



# ScinoPharm Management Presentation

TWSE 1789

November 12, 2013



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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\$ 2.1 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



# 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 45 DMFs in US (658 DMFs WW), leader in supplying oncology injectable APIs with 22 US DMFs
- 70+ NCE CRAMs projects, with 5 in phase III with NDA filing in 2-3 years & 5 projects already launched. The only company in Asia supplying APIs for multiple commercial NCEs



# World Class Facilities

## Taiwan (SPT)

- 6.6 hectares of land, 330K sq. ft. facilities with  $>200\text{M}^3$  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  $\sim 250\text{M}^3$  reactor volume
- 1<sup>st</sup> phase completed in Q1, 2012  
2<sup>nd</sup> phase completing in Q4, 2013
- 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	Differentiators
Taiwan vs China Plant	<ul style="list-style-type: none"> <li>■ Same sizable land area</li> <li>■ Complied with int'l GMP &amp; EHS standards for global market</li> <li>■ Strong R&amp;D capabilities</li> <li>■ Multi-functional plants, able to produce high potency APIs</li> <li>■ Small, mid, to large lines</li> </ul>	<ul style="list-style-type: none"> <li>■ Different reactor chamber volumes (<math>200\text{M}^3</math> in SPT vs. <math>250\text{M}^3</math> in SPC)</li> <li>■ SPC mainly for large volume</li> <li>■ SPT focusing on global export; SPC on China domestic market</li> <li>■ SPT with an injectable plant</li> </ul>

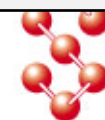


# Financial & Operating Results



# Cumulative P&L - Consolidated

In NT\$ million, except for EPS	1Q~3Q,'13 (Reviewed)	1Q~3Q,'12 (Reviewed)	YoY
Net Sales	3,764	3,168	19%
Gross Profit	1,909	1,601	19%
<i>Gross margin</i>	<i>51%</i>	<i>50%</i>	
Operating Expenses	(794)	(735)	8%
Operating Income	1,115	866	29%
<i>Operating margin</i>	<i>30%</i>	<i>27%</i>	
Other Rev.(Exp.)	20	16	25%
Net Income before Tax	1,135	882	29%
Net Income after Tax	1,009	748	35%
<i>Net margin after tax</i>	<i>27%</i>	<i>24%</i>	
EPS (after tax)	1.49	1.11	34%



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# Balance Sheet- Consolidated

In NT\$ million	2013/09/30 (Reviewed)		2012/09/30 (Reviewed)	
Cash and Cash Equivalents	2,734	25%	2,303	24%
Accounts Receivable	689	6%	959	10%
Inventories	2,359	21%	1,962	20%
Long-Term Investments	264	2%	168	2%
Fixed Assets	4,020	36%	3,265	34%
Total Assets	11,120	100%	9,571	100%
Current Liabilities	1,706	15%	869	9%
L-T Liabilities and Others	66	1%	64	1%
Stockholders' Equities	9,348	84%	8,638	90%

# Cash Flows- Consolidated

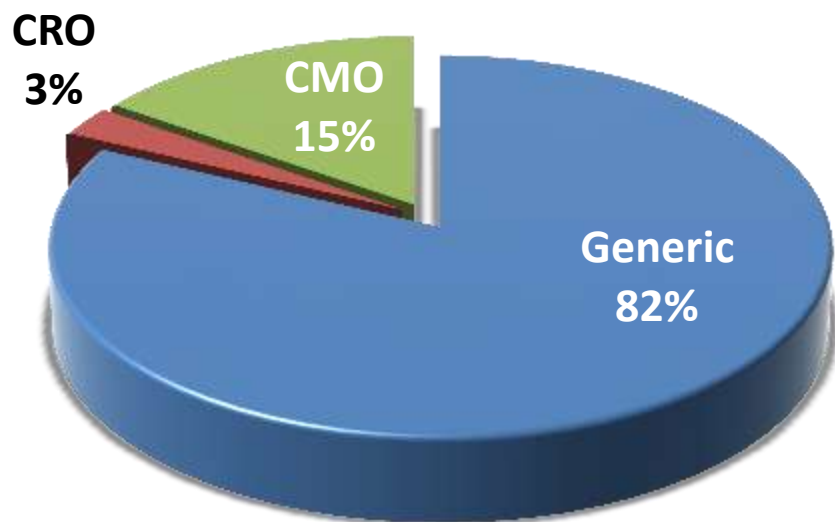
In NT\$ million	1Q~3Q 2013 (Reviewed)	1Q~3Q 2012 (Reviewed)
Cash and cash equivalents at beginning of period	3,035	3,294
Cash flows from operating activities	971	280
CAPEX	(866)	(619)
Long-term Investment	(107)	-
Short-term borrowings	479	-
Cash Dividends	(780)	(631)
Others	2	(21)
Cash and cash equivalents at end of period	2,734	2,303



