

ScinoPharm Investor Conference

January, 2023







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Company Overview

Business Updates

Financial Performance

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 34 referred and approved ANDAs/NDAs*
 - 894 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 1st Pre-Approval Inspection by US FDA in May, 2022; 2nd on-site inspection by US FDA in Oct., 2022

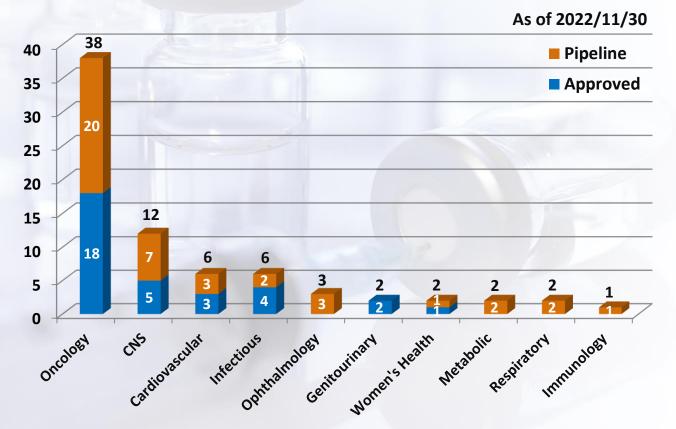
*As of 2022/11/30

Business Updates



Optimize Generic API Portfolio

Generic API Portfolio



Optimize Generic API Portfolio

■ 2022 Generic API Product Approval Plan

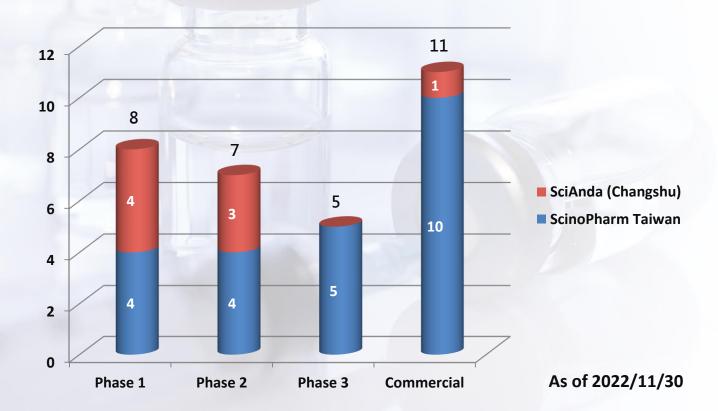
Туре	Product	Region	Indication	Brand Marketer
Generic API	Irinotecan HCl	CN(√)	Colorectal cancer	Pfizer
Generic API	Anastrozole	CN(√)	Breast cancer	ANI Pharmaceuticals
Generic API	Azilsartan	CN(√)	Hypertension	Arbor Pharmaceuticals
Generic API	Bimatoprost	CN	Glaucoma	Allergan
Generic API	Cladribine	CN	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

✓ : Approved

As of 2022/11/30

Expand CDMO Business

CDMO Business Status



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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 2022/11/30

Camcevi

- □ Launched in US in Apr., 2022
- MOH of Israel accepted MAA for substantial review in May, 2022
- □ Approved by EMA in May, 2022
- ☐ Submitted to TFDA for NDA in Jun., 2022
- ☐ Submitted to MHRA of UK for MAA in Jul., 2022
- □ Allowed to proceed with the phase 3 clinical trial in patients with CPP in Aug., 2022
- □ China NMPA accepted the phase 3 IND application for CPP for substantial review in Nov., 2022

Ganaxolone

■ Approved by US FDA in Mar., 2022 and launched in US in Jul., 2022

Advancing to Injectables

■ In-House Drug Product Submission Status

Completed registration batches

Submitted ANDA to US FDA US FDA's On-site Inspection US FDA Approved ANDA

Cartridge line Prefilled-syringe

Passed US FDA Pre-Approval Inspection in May, 2022

Vial line Liquid solution

Passed US FDA Pre-Approval Inspection in May, 2022

Vial line Lyophilized powder

US FDA's on-site inspection in Oct., 2022

Cartridge line
Cartridge product

Registration batches of 1st cartridge product were completed, preparing for ANDA submission

Advancing to Injectables

■ Collaborative Projects for Drug Product







In-house Prefilled syringe product Collaboration on 505(b)(2) for non-small cell lung cancer Collaboration on ANDA for non-small cell lung cancer

