



# ScinoPharm Management Presentation

TWSE 1789

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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\$1.5 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 (300+) in US/EU/Japan, some through Indian generics. Aggressively developing Japan and China markets
- Developed ~60 generic APIs with 21 launched. Filed 43 DMFs in US (631 DMFs WW), leader in supplying oncology injectable APIs with 20 US DMFs
- 70+ NCE CRAMs projects, with 5 in phase III with NDA filing in 2-3 years & 4 already launched. The only company in Asia supplying APIs for multiple commercial NCEs





# World Class Facilities

## Taiwan

- 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

- 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 to be completed in Q4, 2013
- CGMP designed facility for intermediates & high potency API
- Complete capabilities in API development, and manufacturing from small to large scale for generic & CRAMs markets
- Global market including China



# Financial & Operating Results



# Quarterly P&L - Consolidated

In NT\$ million, except for EPS	4Q,'12 (Audited)	3Q,'12 (Reviewed)	4Q,'11 (Audited)	QoQ	YoY
Net Sales	1,404	1,284	1,130	9%	24%
Gross Profit	713	640	597	11%	19%
<i>Gross margin</i>	<i>51%</i>	<i>50%</i>	<i>53%</i>		
Operating Expenses	(320)	(257)	(251)	24%	27%
Operating Income	393	383	346	3%	14%
<i>Operating margin</i>	<i>28%</i>	<i>30%</i>	<i>31%</i>		
Other Rev.(Exp.)	97	9	27	1039%	264%
Net Income before Tax	490	392	373	25%	31%
Net Income after Tax	422	325	320	30%	32%
<i>Net margin after tax</i>	<i>30%</i>	<i>25%</i>	<i>28%</i>		
EPS (after tax)	0.65	0.50	0.49	30%	33%



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# FY P&L - Consolidated

In NT\$ million, except for EPS	2012 (Audited)	2011 (Audited)	YoY
Net Sales	4,573	3,954	16%
Gross Profit	2,313	1,984	17%
<i>Gross margin</i>	<i>51%</i>	<i>50%</i>	
Operating Expenses	(1,054)	(851)	23%
Operating Income	1,259	1,133	11%
<i>Operating margin</i>	<i>28%</i>	<i>29%</i>	
Other Rev.(Exp.)	113	2	5,867%
Net Income before Tax	1,372	1,135	21%
Net Income after Tax	1,170	961	22%
<i>Net margin after tax</i>	<i>26%</i>	<i>24%</i>	
EPS (after tax)	1.80	1.51	19%



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# Balance Sheet- Consolidated

In NT\$ million	2012/12/31 (Audited)		2011/12/31 (Audited)	
Cash and Cash Equivalents	3,035	29%	3,294	35%
Accounts Receivable	841	8%	844	9%
Inventories	1,870	18%	1,465	15%
Long-Term Investments	150	1%	172	2%
Fixed Assets	3,790	37%	3,227	34%
Total Assets	10,313	100%	9,480	100%
Current Liabilities	1,187	12%	843	9%
L-T Liabilities and Others	30	0%	28	0%
Stockholders' Equities	9,096	88%	8,609	91%

# Cash Flows- Consolidated

In NT\$ million	2012 (Audited)	2011 (Audited)
Cash and cash equivalents at beginning of period	3,294	1,908
Cash flows from operating activities	1,021	1,294
CAPEX	(873)	(761)
Short-term borrowings	264	-
Cash dividends	(631)	(61)
Cash injection	-	957
Others	(40)	(43)
Cash and cash equivalents at end of period	3,035	3,294

