



# ScinoPharm Management Presentation

TWSE 1789

May, 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\$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 (320+) 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 (642 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 (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 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<br>vs<br>China<br>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

# Quarterly P&L - Consolidated

| In NT\$ million, except for EPS | 1Q,'13<br>(Reviewed) | 4Q,'12<br>(Audited) | 1Q,'12<br>(Reviewed) | QoQ  | YoY  |
|---------------------------------|----------------------|---------------------|----------------------|------|------|
| Net Sales                       | 1,186                | 1,404               | 971                  | -16% | 22%  |
| Gross Profit                    | 655                  | 713                 | 523                  | -8%  | 25%  |
| <i>Gross margin</i>             | <i>55%</i>           | <i>51%</i>          | <i>54%</i>           |      |      |
| Operating Expenses              | (267)                | (320)               | (240)                | -17% | 11%  |
| Operating Income                | 388                  | 393                 | 283                  | -1%  | 37%  |
| <i>Operating margin</i>         | <i>33%</i>           | <i>28%</i>          | <i>29%</i>           |      |      |
| Other Rev.(Exp.)                | 19                   | 97                  | 7                    | -80% | 171% |
| Net Income before Tax           | 407                  | 490                 | 290                  | -17% | 40%  |
| Net Income after Tax            | 350                  | 422                 | 247                  | -17% | 42%  |
| <i>Net margin after tax</i>     | <i>30%</i>           | <i>30%</i>          | <i>25%</i>           |      |      |
| EPS (after tax)                 | 0.54                 | 0.65                | 0.38                 | -17% | 42%  |



ScinoPharm

# Balance Sheet- Consolidated

| In NT\$ million            | 2013/3/31<br>(Reviewed) |      | 2012/3/31<br>(Reviewed) |      |
|----------------------------|-------------------------|------|-------------------------|------|
| Cash and Cash Equivalents  | 3,411                   | 31%  | 3,236                   | 33%  |
| Accounts Receivable        | 599                     | 5%   | 740                     | 8%   |
| Inventories                | 2,226                   | 20%  | 1,802                   | 19%  |
| Long-Term Investments      | 168                     | 2%   | 168                     | 2%   |
| Fixed Assets               | 3,820                   | 35%  | 2,944                   | 30%  |
| Total Assets               | 11,037                  | 100% | 9,715                   | 100% |
| Current Liabilities        | 1,510                   | 14%  | 864                     | 9%   |
| L-T Liabilities and Others | 66                      | -%   | 64                      | 1%   |
| Stockholders' Equities     | 9,461                   | 86%  | 8,787                   | 90%  |

# Cash Flows- Consolidated

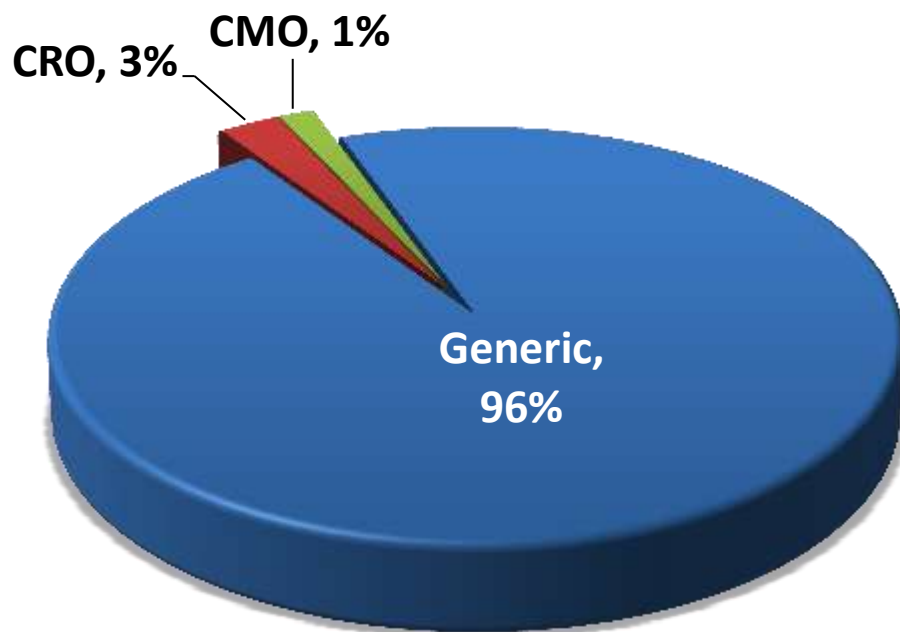
| In NT\$ million                                  | 1Q 2013<br>(Reviewed) | 1Q 2012<br>(Reviewed) |
|--|-----------------------|-----------------------|
| Cash and cash equivalents at beginning of period | 3,035                 | 3,294                 |
| Cash flows from operating activities             | 413                   | 80                    |
| CAPEX  | (144)                 | (114)                 |
| Short-term borrowings                            | 128                   | -                     |
| Others   | (21)                  | (24)                  |
| Cash and cash equivalents at end of period       | 3,411                 | 3,236                 |



