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# ScinoPharm

June 14, 2022



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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
- 74 generic APIs in portfolio with 32 referred and approved ANDAs/NDAs\*
  - 888 active DMFs worldwide with 66 US DMFs\*
- 150+ contract projects with 11 approved/launched (9 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 TFDA and passed 1<sup>st</sup> Pre-Approval Inspection by US FDA in May, 2022

\*As of 2022/05/31





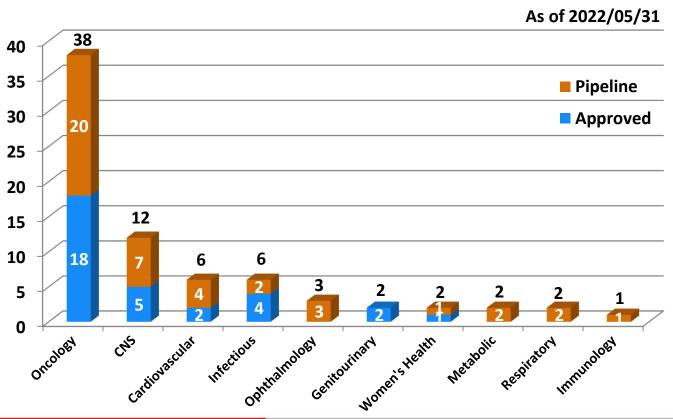
# **Business Update**

Optimize Generic API Portfolio

#### Generic API Business Update

- Leverage Tainan/Changshu production advantage and strengthen sales/production coordination
- Impacts of the Covid-19 pandemic are still manageable

#### ■ Generic API Portfolio





Optimize Generic API Portfolio

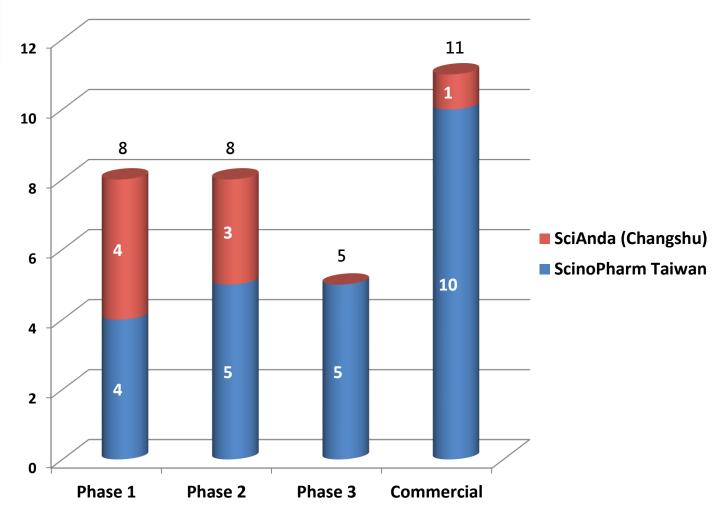
#### **■ 2022** Generic API Product Approval Plan

Туре	Product	Region	Indication	Brand Marketer
Generic API	Irinotecan HCl	CN(✔)	Colorectal cancer	Pfizer
Generic API	Anastrozole	CN(✓)	Breast cancer	ANI Pharmaceuticals
Generic API	Azilsartan	CN	Hypertension	Arbor Pharmaceuticals
Generic API	Bimatoprost	CN	Glaucoma	Allergan
Generic API	Cladribine	CN	Multiple sclerosis	Merck
Generic API	Galantamine HBr	CN	Alzheimer's disease	Janssen
Generic API	Regadenoson	US(✔)	MPI	Astellas
Generic API	Topiramate	EU	Weight management	Vivus



Expand CDMO Business

#### **■ CDMO Business Status**



As of 2022/05/31



# Expand CDMO Business

#### ■ 2022 CDMO API Product Approval Plan

Туре	Product	Region	Indication	Brand Marketer
CDMO API	Camcevi	EU(√)	Cancer	Foresee
CDMO API	Eflornithine	US/EU	FAP	СРР
CDMO API	Ganaxolone	US(✔)	Genetic epilepsy	Marinus
Intermediate for CDMO API	Sotagliflozin	US	Heart failure	Lexicon

✓ : Approved

As of 2022/05/31

#### Camcevi

- Application of registration clinical trial approved by China NMPA in Mar. 2022
- Submitted to the Ministry of Health of Israel for approval in Apr. 2022
- □ Approved by EMA in May, 2022

#### Ganaxolone

□ Approved by US FDA in Mar. 2022



Advancing to Injectables

- Drug Product Business (In-house Injectables and Collaborations)
  - Focus on complex injectables, peptides and combination products
  - Registration batches of cartridge, prefilledsyringe, liquid solution and lyophilized powder products manufactured
    - ANDAs of 1<sup>st</sup> prefilled-syringe product and 1<sup>st</sup> liquid solution product both passed the Pre-Approval Inspection by US FDA in May, 2022
    - ANDA of 1<sup>st</sup> lyophilized powder product submitted to US FDA in Dec. 2021
    - Registration batches of 1<sup>st</sup> cartridge product were completed
  - Vial line and Cartridge line are ready for commercial production and Injectable CDMO business