Collaboration on ANDA for multiple myeloma

Signed marketing agreement with partner Launched in US in Feb., 2022 by customer

Approved by US FDA in Aug., 2022 and by EMA in Dec., 2022

Approved by US FDA in May, 2022

Advancing to Injectables

■ 2022 Drug Product Approval Plan

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

✓ : Approved

As of 2022/11/30

* : Approved in Dec., 2022

China Market

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

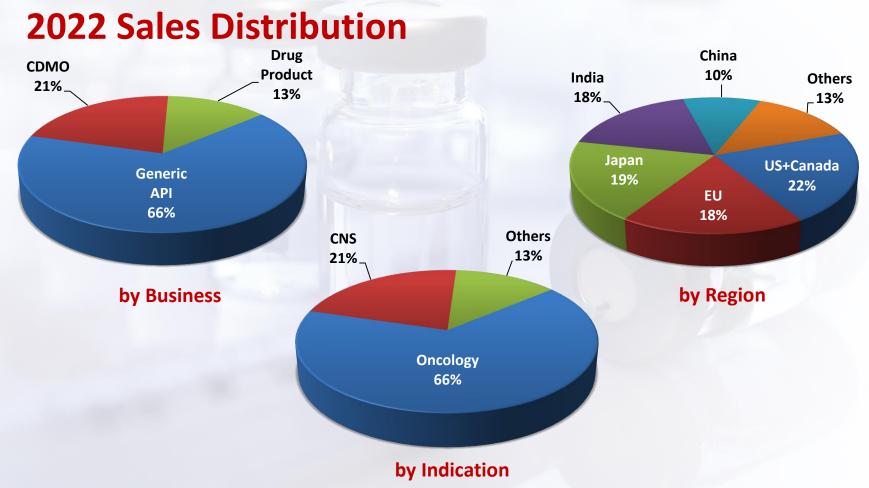
Inspection Date	Product	Approval	Indication	Market
2020.09	Sodium Phenylbutyrate*	2021.05	Urea cycle disorders	Orphan disease medicine
2021.02	Donafenib**	2021.06	Advanced liver cancer first-line treatment	2022 sales projected by research report : c. RMB 400 million
2021.06	Bimatoprost	Expected 2023 Q1	Glaucoma	Prostaglandin drug products c. RMB 1 billion
2022.11	Azilsartan	2022.09	Hypertension	c. RMB 100 million

^{*} Customer's clinical trial for new indication in progress

^{**} NDA for new indication - thyroid cancer approved by NMPA in Aug., 2022

Financial Performance





Sales Distribution - YoY

By Business Unit: USD/M

	Generic API	CDMO	Drug Product
FY 2022 Sales	71.7	23.3	14.4
YoY	-0.3%	58.5%	19.6%

By Indication

	Oncology	CNS	Others
FY 2022 Sales	71.9	23.5	14.0
YoY	5.1%	2.4%	90.8%

By Region

	US & Canada	EU	Japan	India	China	Others
FY 2022 Sales	23.7	19.8	20.9	19.3	11.0	14.7
YoY	-14.3%	-4.6%	-20.0%	135.0%	64.1%	60.0%

Consolidated Income Statement

NTD Million except for EPS	3Q 2022		YoY	3Q 2021	
Revenue	2,248	100%	10%	2,043	100%
Gross Profit	884	39%	-6%	945	46%
Operating Profit	280	12%	23%	227	11%
Net Profit before Tax	314	14%	34%	235	11%
Net Profit after Tax	252	11%	33%	190	9%
EPS (NTD)	0.32	-	-	0.24	-

Consolidated Balance Sheet

NTD Million	2022/09/30		2021/09/30	
Cash and Cash Equivalents	4,246	36%	3,732	33%
Accounts Receivable	339	3%	284	3%
Inventories	1,304	11%	1,373	12%
Property, Plant & Equipment	3,913	33%	4,066	36%
Other Current/Non-Current Assets	1,937	17%	1,994	16%
Total Assets	11,739	100%	11,449	100%
Financial Debt	49	0%	0	0%
Other Current Liabilities	629	5%	503	4%
Other Non-Current Liabilities	665	6%	624	6%
Total Liabilities	1,343	11%	1,127	10%
Total Shareholders' Equities	10,396	89%	10,322	90%

Consolidated Cash Flow Statement

NTD million	3Q 2022	3Q 2021
From Operating Activities	669	331
From Investing Activities	(172)	(238)
From Financing Activities	(341)	(411)
Effect of foreign exchange rate changes	9	(5)
Net Change in Cash	165	(323)
Beginning Balance	4,081	4,055
Ending Balance	4,246	3,732

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Q & A





Brand Quality with Asian Advantages

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