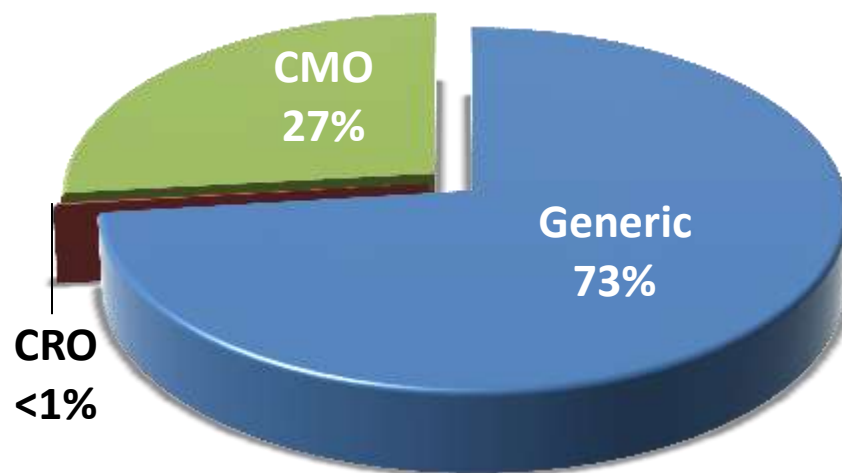
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# Sales by Business