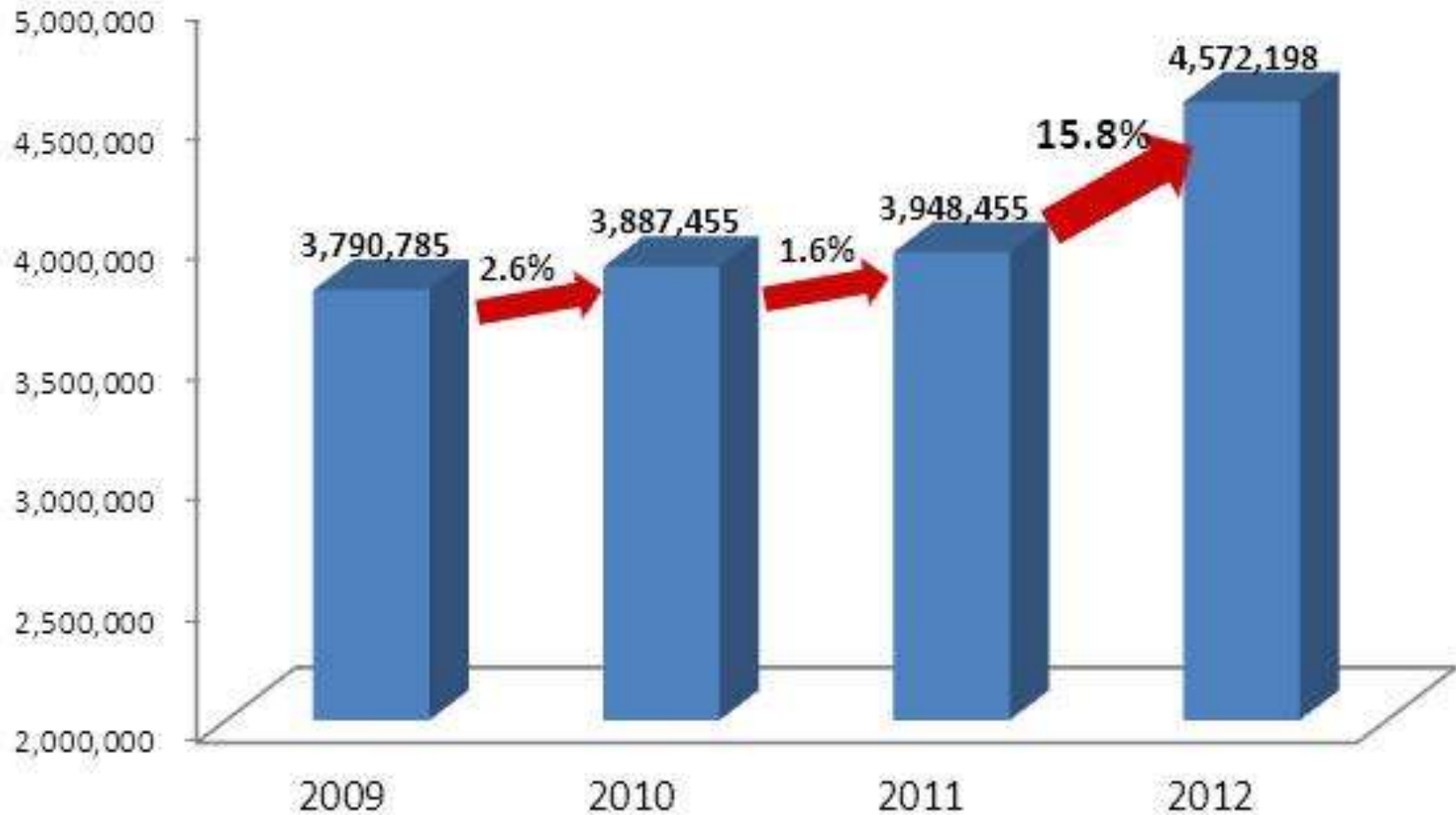


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# 2012 Sales Growth

(NT\$,000)