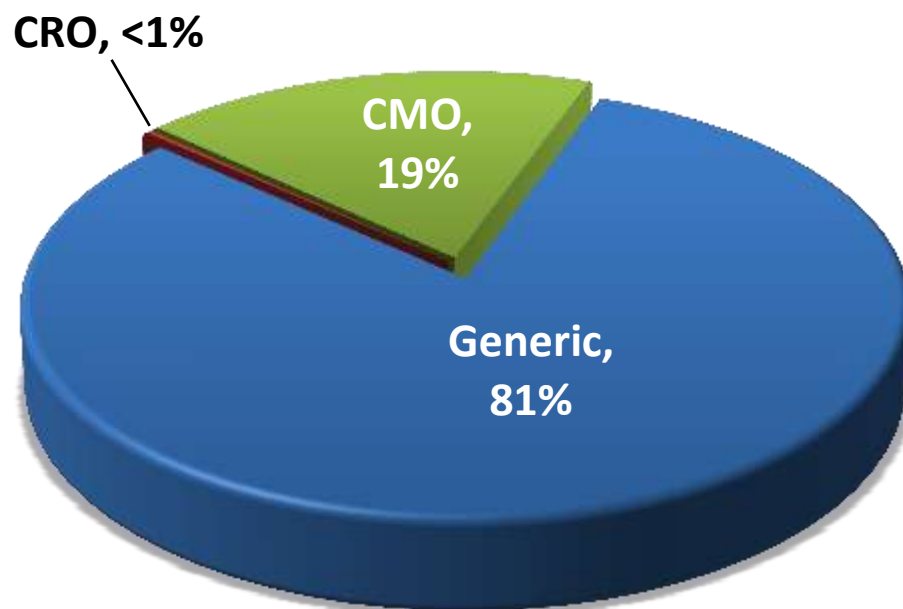
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# Sales by Business

