



# ScinoPharm Management Presentation

TWSE 1789

April 9, 2014



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# Overview of ScinoPharm

- An API + ANDA Company

Active Pharmaceutical Ingredients

Abbreviated New Drug Application

# Background

- Established in 1997 in Taiwan by founders from Syntex, listed on TWSE, current market cap ~ US\$ 2.0 billion
- Major shareholders include Uni-President Group, Government's Development Fund, Taiwan Sugar, etc.
- Facility & organization designed & built in Taiwan by experienced Syntex team, received multiple regulatory inspections from US FDA, Australia, EU, Japan, etc.
- Specializes in high potency (steroid, cytotoxic) & injectable APIs
- Expanding in China with a new plant in Changshu & sales/marketing base in Shanghai



ScinoPharm

# Business Overview

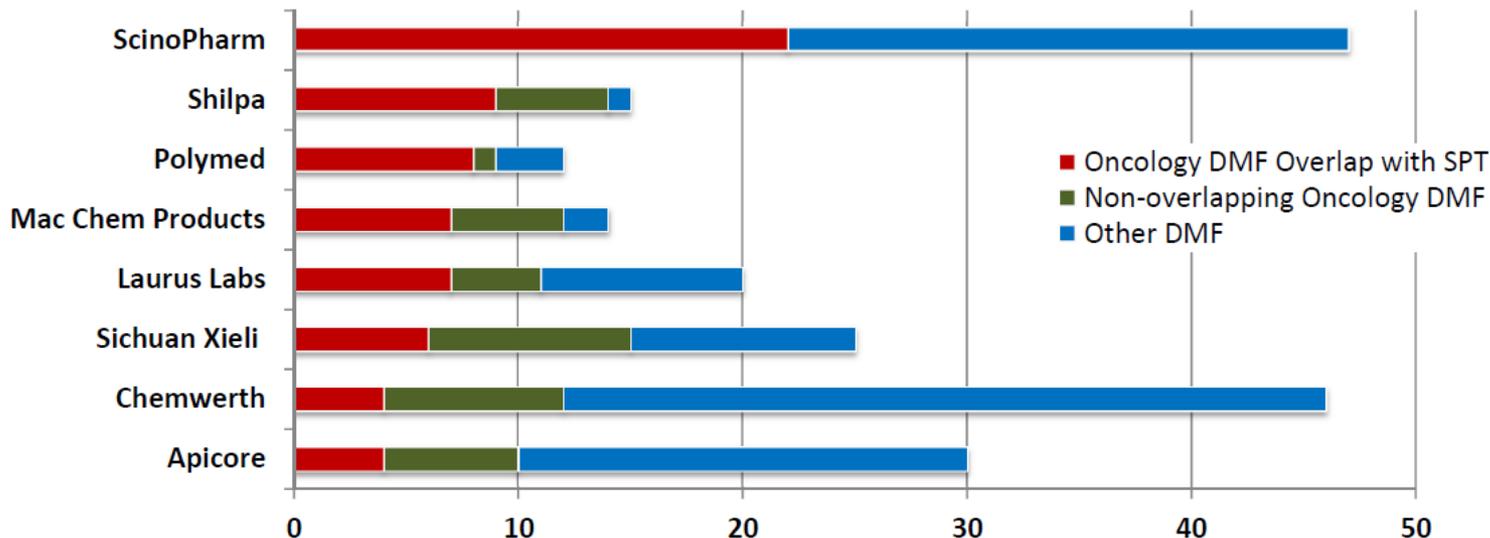
- Maintain dominant position in Specialty APIs for generic market. Strong customer base (320+) in US/EU/Japan, some through Indian generics. Aggressively developing Japan and China markets
- Developed ~70 generic APIs with 23 launched. Filed 47 DMFs in US (663 DMFs WW), leader in supplying oncology injectable APIs with 22 US DMFs
- 80+ NCE CRAMs projects, with 6 in phase III for NDA filing in 2-3 years & 5 projects already launched. The only company in Asia supplying APIs for multiple commercial NCEs