Sales Growth



# Production Optimization

- Efficiency Optimized

Production batches increased 16.5%, from 1,553 batches in 2011 to 1,810 in 2012

- Yield Rate Optimized

Yield rate improved from 91% in 2011 to 96% in 2012

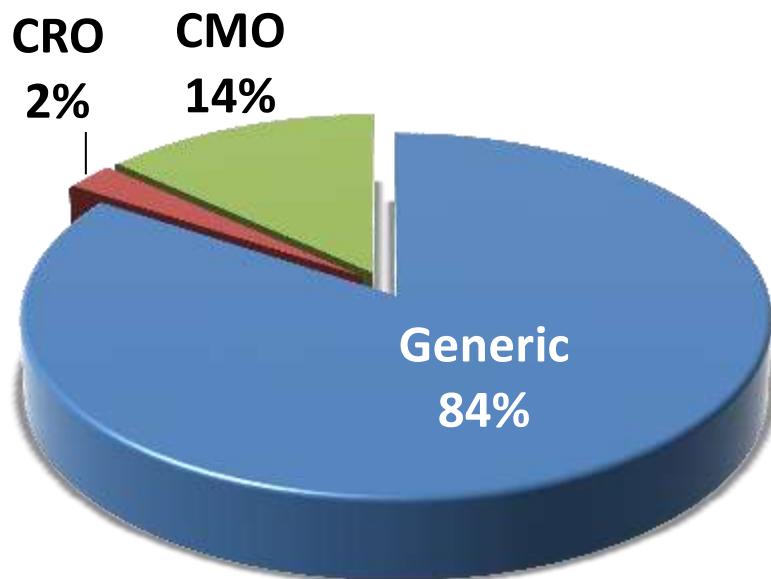
- Outsourcing

Outsourcing's contribution was equivalent to 1.5 production lines

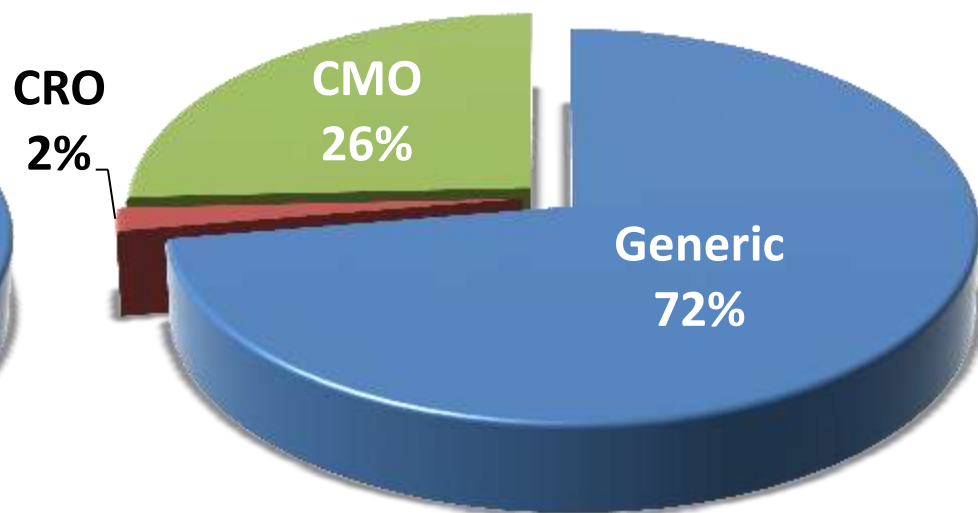


# Sales by Business

**2011**

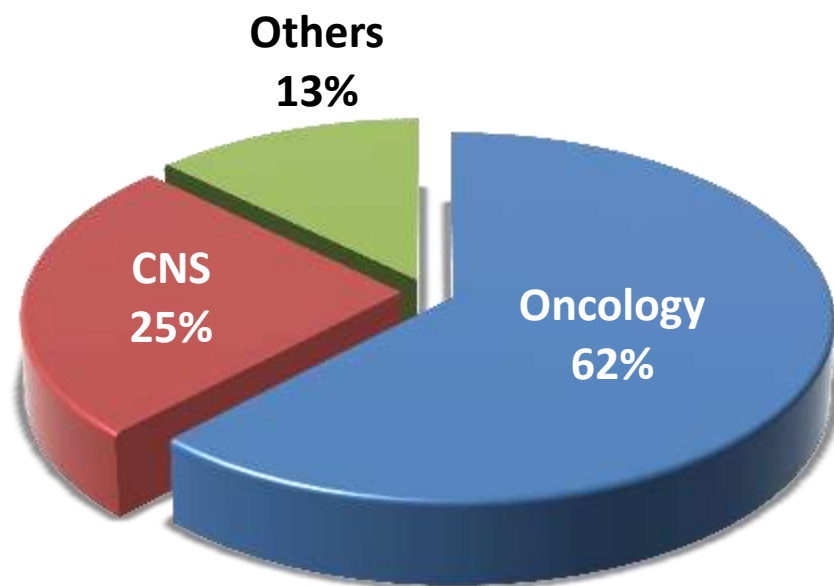


**2012**

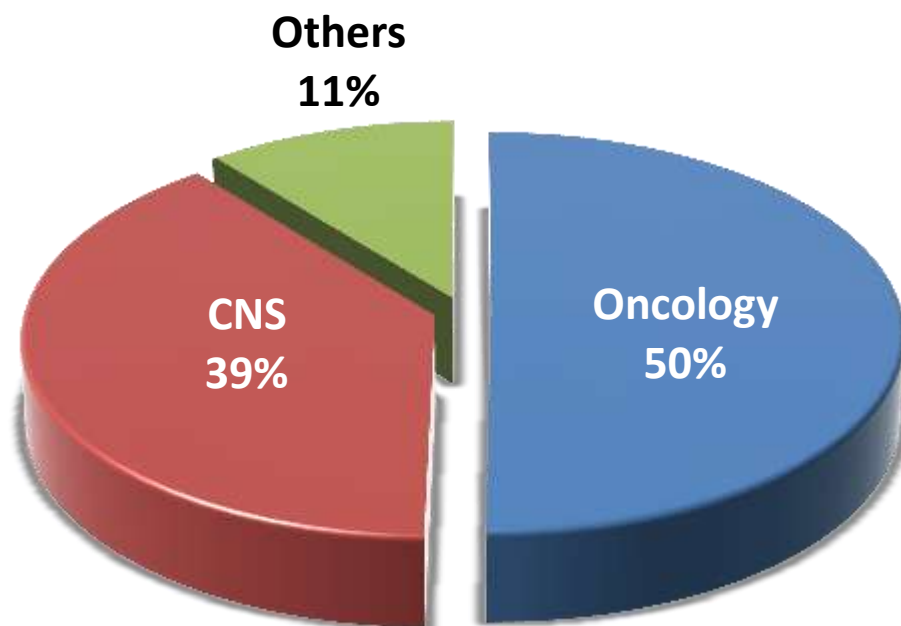