Q1/2012

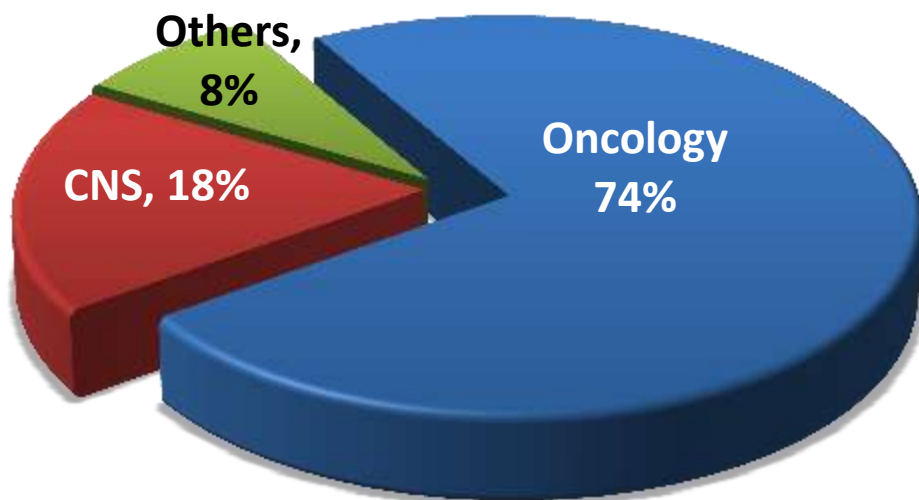


Q1/2013

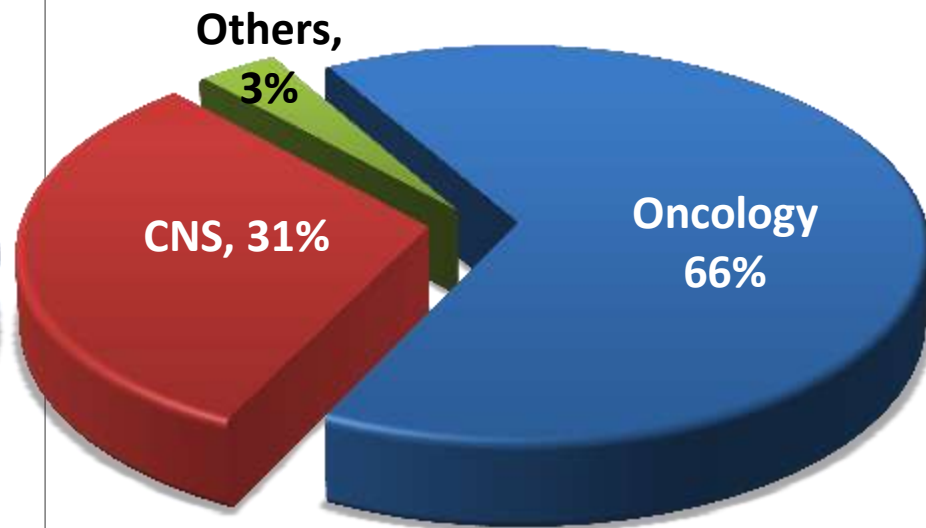


# Sales by Indications

**Q1/2012**



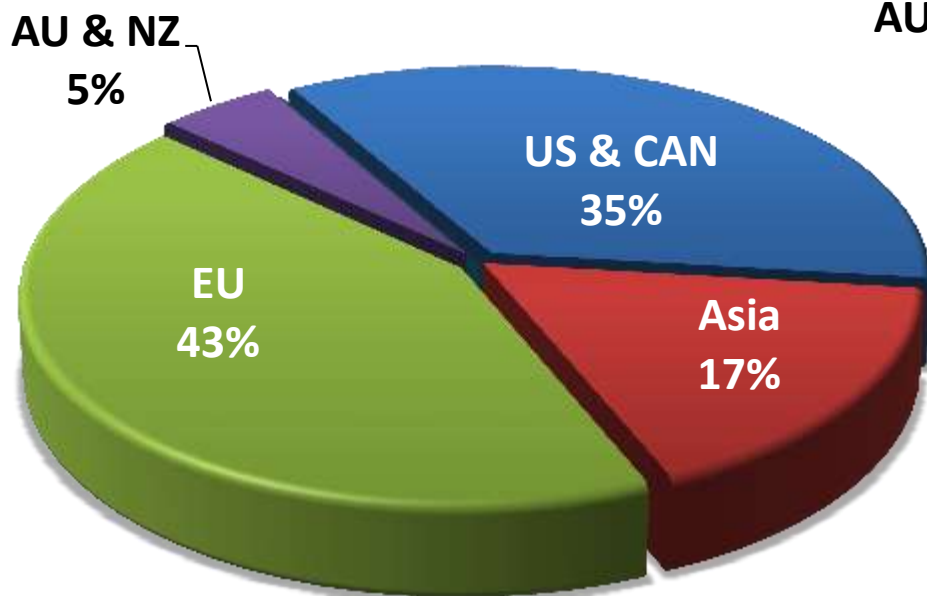
**Q1/2013**



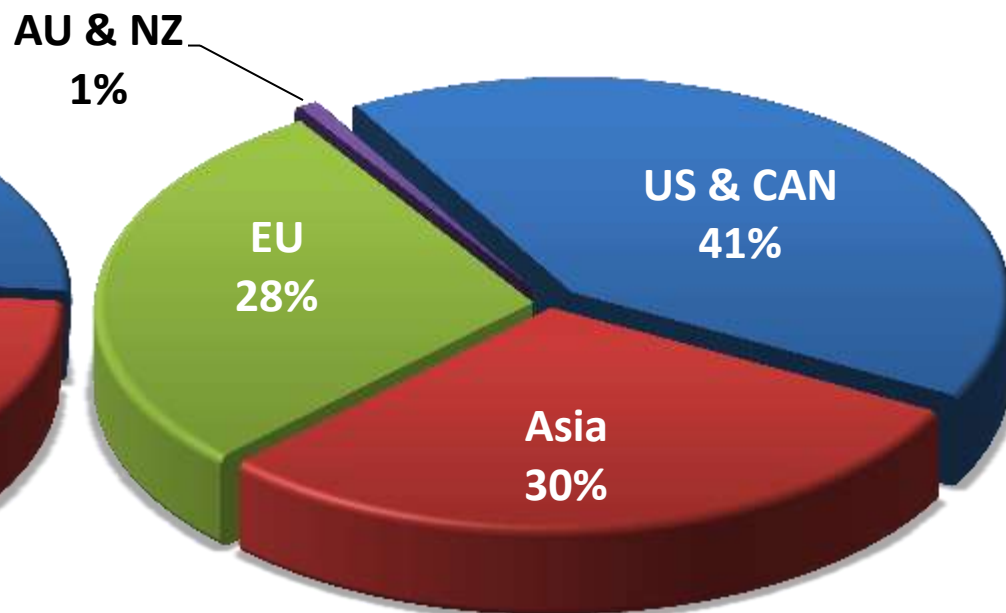
**ScinoPharm**

# Sales by Region

**Q1/2012**



**Q1/2013**



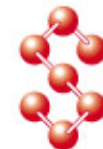
**ScinoPharm**

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# **ScinoPharm's Opportunities and Strategies**

# Opportunities & Strategies

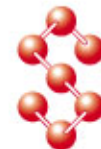
- Sustaining World Leadership of Oncological APIs
- Japan Market Development
  - Meeting Oncological API Demand
