (9 NCEs) and 6 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**



### Optimize Generic API Portfolio

#### **Generic API Portfolio**



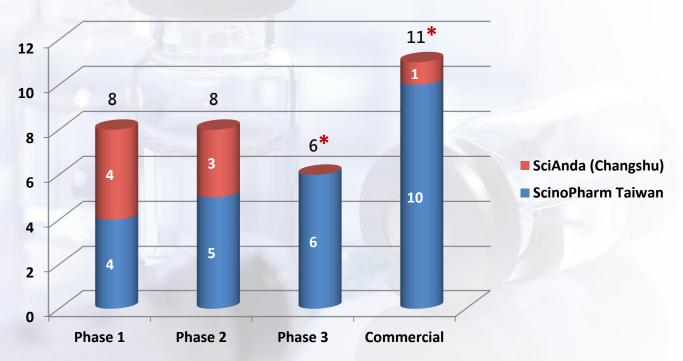


## **2023 Generic API Product Approval Plan**

Туре	Product	Region	Indication	Brand Marketer
Generic API	Bimatoprost	CN(√)	Glaucoma	Allergan
Generic API	Cladribine	CN	Multiple sclerosis	Merck
Generic API	Galantamine HBr	CN(√)	Alzheimer's disease	Janssen
Generic API	Azacitidine	EU	Myelodysplastic syndromes	Celgene

 Expand CDMO Business

#### **CDMO** Business Status



\* One phase III CDMO product was approved by US FDA in Dec., 2023, so business status will change from Phase III to Commercial

As of 2023/11/30

Expand CDMO Business

### **2023 CDMO Product Approval Plan**

Туре	Product	Region	Indication	Brand Marketer
CDMO API	Ganaxolone	EU( <b>√</b> )	Genetic epilepsy	Marinus
CDMO API	Eflornithine	US/EU	FAP	Post-marketing Disclosure
CDMO API	Eflornithine	US(*) EU	Pediatric neuroblastoma	Post-marketing disclosure
Intermediate for CDMO API	Sotagliflozin	US(✔)	Heart failure	Lexicon

✓ : Approved

As of 2023/11/30

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\* : Approved in Dec., 2023

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 with NAI status in May, 2022

Vial Line
Liquid Solution

Passed Pre-Approval Inspection with NAI status in May, 2022

Cartridge Line
Cartridge in Device

Two in-house cartridge products submitted to FDA in Jun., 2023 and Dec., 2023, respectively

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



**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 to facilitate China market growth

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	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	2023 sales projected by research report : c. RMB 680 million
2021.06	Bimatoprost	2023.02	Glaucoma	Prostaglandin drug products c. RMB 1 billion
2022.11	Azilsartan	2022.09	Hypertension	c. RMB 100 million

<sup>\*</sup> Customer's clinical trial for new indication in progress

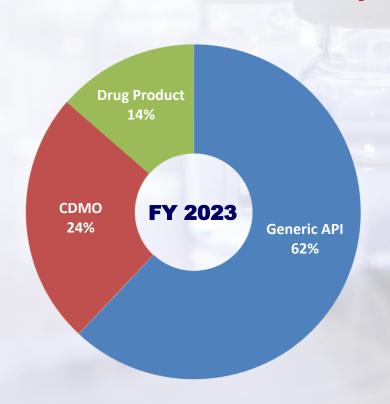
Changshu site expects more inspections in 2024

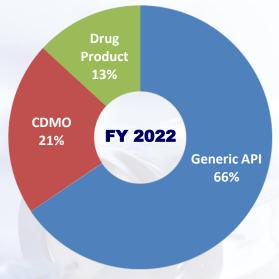
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# **Financial Performance**