# Sales by Indications

**2011**



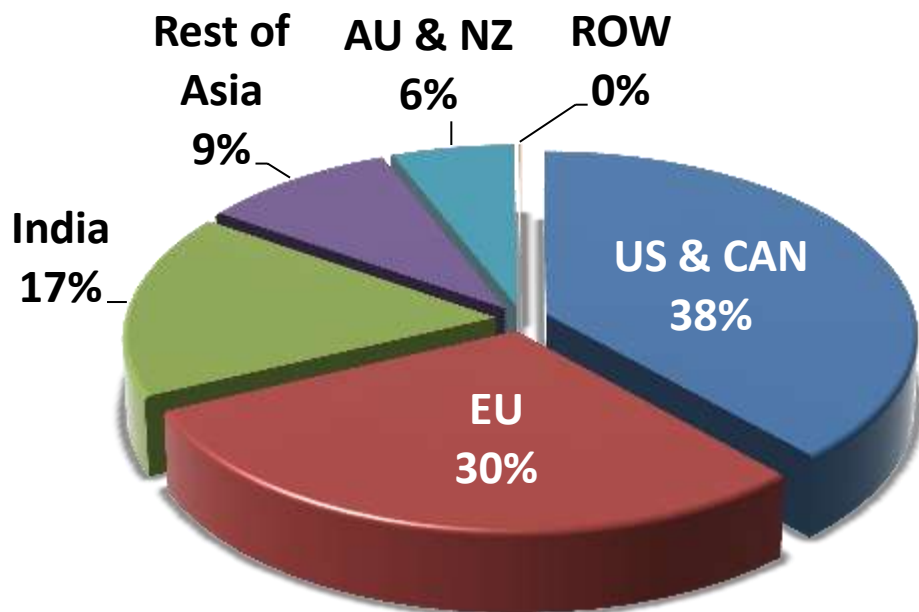
**2012**



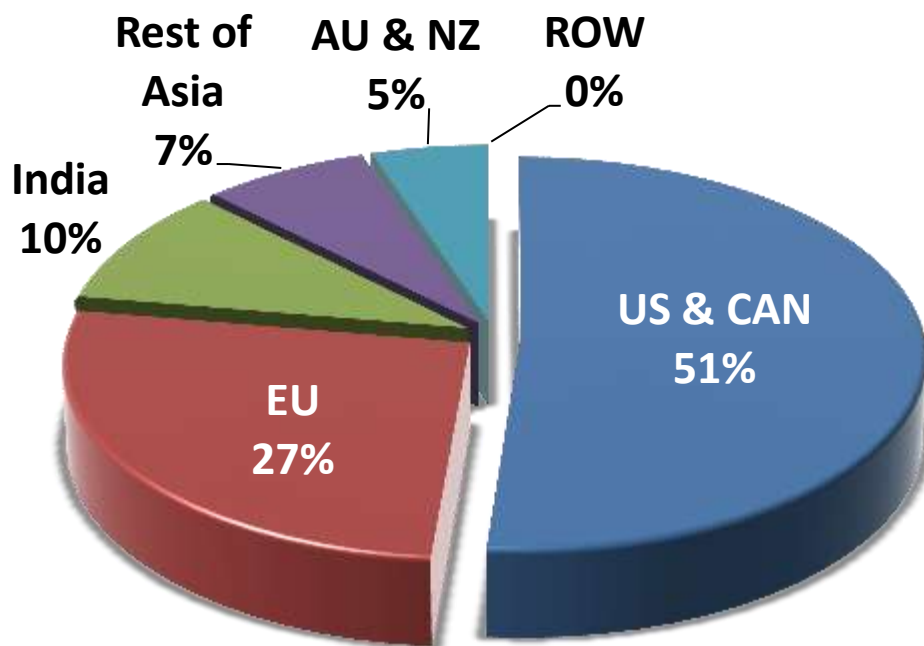
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# Sales by Region

**2011**



**2012**



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# **ScinoPharm's Opportunities and Strategies**

# Opportunities & Strategies

- Sustaining World Leadership of Oncological APIs
- Japan Market Development
  - Meeting Oncological API Demand
- China Angles
  - Supply Chain Management
  - Generic Market Demand – Oncological, Antiviral, Diabetes
