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# ScinoPharm

November 10, 2021



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# **Business Update**

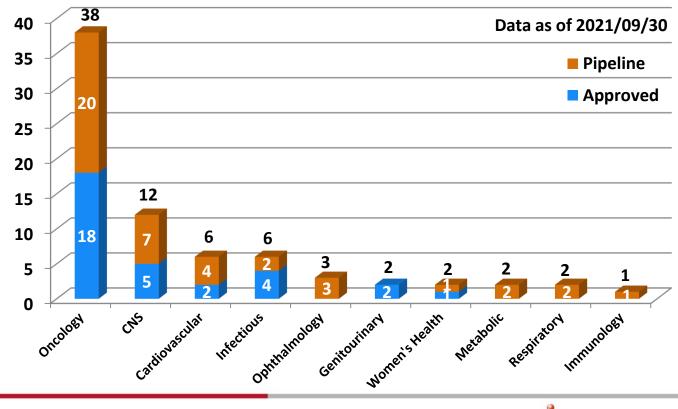


#### Optimize Generic API Portfolio

### Generic API Business Update

- Leverage Tainan/Changshu production advantage and strengthen sales/production coordination
- The impact of Covid-19 pandemic and dual control of energy consumption in China are still manageable

### Generic API Portfolio



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Optimize Generic API Portfolio

### 2021 Generic API Product Approval Plan

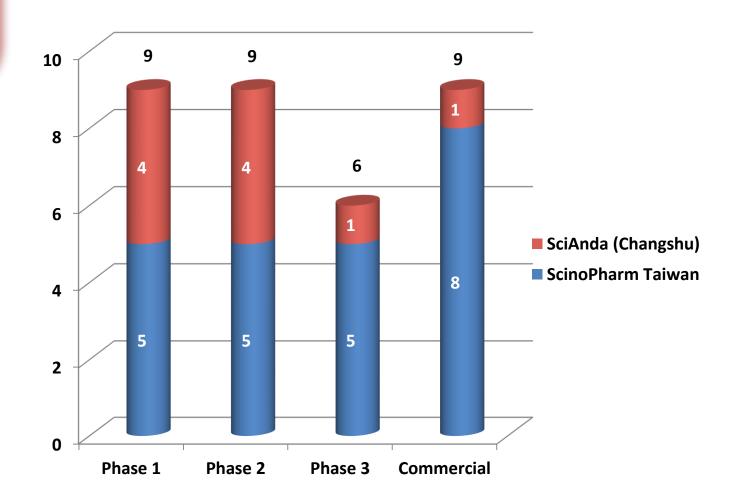
Туре	Product	Region	Indication	Brand Marketer
Generic API	Fondaparinux Sodium	CN(🗸)	Anti-thrombotic	Mylan
Generic API	Irinotecan HCI	CN	Colorectal cancer	Pfizer
Generic API	Anastrozole	CN	Breast cancer	ANI Pharmaceuticals
Generic API	Sodium Phenylbutyrate	CN(🗸)	Urea cycle disorders	Horizon Therapeutics
Generic API	Azilsartan	CN	Hypertension	Arbor Pharmaceuticals
Generic API	Letrozole	CN(🗸)	Breast cancer	Novartis
Generic API	Bimatoprost	CN	Glaucoma	Allergan
Generic API	Regadenoaon	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

Substitution : Collaborative project for drug product development Data as of 2021/09/30



#### Expand CDMO Business

### **CDMO Business**



Data as of 2021/09/30



#### Expand CDMO Business

### 2021 CDMO API Product Approval Plan

Туре	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	СРР

Data as of 2021/09/30

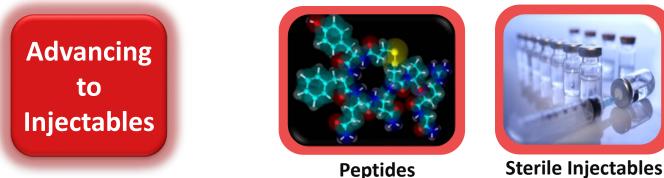
#### Donafenib:

- □ Approved and launched in China in June, 2021
  - (Indication: Advanced liver cancer)
- □ Summited to NMPA in Oct. 2021 (Indication: RAIR-DTC)

#### Camcevi:

- □ Approved by FDA in May, 2021; MAA review in progress
- □ Replied Canada Healthcare in Sep. 2021
- Eflornithine:
  - Submitted to FDA and EMA by customer