Advancing to Injectables

#### **■ Collaborative Projects for Drug Products**

- Signed marketing agreement for in-house prefilledsyringe product
- Collaboration on 505(b)(2) for non-small cell lung cancer launched in US in Feb. 2022
- Collaboration on ANDA for non-small cell lung cancer submitted to US FDA and EMA by customer
- Collaboration on ANDA for multiple myeloma approved by US FDA in May, 2022

#### **■ 2022 Drug Product Approval Plan**

Туре	Product	Region	Indication	Brand Marketer
Generic Drug	Glatiramer Acetate	US	Multiple sclerosis	Teva
Generic Drug	Pemetrexed 2Na	US	Non-small cell lung cancer	Eli Lilly
Generic Drug	Clofarabine	US	Leukemia	Sanofi
Generic Drug	Bortezomib	US(√) EU(√)	Multiple myeloma	Takada



#### **China Market**

3 CFDI on-site inspections completed in Changshu site to facilitate China market growth

Inspection Date	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 Q4	Glaucoma	Prostaglandin drug products c. RMB 1 billion

Customer's clinic trial for new indication in progress

Changshu site expects more inspections in 2022



<sup>\*\*</sup> Customer summited to NMPA in Oct. 2021 for new indication - Thyroid cancer



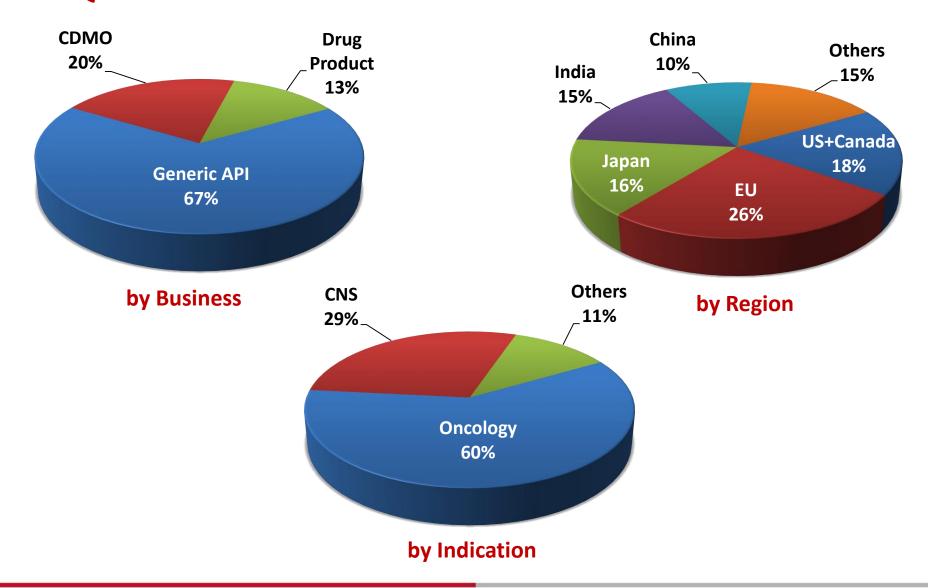
# **Financial Performance**



## **Consolidated Income Statement**

NTD Million except for EPS	1Q 2022		YoY	1Q 2021	
Revenue	738	100%	15%	641	100%
Gross Profit	298	40%	-18%	365	57%
<b>Operating Profit</b>	88	12%	-20%	110	17%
Net Profit before Tax	97	13%	-14%	113	18%
Net Profit after Tax	77	10%	-14%	90	14%
EPS (NTD)	0.10	-	-	0.11	-

# 1Q 2022 Sales Distribution





### Sales Distribution – YoY

By Business Unit: USD

	Generic API	СОМО	Drug Product
1Q 2022 Sales	17.7M	5.4M	3.3M
YoY	3.5%	26.2%	161.6%

#### **By Indication**

	Oncology	CNS	Others
1Q 2022 Sales	15.8M	7.6M	3.0M
YoY	-3.1%	63.7%	79.0%

#### **By Region**

	US & Canada	EU	Japan	India	China	Others
1Q 2022 Sales	4.8M	6.9M	4.2M	4.0M	2.6M	3.9M
YoY	-25.8%	-23.8%	64.3%	610.3%	30.9%	92.9%



## **Consolidated Balance Sheet**

NTD Million	Million 2022/3/31		2021/3/31	
Cash and Cash Equivalents	4,166	35%	4,040	33%
Accounts Receivable	449	4%	321	3%
Inventories	1,299	11%	1,423	12%
Property, Plant & Equipment	4,043	34%	4,164	34%
Other Current/Non-Current Assets	1,984	16%	2,230	18%
Total Assets	11,941	100%	12,178	100%
Financial Debt	17	0%	43	0%
Other Current Liabilities	611	5%	696	6%
Other Non-Current Liabilities	673	6%	628	5%
Total Liabilities	1,301	11%	1,367	11%
Total Shareholders' Equities	10,640	89%	10,811	89%



## **Consolidated Cash Flow Statement**

NTD million	1Q 2022	1Q 2021
From Operating Activities	135	117
From Investing Activities	(79)	(162)
From Financing Activities	16	31
Effect of foreign exchange rate changes	13	(1)
Net Change in Cash	85	(15)
Beginning Balance	4,081	4,055
Ending Balance	4,166	4,040





# **Q&A**





## **Brand Quality with Asian Advantages**

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