  - CMO for MNCs
- Double A Strategy “API + ANDA”
  - Focusing on Oncological Injectables

# World Leader of Oncological APIs

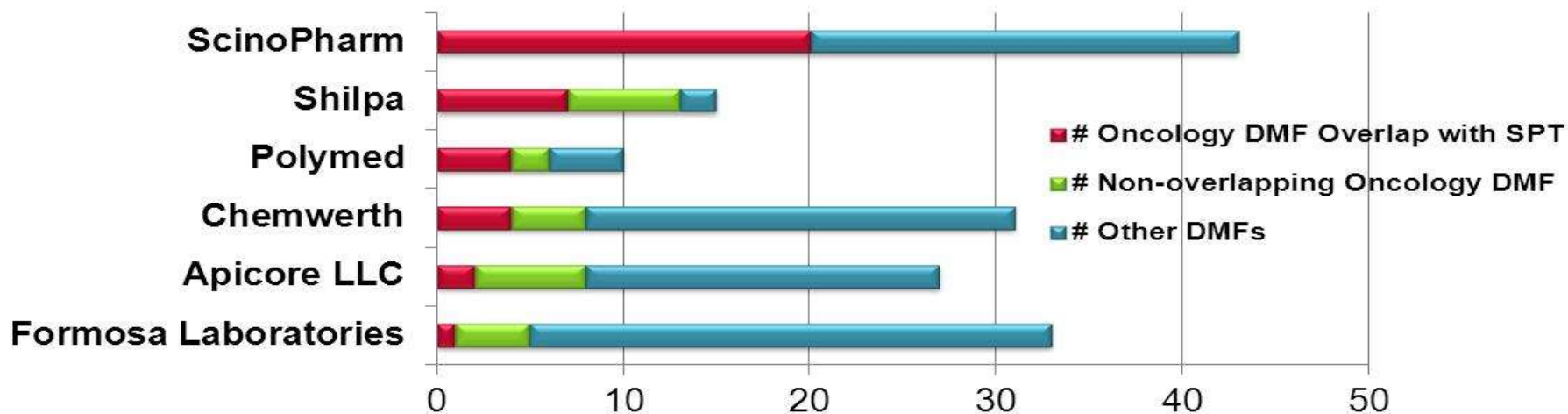
- 25 oncological APIs in the portfolio with 10 launched
- Continue to add 2-4 new oncological APIs each year in research pipeline
- Market research/new product selection parallel with key customers including Teva, Sandoz, Actavis, Hospira, etc.
- Major market penetrations of key products
  - Docetaxel 53%, Irinotecan 40%, Paclitaxel 20%