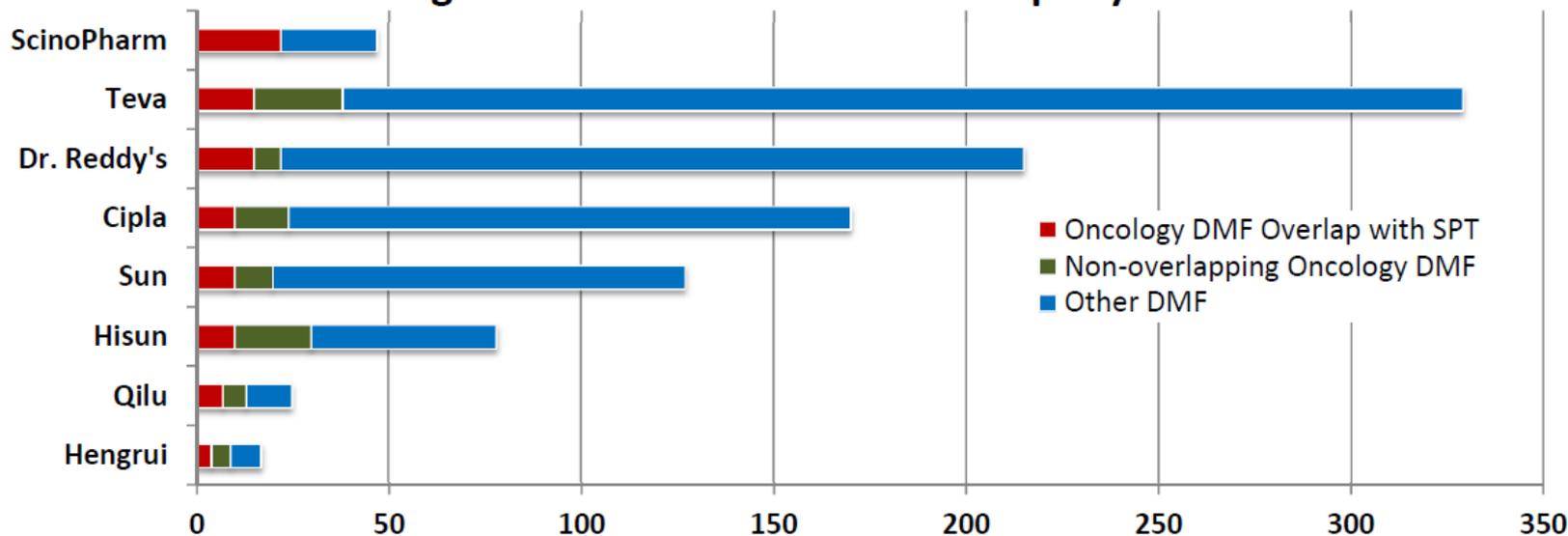
# ScinoPharm - Oncological API Leader

## Stand-Alone API Company

Source: FDA 2013Q4 DMF database



## Big Generic Pharmaceutical Company



# World Class Facilities

## Taiwan (SPT)

- 6.6 hectares of land, 330K sq. ft. facilities with  $>200M^3$  reactor volume
- 8 of 18 production lines equipped with high potency capabilities for cytotoxics or steroids
- US FDA approved & 200+ GMP audits by customers
- Provides full CRAMs for brand drugs
- Building an oncological injectable plant
- Global market

## China (SPC)

- 6.6 hectares of land with  $\sim 250M^3$  reactor volume
- 2 of 8 production lines equipped with high potency capabilities for cytotoxics
- CGMP designed facility for intermediates & high potency API
- Full scope capabilities in developing and manufacturing APIs from small to large scale for generic & CRAM markets
- Global market including China

### Common Strength

- Same sizable land area
- Complied with int'l GMP & EHS standards for global market
- Strong R&D capabilities
- Multi-functional plants, able to produce high potency APIs
- Small, mid, to large lines

### Differentiators

- Different reactor chamber volumes ( $200M^3$  in SPT vs.  $250M^3$  in SPC)
- SPC mainly for large volume
- SPT focusing on global export; SPC on China domestic market
- SPT with an injectable plant

