





#### **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\$1.8 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 ~60 generic APIs with 22 launched. Filed 44 DMFs in US (647 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. <u>The</u> <u>only company in Asia supplying APIs for multiple</u> <u>commercial NCEs</u>



### **World Class Facilities**

#### Taiwan (SPT)

- 6.6 hectares of land, 330K sq. ft. facilities with >200M<sup>3</sup> 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 ~250M<sup>3</sup> 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
- 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> <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> <li>Different reactor chamber volumes (200M<sup>3</sup> in SPT vs. 250M<sup>3</sup> 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

# Quarterly P&L - Consolidated

In NT\$ million, except for EPS	2Q,'13 (Reviewed)	1Q,'13 (Reviewed)	2Q,'12 (Reviewed)	QoQ	YoY
Net Sales	1,339	1,186	913	13%	47%
Gross Profit	724	655	437	11%	66%
Gross margin	54%	55%	48%		
Operating Expenses	(267)	(267)	(238)	0%	12%
Operating Income	457	388	199	18%	130%
Operating margin	<b>34%</b>	33%	22%		
Other Rev.(Exp.)	11	19	1	-42%	1000%
Net Income before Tax	468	407	200	15%	134%
Net Income after Tax	406	350	176	16%	131%
Net margin after tax	<b>30%</b>	30%	19%		
EPS (after tax)	0.62	0.54	0.27	15%	130%
				Scino	Pharm

# Half Year P&L - Consolidated

	(Reviewed)	(Reviewed)	YoY
Net Sales	2,524	1,884	34%
Gross Profit	1,379	961	43%
Gross margin	55%	51%	
Operating Expenses	(534)	(478)	12%
Operating Income	845	483	75%
Operating margin	33%	26%	
Other Rev.(Exp.)	30	7	329%
Net Income before Tax	875	490	<b>79%</b>
Net Income after Tax	756	423	<b>79%</b>
Net margin after tax	30%	22%	
EPS (after tax)	1.16	0.65	78%

# **Balance Sheet- Consolidated**

In NT\$ million	2013/6 (Review		2012/6/30 (Reviewed)		
Cash and Cash Equivalents	3,379	29%	2,972	30%	
Accounts Receivable	870	7%	732	7%	
Inventories	2,288	20%	2,022	21%	
Long-Term Investments	273	2%	168	2%	
Fixed Assets	3,897	33%	3,080	31%	
Total Assets	11,702	100%	9,849	100%	
Current Liabilities	2,527	22%	1,444	15%	
L-T Liabilities and Others	66	-%	64	-%	
Stockholders' Equities	9,109	78%	8,341	85%	



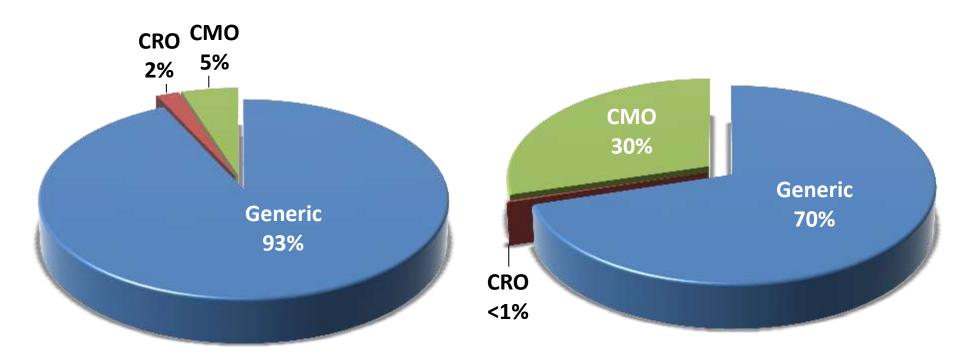
### **Cash Flows- Consolidated**

In NT\$ million	1H 2013 (Reviewed)	1H 2012 (Reviewed)
Cash and cash equivalents at beginning of period	3,035	3,294
Cash flows from operating activities	456	61
CAPEX	(506)	(378)
Long-term Investment	(107)	-
Short-term borrowings	491	-
Others	10	(5)
Cash and cash equivalents at end of period	3,379	2,972