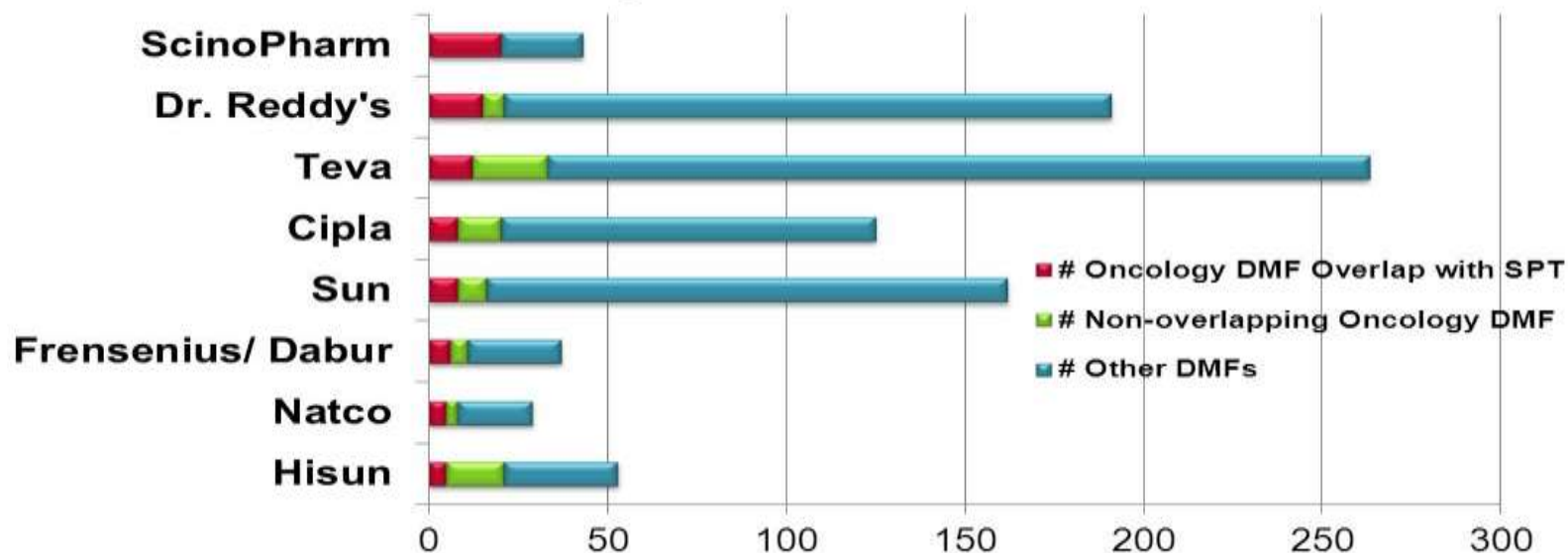


# ScinoPharm - Oncological API Leader

## Stand-Alone API Companies

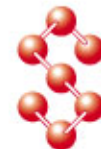


## Large Generic Pharmas



# Japan API Market

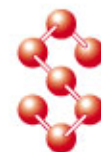
- Second (to US) largest market with significant growth potential
- Government sets goal to increase generic penetration from 19% to 30% by 2012 including urging brand companies to launch generics
- Generic APIs depends on imports mostly, especially for oncological injectables
- ScinoPharm working with top customers, so far launched 6 generic APIs



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# China Angles - Supply Chain

- Control sourcing of key intermediates for Taiwan Plant to free up more API capacity for existing demand in US, EU and Japan
- Site transfer of larger volume APIs from Taiwan for cost competitiveness
- Development and supply of new larger volume APIs for generics and NCEs
- Provide back up supply capabilities for oncological APIs