Taiwan  
vs  
China  
Plant

# Financial & Operating Results

# Cumulative P&L - Consolidated

In NT\$ million, except for EPS	FY2013 (Audited)	FY2012 (Audited)	YoY
Net Sales	5,088	4,573	11%
Gross Profit	2,543	2,313	10%
<i>Gross margin</i>	<i>50%</i>	<i>51%</i>	
Operating Expenses	(1,145)	(1,053)	9%
Operating Income	1,398	1,260	11%
<i>Operating margin</i>	<i>28%</i>	<i>28%</i>	
Other Rev.(Exp.)	11	112	-90%
Net Income before Tax	1,409	1,372	3%
Net Income after Tax	1,273	1,171	9%
<i>Net margin after tax</i>	<i>25%</i>	<i>26%</i>	
EPS (after tax)	1.88	1.73	9%

# Balance Sheet- Consolidated

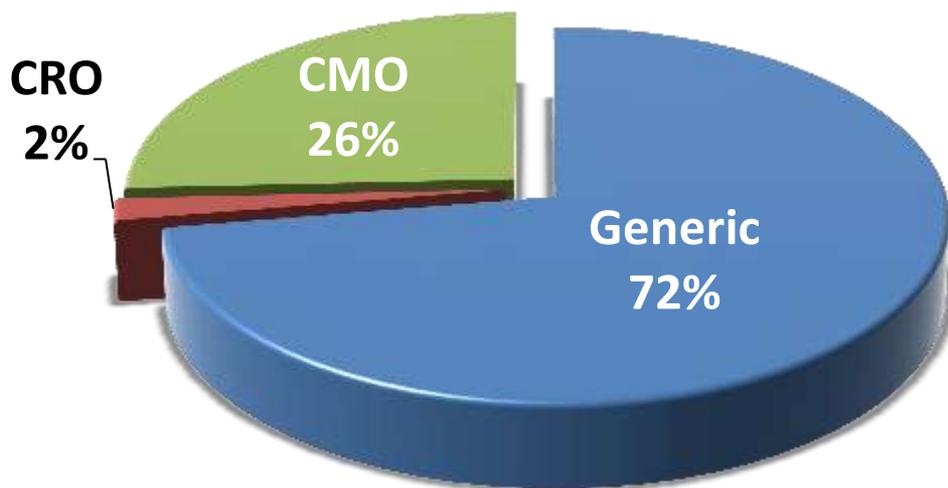
In NT\$ million	2013/12/31 (Audited)		2012/12/31 (Audited)	
Cash and Cash Equivalents	2,289	20%	3,035	29%
Accounts Receivable	971	8%	841	8%
Inventories	2,512	22%	1,870	18%
Long-Term Investments	258	2%	168	2%
Fixed Assets	4,214	37%	3,559	34%
Total Assets	11,484	100%	10,340	100%
Current Liabilities	1,775	15%	1,204	12%
L-T Liabilities and Others	66	1%	65	-%
Stockholders' Equities	9,643	84%	9,071	88%