**Pen Injectors** 

- **Registration batches of Vial line (prefilled-syringed /pen device)** and Cartridge line (liquid solution/ 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 CRL in Sep. 2021
  - ANDA of 1<sup>st</sup> in-house liquid solution product was submitted to FDA in June, 2021 – FDA's review in progress
  - **Registration batches of 2<sup>nd</sup> prefilled-syringed product in progress**
  - Target to summit the ANDA of 1<sup>st</sup> in-house lyophilized powder product to FDA in year-end of 2021
- Completed the 1<sup>st</sup> TFDA on-site inspection in April, 2021 - Replied TFDA in Q3, 2021, and TFDA's review in progress



Actively Develop Japan, China and Emerging Markets

### Japan Market

- Completed the establishment of Japan branch in Q3, 2021 to cultivate Japan market
- 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

#### CFDI on-site inspection in Changshu site

Inspection	Product	Approval	Indication	Market
2020.09	Sodium Phenylbutyrate	2021.05	Urea cycle disorders	Urea cycle disorders
2021.02	Donafenib	2021.06	Advanced liver cancer first-line treatment	1 <sup>st</sup> year sales projected by research report : c. RMB 220 million
2021.06	Bimatoprost	Expected by 2021 year-end	Glaucoma	c. RMB 1 billion

- Clinic trial of customer's Sodium Phenylbutyrate for new indication in progress
- Customer's Donafenib summited to NMPA in Oct. 2021 for new indication RAIR-DTC





# **Financial Performance**

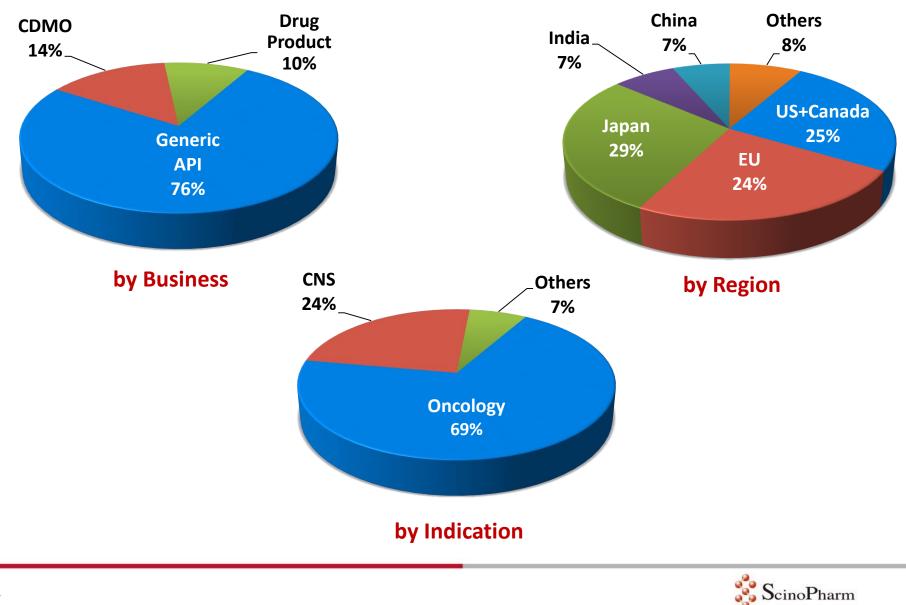


## **Consolidated Income Statement**

In NTD Million, except for EPS	3Q 2021 (Reviewed)		ΥοΥ	3Q 20 (Review	
Revenue	2,043	100%	-8%	2,209	100%
Gross Profit	945	46%	-11%	1,058	48%
<b>Operating Profit</b>	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	-



## **3Q 2021 Sales Distribution**



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# **Sales Distribution – YoY**

#### **By Business**

Unit: USD

	Generic API	CDMO	Drug Product
3Q 2021 Sales	55.2M	10.4M	7.3M
YoY	3.4%	-39.4%	105.3%

#### **By Indication**

	Oncology	CNS	Others
3Q 2021 Sales	50.6M	17.6M	4.7M
YoY	5.6%	-16.0%	-10.4%

#### **By Region**

	US & Canada	EU	Japan	India	China	Others
3Q 2021 Sales	18.4M	17.6M	20.8M	5.3M	4.8M	6.0M
ΥοΥ	27.1%	-42.1%	71.7%	-46.7%	125.7%	17.0%



## **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%
Total Assets	11,449	100%	12,000	100%
Financial Debt	0	0%	244	2%
Other Current Liabilities	503	4%	638	6%
Other Non-Current Liabilities	624	6%	633	5%
Total Liabilities	1,127	10%	1,515	13%
Total Shareholders' Equities	10,322	90%	10,485	87%



## **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





# Q&A





# Appendix 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\*
  - 875 active DMFs worldwide with 64 US DMFs\*
- 150+ contract projects with 9 approved/launched (7 NCEs) and 6 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

\* Data as of 2021/09/30





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

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