Sales Distribution – By Business

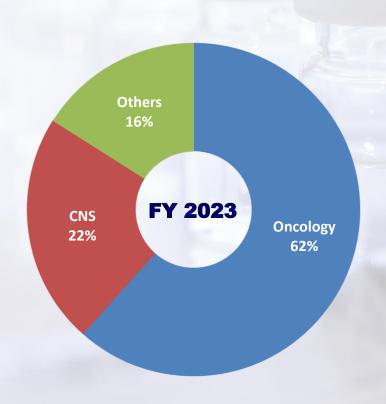


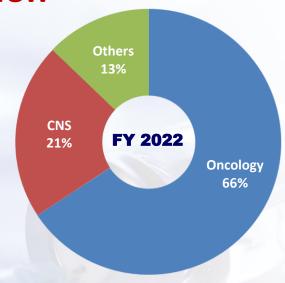


Unit: USD/M
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	Generic API	CDMO	Drug Product
FY 2023 Sales	62.9	25.1	14.1
YoY	-12.2%	7.8%	-2.4%

Sales Distribution – By Indication

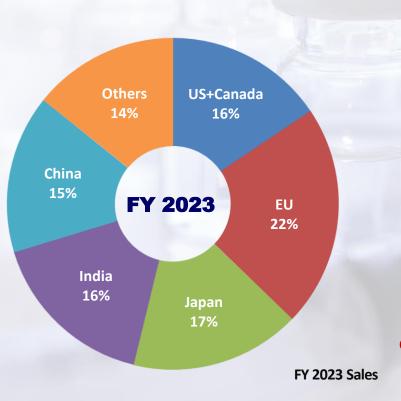


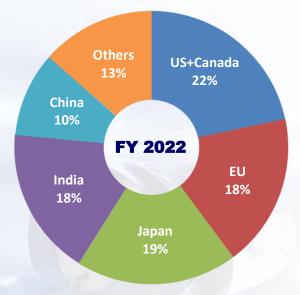


Unit: USD/M

	Oncology	CNS	Others	
FY 2023 Sales	63.5	22.1	16.5	
YoY	-11.7%	-5.9%	18.0%	

Sales Distribution – By Region





India

Unit: USD/M

Others

China

	Canada	EU	Jupun	maia	Cillia	Others
Y 2023 Sales	15.9	22.1	16.9	16.9	15.8	14.5
YoY	-33.0%	11.5%	-19.0%	-12.5%	43.9%	-1.4%

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**US &** 

#### **Consolidated Income Statement**

NTD Million except for EPS	3Q 2023		YoY	3Q 20	22
Revenue	2,063	100%	-8%	2,248	100%
<b>Gross Profit</b>	758	37%	-14%	884	39%
<b>Operating Expenses</b>	(635)	-31%	5%	(604)	-27%
<b>Operating Profit</b>	123	6%	-56%	280	12%
Net Profit before Tax	158	8%	-50%	314	14%
Net Profit after Tax	130	6%	-48%	252	11%
EPS (NTD)	0.16	-	-	0.32	-

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#### **Consolidated Balance Sheet**

NTD Million	2023/09/30		2022/09	2022/09/30	
Cash and Cash Equivalents	3,995	35%	4,246	36%	
Accounts Receivable	364	3%	339	3%	
Inventories	1,642	14%	1,304	11%	
Property, Plant & Equipment	3,653	32%	3,913	33%	
Other Current/Non-Current Assets	1,913	16%	1,937	17%	
Total Assets	11,567	100%	11,739	100%	
Financial Debt	58	1%	49	0%	
Other Current Liabilities	638	5%	629	5%	
Other Non-Current Liabilities	629	5%	665	6%	
Total Liabilities	1,325	11%	1,343	11%	
Total Shareholders' Equities	10,242	89%	10,396	89%	

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

NTD million	3Q 2023	3Q 2022	Dif.
From Operating Activities	173	669	-496
Depreciation & Amortization	344	323	21
From Investing Activities	(157)	(172)	15
Capital Expenditure	(209)	(168)	-41
From Financing Activities	(313)	(341)	28
Effect of foreign exchange rate changes	(2)	9	-11
Net Change in Cash	(300)	165	-465
Beginning Balance	4,295	4,081	214
Ending Balance	3,995	4,246	-251

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Q & A





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

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