# Cash Flows- Consolidated

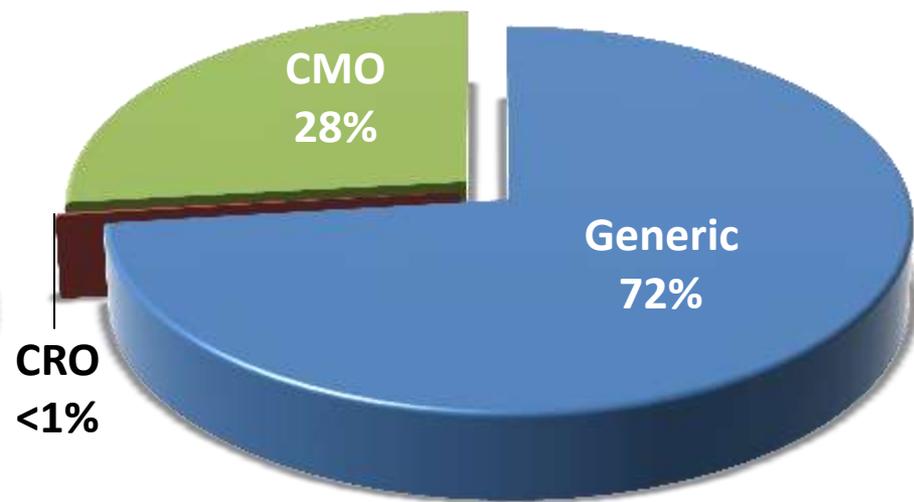
In NT\$ million	FY2013 (Audited)	FY2012 (Audited)
Cash and cash equivalents at beginning of period	3,035	3,294
Cash flows from operating activities	939	982
CAPEX	(1,226)	(873)
Long-term Investment	(107)	-
Short-term borrowings	426	264
Cash Dividends	(780)	(631)
Others	2	(1)
Cash and cash equivalents at end of period	2,289	3,035