- China Angles
  - Supply Chain Management
  - Generic Market Demand – Oncological, Antiviral, Diabetes
  - CMO for MNCs
- Double A Strategy “API + ANDA”
  - Focusing on Oncological Injectables



ScinoPharm

# World Leader of Oncological APIs

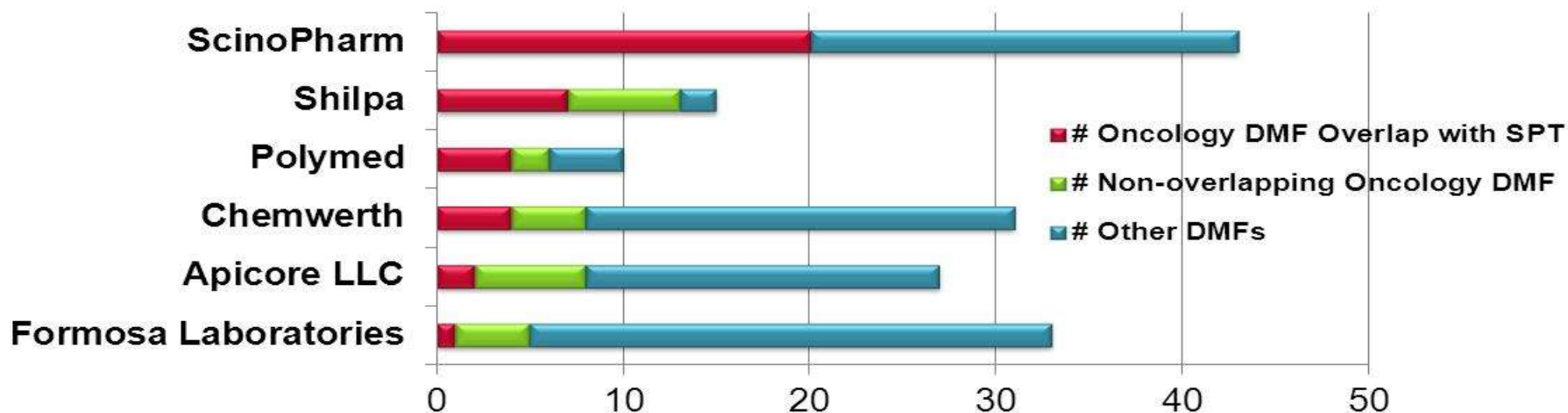
- 25 oncological APIs in the portfolio with 10 launched
- Continue to add 2-4 new oncological APIs each year in research pipeline
- Market research/new product selection parallel with key customers including Teva, Sandoz, Actavis, Hospira, etc.
- Major market penetrations of key products
  - Docetaxel 51%, Irinotecan 40%, Paclitaxel 20%