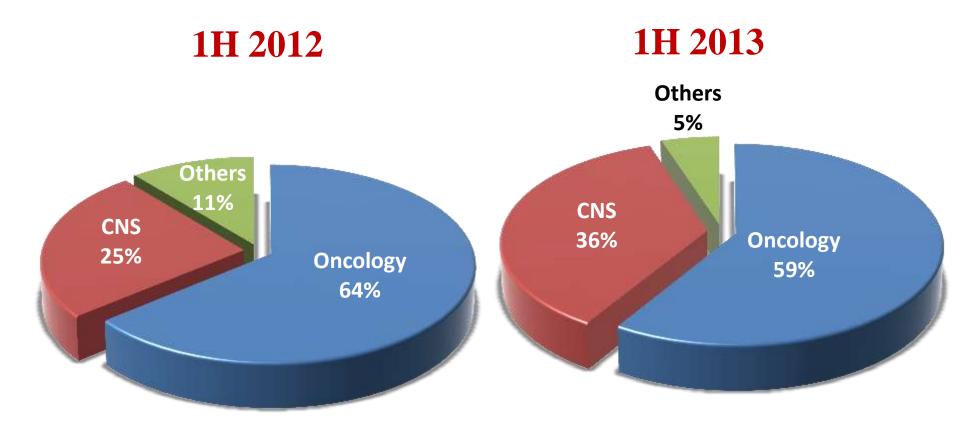
# Sales by Business

#### 1H 2012 1H 2013





# **Sales by Indications**

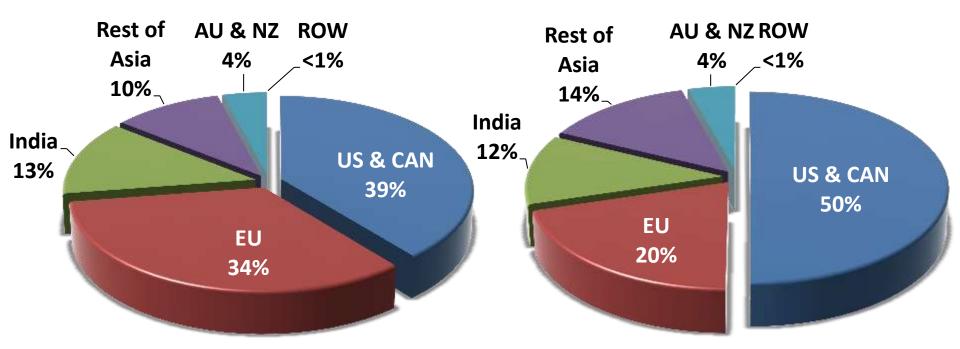




# Sales by Region

1H 2012

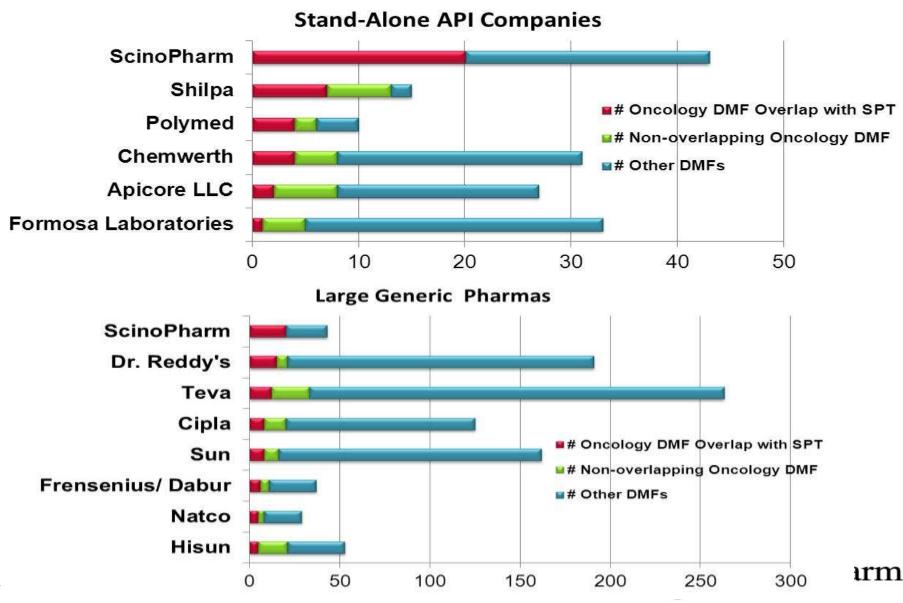
1H 2013





# **Oncology Market Trend**

### ScinoPharm - Oncological API Leader



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# Key Facts about Oncology Market