# Sales by Business

**FY2012**

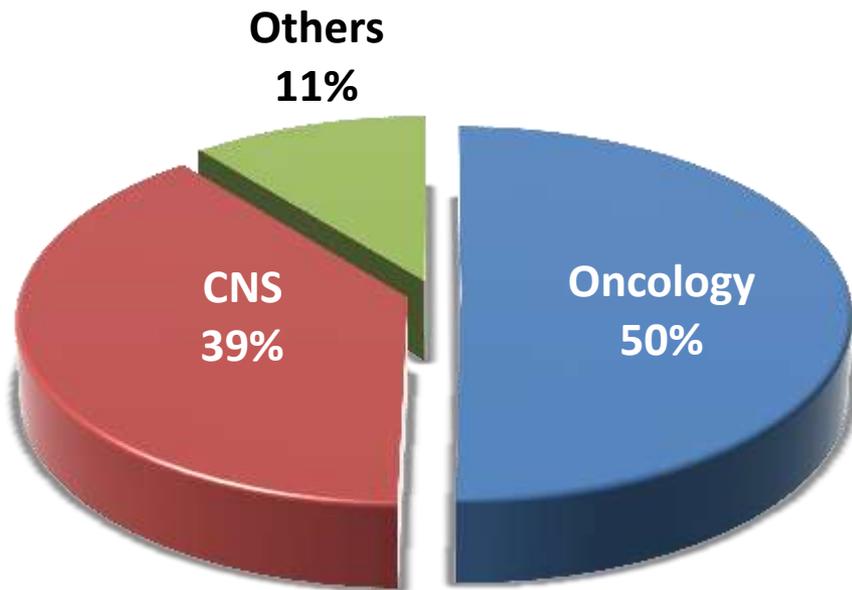


**FY2013**

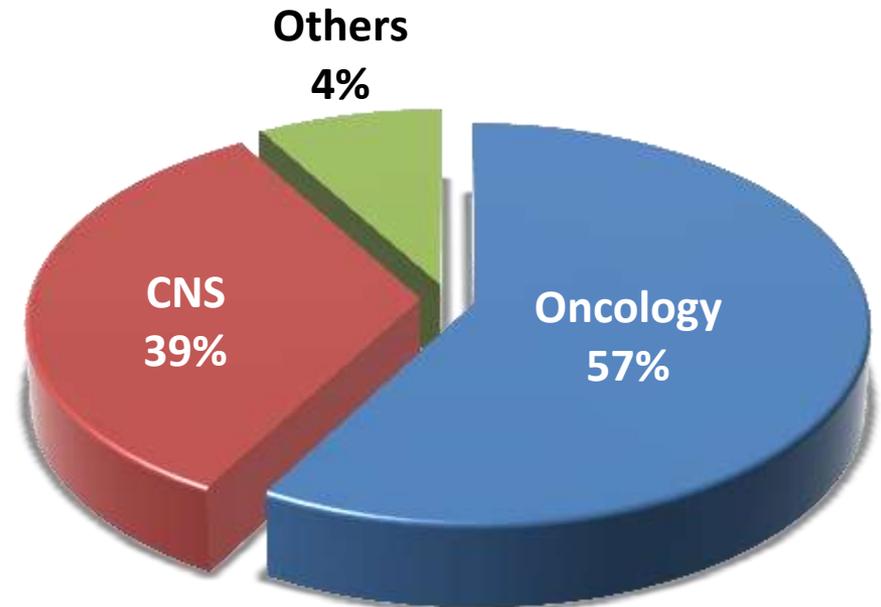


# Sales by Indications

**FY2012**

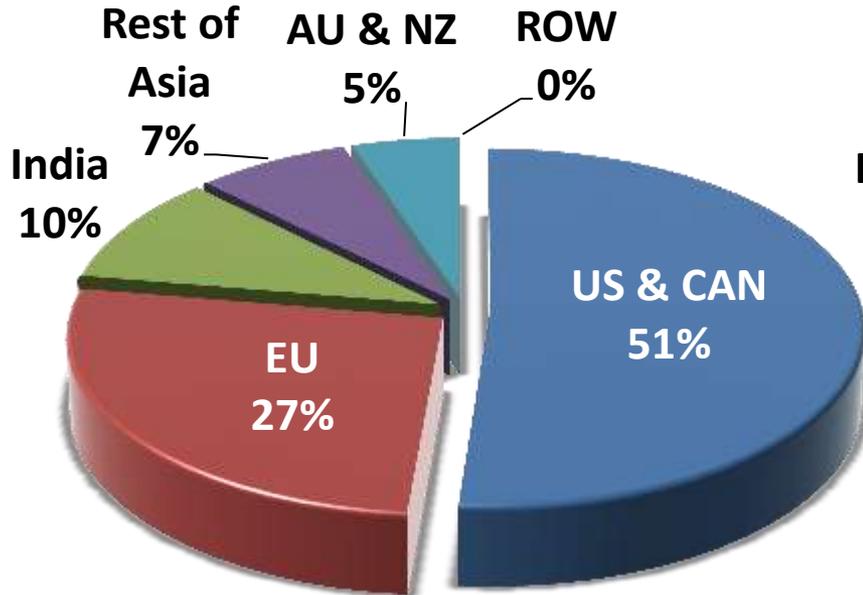


**FY2013**

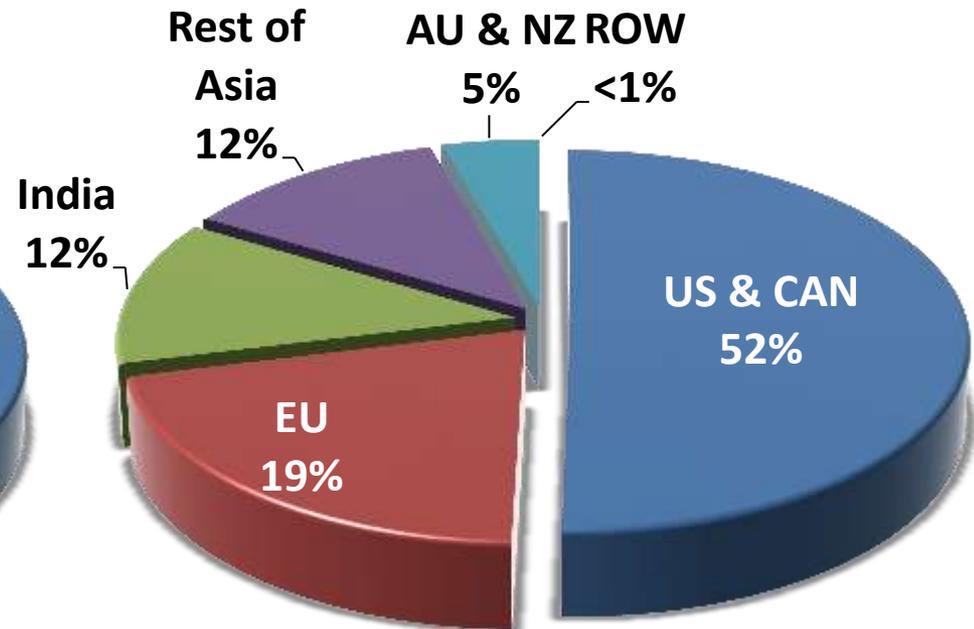


# Sales by Region

**FY2012**



**FY2013**



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# China Operations Update

# Key Progress for China Market

## ScinoPharm Changshu

- Obtained drug production permits for 4 APIs (3 for anti-cancer and 1 for anti-viral)
- Submitted 1 drug license application for an anti-cancer API