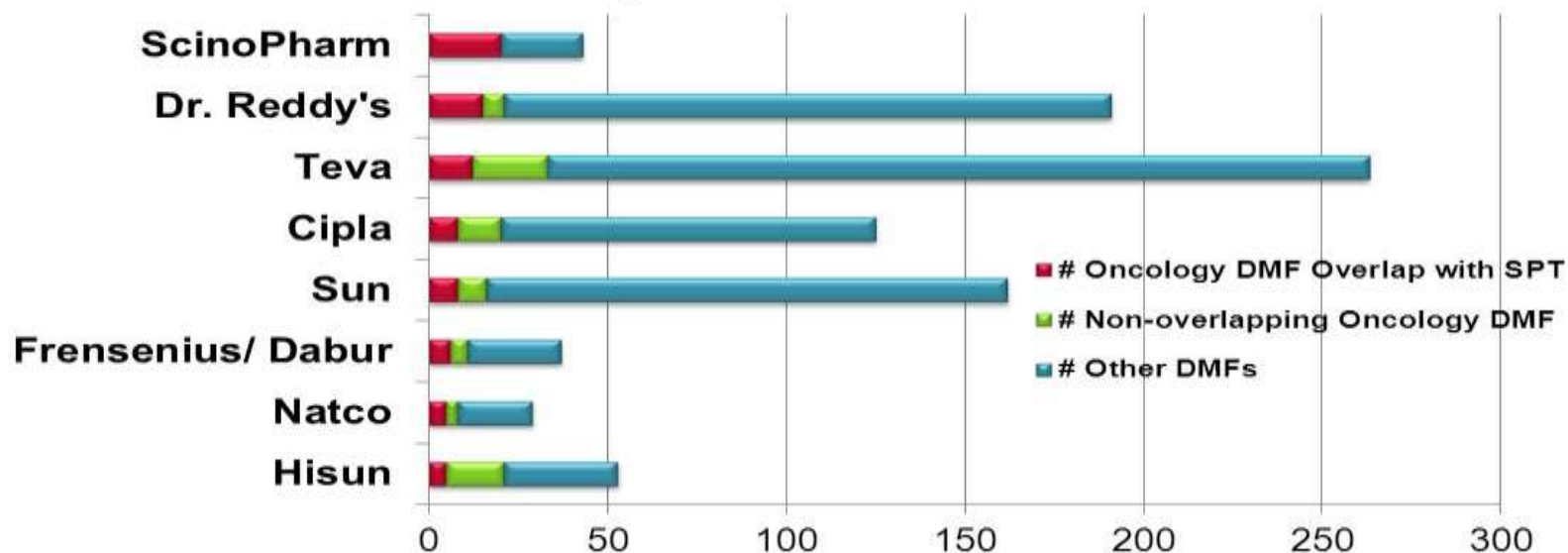
ScinoPharm

# ScinoPharm - Oncological API Leader

## Stand-Alone API Companies



## Large Generic Pharmas



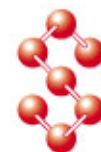
# Japan API Market

- 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



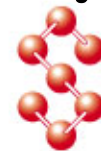
# China Angles - Supply Chain

- 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

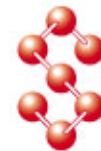
- Government's 12<sup>th</sup> five-year plan sets a goal for pharma to grow at a CAGR of 20%
- **Require 100% compliance of the latest GMP**
- Encourage companies to apply for int'l ANDAs which require world class APIs
- **Generic oncological products dominated by 3 players with in-house APIs. Huge 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

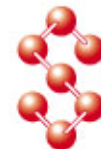


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# **China Market Access Action Plans**

# Ways to Access China Market

- A. Sell APIs to local Pharma companies
- B. Develop, register, produce and sell our own drug products made of our APIs
- C. Collaborate with Chinese marketers to develop, register, produce, and sell drug products with our APIs and share ultimate B2C profits



# ScinoPharm-Coland-Jinrui Alliance

## Collaboration Framework

ScinoPharm, Coland, and Jinrui work jointly for the Bortezomib injectables:

- ScinoPharm provides Bortezomib API
- Jinrui develops formulation and files with CFDA
- Coland markets the drug product in China

## Market Potential

- Bortezomib injectables are for Multiple Myeloma, sales in China reached RMB330MM in 2011, YoY growth of 40%



# Strategic Alliance between ScinoPharm and Coland

# ScinoPharm-Coland Strategic Alliance

- ScinoPharm and Coland collaborate to develop oncology drugs for China market
- The strategic alliance will develop a series of oncology injectables per ScinoPharm's APIs mainly for MDS, lung, breast, ovarian, and pancreatic cancers. The drug product sales in 2012 was estimated at RMB5billion\* in China

# Alliance Framework

- ScinoPharm exclusively provides all APIs
- 3<sup>rd</sup> party CRO and CMO develop and produce injectable drug products
- Coland helps register drugs and build a dedicated sales team at beginning
- Initial cost is estimated at USD5-7 million
- ScinoPharm and Coland jointly penetrate into the niche oncological market in China

# 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     | Antinarcolepsy       | 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

- 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)