- Cancer is the leading cause of death, accounting for 7.6 million deaths worldwide (around 13% of all deaths) in 2008
- Deaths from cancer worldwide are projected to keep rising to over 13.1 million in 2030
- The global oncology market reached US\$62.2 billion in 2011 (CAGR: 5.5%), driven by the growing pharmerging markets
- The oncology market will continue to grow to \$75-80 billion by 2015, due to targeted therapeutics, earlier detection, longer treatment duration, and extended indications



# **Market Value by Therapeutics**

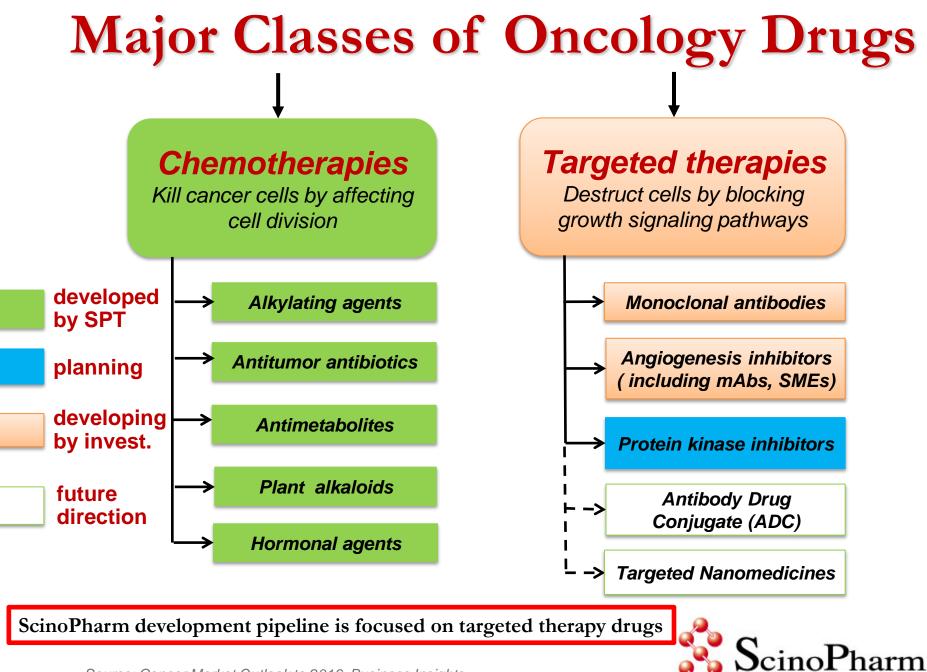
#### Oncology drug market value to reach \$75-80bn in 2015

#### **Leading Therapy Classes in 2015**

Oncology	\$75-	80Bn 5-8%
Antidiabetics	\$43-48Bn	4-7%
Respiratory	\$41-46Bn	2-5%
Lipid regulators	\$29-34Bn	-2 to -5%
Angiotensin inhibitors	\$28-33Bn	1-4%
Autoimmune	\$27-32Bn	6-9%
HIV antivirals	\$20-24Bn	5-8%
Antipsychotics	\$18-22Bn	-3 to -6%
Platelet aggregation inhibitors	\$18-22Bn	4-7%
Anti-ulcerants	\$18-22Bn	-5 to -8%
Antidepressants	\$13-16Bn	-5 to -8%
Anti-epileptics	\$13-16Bn	1-4%
Multiple sclerosis	\$12-15Bn	5-8%
Osteoporosis	\$11-13Bn	8-11%
Narcotic analgesics	\$10-12Bn	0 to -3%
ttention Deficit Hyperactivity Disorder	\$9-11Bn	4-7%
Erythropoeisis stimulating agents	\$9-11Bn	0 to -3%
Alzheimer's	\$9-11Bn	1-4%
Antivirals excl. HIV	📕 \$8-10Bn	1-4%
Glaucoma	\$5-6Bn	0 to -3%
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Source: The Global Use of Medicines: Outlook Through 2016, IMS, Jul 2012



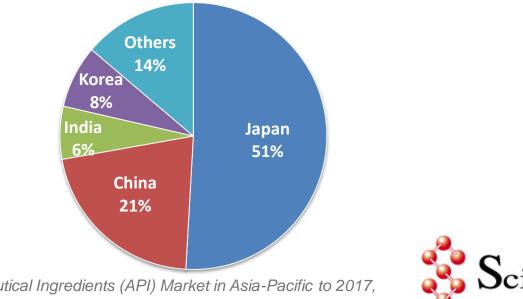
Progress Made in Japanese Market

# **Continued API Growth in Asia**

Asia is the global third largest regional market for APIs only next to North America and Europe