## ScinoPharm Taiwan

- Submitted drug import license application for 9 APIs (5 for anti-cancer, 2 for cardiovascular disease, 1 for Alzheimer's disease, and 1 for benign prostatic hyperplasia)

## Strategic Alliance

- Formulation development of Bortezomib began in June 2013; Stability batches expected to be completed in Feb. 2014
- Formulation development of Azacitidine to start in early 2014



# SPC passed CRAM customer audits

- ASLAN Pharmaceuticals and a multinational pharmaceutical company have been jointly developing an oncology compound
- ScinoPharm Changshu has undertaken the API CRAM Services for this project and successfully passed the GMP audit by this customer
- This targeted delivery drug is entering into clinical trial phase II, focused on solid tumor treatment, including prostate cancer and breast cancer
- Global patient population of these two cancers is currently ~3.5MM and 6MM, respectively, while the market value is expected to reach US\$6.5Bn by 2020 and US\$18.7Bn by 2022



# Summary of SPC's CRAMS projects

Product code	Customer	Indications	Type	Stage
CN02-M006	Lee's Pharma	Ovarian Cancer	API	Phase III
CN02-M002	Customer T	Gastric disease	API	Phase II
CN02-R006	Aslan JV	Prostate cancer, Breast cancer	API	Phase II
CN02-M005	Customer I	AIDS prevention	API	Phase II
CN02-M007	Customer Z	Liver cancer	API	Phase II
CN02-M001	Forest Lab	Depression	Intermediate	Commercial
CN02-G026	Vivus	Obesity	API	Commercial
CN02-G030	Customer S	Antinarcology	API	Commercial

**\* All above items are audited by CRAM customers,  
commercial sales of APIs need FDA approvals**



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# **Business Outlook**

# 2014 Product Launch Plan

API	Region	Indications	Brand Marketer	Regional Sales	WW Sales
Azacitidine	US	MDS, Anti-cancer	Celgene	US\$365MM*	US\$792 MM*
Dantrolene (injectable)	US	Malignant hyperthermia	JHP Pharmaceuticals	US\$22 MM*	US\$50 MM*
Decitabine	US	MDS, AML Anti-cancer	Eisai	US\$254 MM*	US\$278 MM*
Docetaxel trihydrate	JP	Anti-cancer	Sanofi Aventis	US\$180 MM** (Taxotere)	US\$1,570 MM*
Entecavir	TW	Hepatitis B virus	BMS	US\$67 MM***	US\$1,344 MM*
Riluzole (liquid)	EU	Amyotrophic lateral sclerosis	Sanofi Aventis	US\$56 MM*	US\$227 MM*
Zoledronic acid	JP	Osteoporosis	Novartis	US\$120 MM***	US\$1,755 MM*

Source: \* Newport/IMS Data (Jul2012-Jun2013)  
 \*\*Datamonitor \*\*\*In-house research



# Outlook

- Sustain Leadership in Oncological APIs

Continue to launch and develop oncological injectable APIs & others with high technological barriers including Peptides

- Establish Presences in China

Develop APIs and formulations to timely capture the generic business with strategic alliance and CRAMs from MNCs

- Japanese Market Penetration

Expand strategic partnerships with major pharma

- Vertical Integration – API+ANDA

Select difficult-to-make APIs to formulate dossiers and build an oncology injectable plant to provide value-added total solution to customers





## **Brand Quality with Asian Advantages**

[www.scinopharm.com](http://www.scinopharm.com)