1Q~3Q 2012

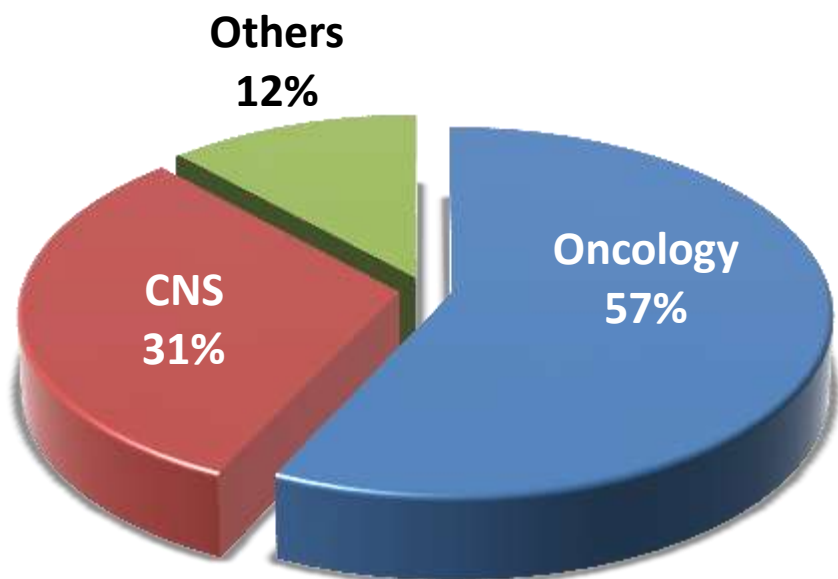


1Q~3Q 2013

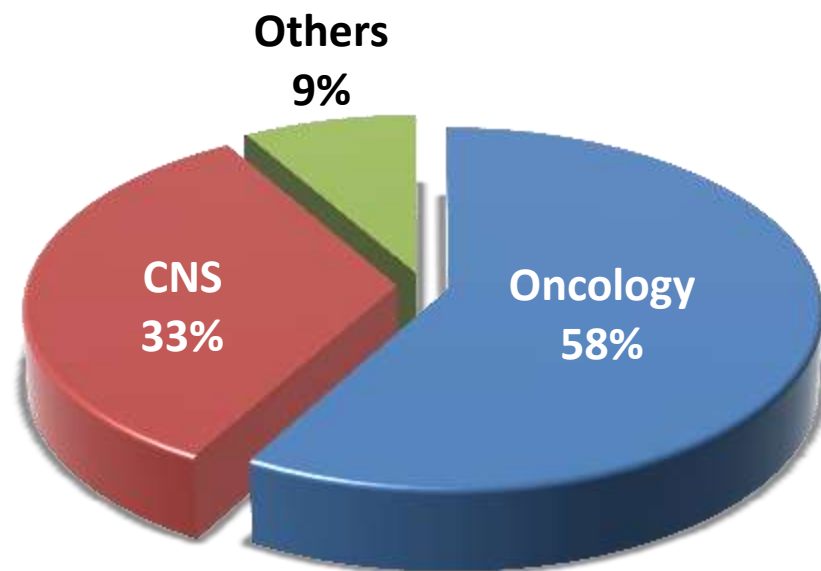


# Sales by Indications

**1Q~3Q 2012**

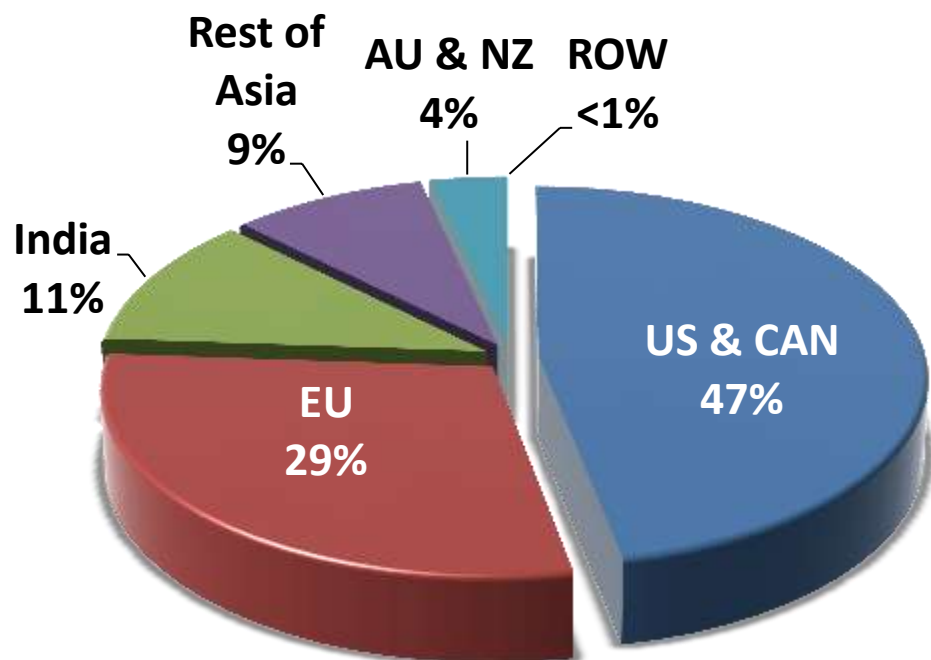


**1Q~3Q 2013**

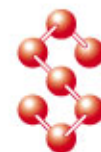
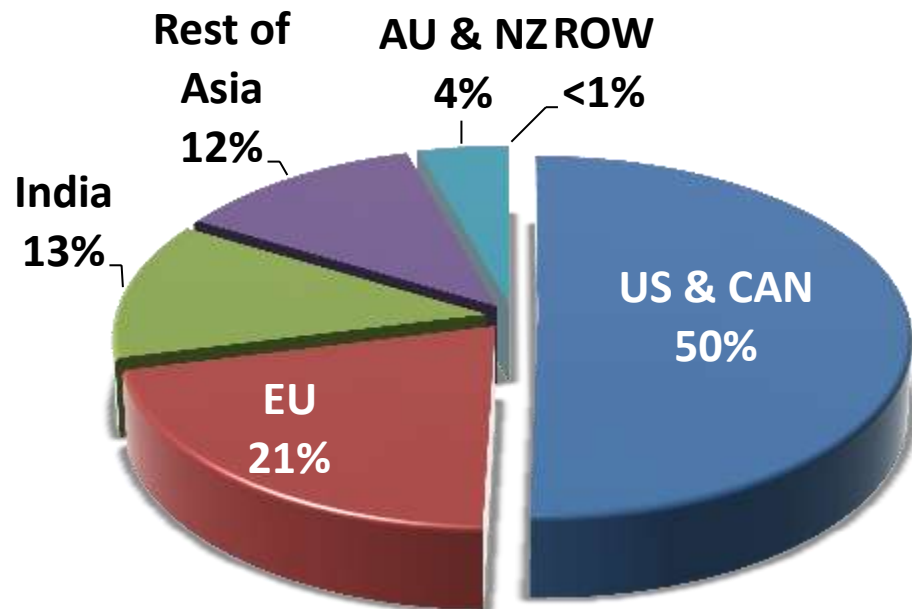