2005-2011 : CAGR ~ 9.1% 2011-2017 : CAGR ~ 8.5% (vs. 7.4% WW)

API Market Share in Asia by Country in 2011



Source: Active Pharmaceutical Ingredients (API) Market in Asia-Pacific to 2017, GBI Research, Nov 2012

# Japanese Generics Landscape

- The second largest market next to the US, presenting a significant growth potential in generics
- Japanese government aims to lift the generic volume penetration rate from current 25% to 60% by 2018
- Most domestic demand of generic APIs depends on imports, especially for oncology injectable drug
- Japanese government requires high quality APIs manufactured under stringent GMP norms. Japanese customers prefer one-stop-shop service (from API manufacturing to dosage form) from Taiwan



# **Target Top Tier Japanese Firms**

Top Generic Companies20NichiikoTevaTevaSawaiTowaNiproNiproNippon KayakuDaitoShiono ChemicalFuji Pharma	012 Sales (Million Yen) 77,740 70,000 67,600 48,720 42,550 28,510 27,100 25,300 21,620	<ul> <li>ScinoPharm's main target customers include tier 1 generic and new drug co.'s.</li> <li>12 out of the top 14 drug companies have partnered with us.</li> </ul>
Top 5 Brand name Companies Takeda Astellas Daiichi Sankyo Otsuka (Taiho) Eisai	2012 Sales (Million Yen) 1,508,900 969,400 938,700 782,200 648,000	<ul> <li>Our customers' market shares are high and stable.</li> </ul>



### **Growing Customer Base in Japan**

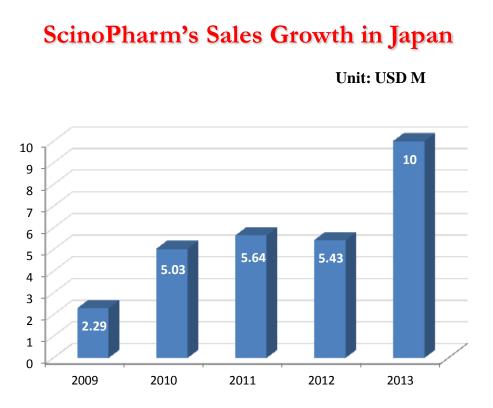
- Our Japanese customers will be over 10 by 2013
- Target to be a vital API supplier to the generic and brand name drug companies in Japan within 3-5 years

Year	2006	2007	2008	2009	2010	2011	2012	2013 (E)	2014 (E)
# of accumulated customer for R&D	4	7	9	14	19	21	24	26	28+
<ul><li># of accumulated customer for Commercial Sales</li></ul>	0	0	2	3	3	6	7	10	11+



# **Booming Market Presence in Japan**

- As the first Taiwanese API company qualified by PMDA, ScinoPharm aims to capitalize on its qualified APIs and formulation business





# **ScinoPharm Japan Office**

#### **Strategic Goals**

- **JDMF** registration and management
- API regulatory support for customers importing dosages to Japan
- Contacts for Japanese agents and customers
- Market research and intelligence collection
- Business support for future formulation products



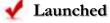


# **Business Outlook**

### **2013 Product Launch Plan**

	ΑΡΙ	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*
1	Docetaxel Anhydrous	JP	Anti-neoplastic	Sanofi Aventis	US\$236.9MM**	US\$2,051MM*
1	Modafinil	US	Antinarcolepsy	Cephalon	US\$1,219MM*	US\$1,319MM*
1	Paclitaxel	JP	Anti-neoplastic	<b>Bristol Myers</b>	US\$307.1MM**	US\$1,654MM*
1	Riluzole	US	ALS	Sanofi Aventis	US\$55.0MM*	US\$237.1MM*
	Topiramate	US	Seizures	Customer	NDA ( FDA tentat	ive approval)
			J Launched		2	

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





# **CRAM Business Updates**

- One CMO new drug has obtained another FDA approval to treat HAP (Hospital Acquired Pneumonia), in addition to its original skin infection indication
  - ScinoPharm Changshu has formed a strategic alliance with Sundia MediTech Co. (a Shanghaibased CRO) to combine their NCE R&D capabilities and our CGMP manufacturing facilities to strive for Chinese local and int'l CRAMS business opportunities



### 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



Confidential



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

www.scinopharm.com