# China Angles - API Market

- Government's 12<sup>th</sup> five-year plan sets a goal for pharma to grow at a CAGR of 20%
- Require 100% compliance of the latest GMP
- Encourage companies to apply for int'l ANDAs which require world class APIs
- Generic oncological products dominated by 3 players with in-house APIs. Huge demand in merchant market for oncological, antiviral & diabetes APIs
- Via import from Taiwan and local production in Changshu, ScinoPharm intends to timely capture the oncological API business



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# China Angles - CMO for MNCs

- Strong outsourcing needs from multinationals for development & manufacturing, for speed and cost
- Lack of qualified suppliers meeting MNC's Technical, Quality, GMP, and EHS standards
- None with experience in supplying multiple NCEs to US & EU on exclusive basis
- ScinoPharm has been approached by several big pharmas for opportunities to support their development from phase II/III to commercial API supplies



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# Double A Strategy - API + ANDA

- **Drug Product Supply for Difficult APIs**
  - Difficult to Make APIs
  - Some Oncological APIs & All New Peptides
  - Injectable Drug Products – In-house facility being built
- **Certain APIs will be sold only via Drug Products**
- **Maintain “B to B” Business Model**
- **Strategic Alliance – Worldwide Market**
  - Co-Development
  - Exclusive Supply



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# **New Drug Development - via JV investment**

# Investment Summary

## ■ JV partner:

### Foresee Pharmaceuticals, Inc.

- Founded in 2004 by a group of Taiwanese American experts, owning patents & know-hows in “controlled release drug delivery system” for small molecule, peptide, protein new drugs
- Current product portfolio under development include injectables for prostate cancer, Acromegaly, diabetic retinopathy (DR), in the preclinical phase

# Investment Summary

## ■ JV structure

- ScinoPharm will be the exclusive supplier of the peptide APIs for the JV as well as investing **US\$3.6MM** in the JV. Foresee will transfer all related product patents & know-hows as well as investing cash into the JV. ScinoPharm will **obtain 15% shareholding and a board seat.**

## ■ JV product

- Injectable for Leuprolide for prostate cancer, which has a WW demand of US\$2.6 billion.
- Will file an NDA under the provisions of 505(b)(2). Entering Phase III in 2013, launch in US ~4 years later. Will pursue WW approvals.



# Prostate Cancer Market

- Prostate cancer is one of the most common cancers among men and it's the 2<sup>nd</sup> most deadliest cancer among American males
- More than 2 million American males are diagnosed of prostate cancer and the population is growing at more than 240,000 patients per year
- 2011 global market for treatment of prostate cancer using Leuprolide is as follows:

LHRH Product	Vendor	2011 Annual Sales (\$Million)			
		WW	US/Canada	EU	JP
Leuprolide (Lupron)	Abbott/Tekeda	\$ 2,330	\$ 810	~\$662	\$ 858
Leuprolide (Eligard)	Sanofi/Astellas	\$ 330	\$ 155	\$ 175	
	Total	\$ 2,660	\$ 965	\$ 837	\$ 858

# Strategic Values of JV to ScinoPharm

- Establish and accumulate experiences in New Drug formulation, to support long-term growth
- Secured the rights of providing Leuprolide API and contract injectable formulation services for future products, realizing the “Double A” strategy
- Enjoy the possible investment return from the great potentials of the product after launch

# **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, Trihydrate	JP	Anti-neoplastic	Sanofi Aventis	US\$236.9NM**	US\$2,051MM*
Modafinil	US	Antinarcoclepsy	Cephalon	US\$1,219MM*	US\$1,319M*
Paclitaxel	JP	Anti-neoplastic	Bristol Myers	US\$307.1MM**	US\$1,654M*
Riluzole	US	ALS	Sanofi Aventis	US\$55.0MM*	US\$237.1MM*
Topiramate	US	Seizures	Customer	NDA ( FDA tentative approval)	

Source: \* Newport/IMS Data

\*\*In-house research



# Outlook

- Sustain Leadership in Oncological APIs

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

- Japanese Market Penetration

Expand strategic partnerships with major pharma

- Establish Presences in China

Develop API business to timely capture the generic business and CMO by MNCs

- Vertical Integration – Double A Strategy

Select difficult-to-make APIs to formulate dossiers for value added one-stop-shop services to customers. Build an oncology injectable formulation plant





## Brand Quality with Asian Advantages

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