# Sales by Region

1Q~3Q 2012



1Q~3Q 2013



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# **Stable Long Term Partnership**



# Prolonged Business Building Process

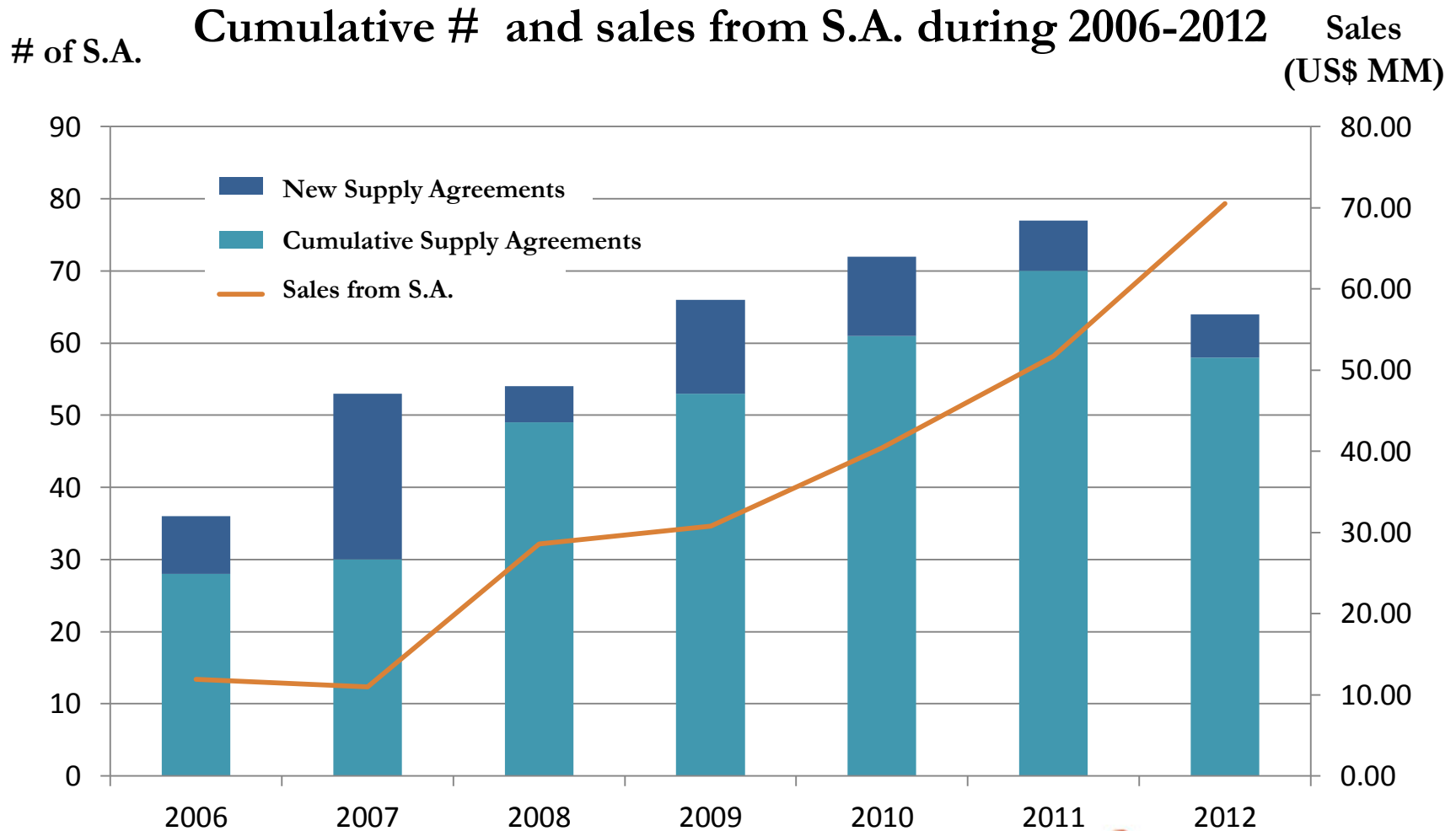
NCE Customers	Clinical Phase II	Clinical Phase III	NDA Filing	1 Yr before Launch	NCE Commercial Launch	Patent Protection	Patent Expiry
ScinoPharm	Develop API Process	Provide Clinical Material	Supply Agreement	Commercial Scale Production	Continuous Supply		
Generic Customers		API Source Identification		Formulation Development	ANDA Filing	1 Yr before Patent Expiry	Generic Launch
ScinoPharm		Product Selection & API Development		Registration Material Supply	Supply Agreement	Commercial Scale Production	Continuous Supply

# Stable Partnership with Customers

- ScinoPharm has many Supply Agreements (S.A.) with customers to secure mid- to long-term sales growth
- High entry barriers to API sourcing: US/EU markets apply the same stringent standards for API as for drug products. Changing the API supplier would be extremely difficult and costly, which creates high entry barriers
- Based on mutual trust and long term partnership, customers would enter into S.A. with ScinoPharm. These S.A. resulted in 45% of our 2012 sales, from 26 customers and 18 products
- Of the total S.A. in 2012, 80% were generic APIs and 20% CRAM APIs. 86% of the total S.A. have been launched and 14% are still in the pipeline



# Long Term Sales Increasing



\*including signed and in-process S.A.



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# **First Launch of Double A Strategy**

# First Formulation Product Launch

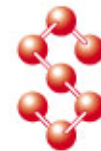
Under our Double A strategy, Entecavir is the 1<sup>st</sup> formulation extending the values from our specialty API to ANDA

- **API advantages:** ScinoPharm started to develop Entecavir 7-8 years before the patent expires. We successfully developed highly efficient process technology and obtained patents in many countries
- **Formulation co-development & profit sharing:** co-developed formulation with Genovate (4130.TT) per exclusive API supply from ScinoPharm, targeting Taiwan and China markets and sharing end profits. TFDA approval obtained and expect to be launched in Taiwan in late 2013



# Huge Potential for Hepatitis B Drugs

- Hepatitis B is a chronic inflammation of liver, which in the longer term may induce liver cirrhosis, and ultimately cause liver cancer.
- According to WHO statistics, 350 million people globally are diagnosed with hepatitis B, 75% of them in Asia. The treatment of chronic hepatitis B has been one of the most important medical issues in Chinese society. 3 million Taiwanese, 1/8 of total population, are diagnosed with hepatitis B.



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# ScinoPharm Successfully Developed a New Generation of Hepatitis B Drug

- Entecavir is a new generation, high potent oral drug for treating hepatitis B. This drug not only effectively reduces the amount of the hepatitis B virus to undetectable levels, but also causes no drug resistance.
- In 2012, Entecavir had a global market value of US\$ 1.3 billion. US market sales were about \$300 million, while ROW contributed \$1 billion, with Asia as the major market



# **Business Outlook**

# 2013 Product Launch Plan

API	Region	Indications	Brand Marketer	Regional Sales	WW Sales
Azacitidine	US	MDS, Anti-neoplastic	Pharmion	US\$331.3MM*	US\$729.7MM*
Decitabine	US	MDS, Anti-neoplastic	MGI Pharma	US\$238.0MM*	US\$249.1MM*
✓ Docetaxel Anhydrous	JP	Anti-neoplastic	Sanofi Aventis	US\$236.9MM**	US\$2,051MM*
✓ Modafinil	US	Antinarcoclepsy	Cephalon	US\$1,219MM*	US\$1,319MM*
✓ Paclitaxel	JP	Anti-neoplastic	Bristol Myers	US\$307.1MM**	US\$1,654MM*
✓ Riluzole	US	ALS	Sanofi Aventis	US\$55.0MM*	US\$237.1MM*
✓ Topiramate	US	Seizures	Customer	NDA	

Source: \* Newport/IMS Data  
 \*\*In-house research

✓ Launched



# 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)