

TWSE 1789

# ScinoPharm Management Presentation

Second Quarter 2015 On-Line Investor Conference

August 5, 2015



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# Overview of ScinoPharm

- An API + ANDA Company

Active Pharmaceutical Ingredients  
Abbreviated New Drug Application

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# Business Overview

- Established in 1997 in Taiwan, listed on TWSE in 2011, and honored as the top 5% TWSE issuer in information disclosure & corporate governance
- Specializes in high potency (steroid/cytotoxic) APIs and expands to injectable formulations
- Facility & organization built in Taiwan and expanding in China with a new GMP plant in Changshu & marketing base in Shanghai
- 70 generic APIs developed with 27 APIs launched; 50 US DMFs filed (707 DMFs WW), 24 US DMFs in oncological APIs. 80+ NCE CRAM projects, with 5 launched and 9 in phase III for NDA filing in 2-3 years
- Fully Complied with world-class cGMP and regulatory requirements; Certified by US FDA, EMA, Australian TGA, Japanese PMDA, etc.

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# Long Term Strategies

Transforming to a full-scope pharma company per our core competency of R&D and cGMP manufacturing in high-technical barrier APIs

- Vertical Integration to Generic Formulations: Developing dossiers per our difficult-to-make APIs to increase value proposition in the supply chain
- Innovative Delivery Formulations: Targeted delivery & extended release of proven APIs via 505(b)2 fast track
- Brand New Chemical Entities (New Drugs): Collaborating with academic research institutes, focusing on un-met oncological medical needs of high prevalence in Asia

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# Keys to Generic Formulation Business

- Expanding formulation portfolio
- Building on-site injectable facility and forming a complete supply chain of drug products
- Promoting our formulations via strategic alliance, especially in China and US
- Acquiring critical resources via M&A

# Observations from CPhI China



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# China API Industry Observations

- Tightened GMP, Environment/Health/Safety laws and drug license approval process pushing out low-quality API suppliers
  - To stabilize API sourcing, US/EU big pharmas switching to high-quality, EHS/GMP complied vendors, like ScinoPharm
- Chinese players moving up to key positions in global value chain after succeeding in domestic market
  - ScinoPharm partnering with Chinese peers to enjoy big domestic market and bridging them into global market
- Government support upgrading Chinese API from massive, low price items to high-end specialty
  - ScinoPharm expediting its premium API development and accelerating its transformation to specialty formulation

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# Strategic Goals in China

**Short Term:** Pass US FDA/EMA/CFDA inspections and expand CRAM services to diversified indications & processes to optimize portfolio and capacity utilization

**Mid Term:** Execute API+ANDA strategy by collaborating with formulators to apply for ANDA in US/EU/CN and share profits from drug product sales globally

**Long Term:** Expand into new delivery formulations and new drugs via strategic alliance, investment, & M&A



# **Financial & Operating Results**

# Quarterly P&L - Consolidated

In NT\$ million, except for EPS	2Q,'15 (Reviewed)	1Q,'15 (Reviewed)	2Q,'14 (Reviewed)	QoQ	YoY
Net Sales	963	979	1,148	-2%	-16%
Gross Profit	365	344	500	6%	-27%
<i>Gross margin</i>	<i>38%</i>	<i>35%</i>	<i>44%</i>		
Operating Expenses	(239)	(203)	(287)	18%	-17%
Operating Income	126	141	213	-11%	-41%
<i>Operating margin</i>	<i>13%</i>	<i>14%</i>	<i>19%</i>		
Other Rev.(Exp.)	106	(7)	(1)	1614%	10700%
Net Income before Tax	232	134	212	73%	9%
Net Income after Tax	132	113	193	17%	-32%
<i>Net margin after tax</i>	<i>14%</i>	<i>12%</i>	<i>17%</i>		
EPS (after tax)	0.19	0.16	0.27	19%	-30%

# Half Year P&L - Consolidated

In NT\$ million, except for EPS	1H,'15 (Reviewed)	1H,'14 (Reviewed)	YoY
Net Sales	1,942	2,245	-13%
Gross Profit	709	933	-24%
<i>Gross margin</i>	<i>37%</i>	<i>42%</i>	
Operating Expenses	(442)	(538)	-18%
Operating Income	267	395	-32%
<i>Operating margin</i>	<i>14%</i>	<i>18%</i>	
Other Rev.(Exp.)	99	2	4850%
Net Income before Tax	366	397	-8%
Net Income after Tax	245	358	-32%
<i>Net margin after tax</i>	<i>13%</i>	<i>16%</i>	
EPS (after tax)	0.35	0.51	-31%

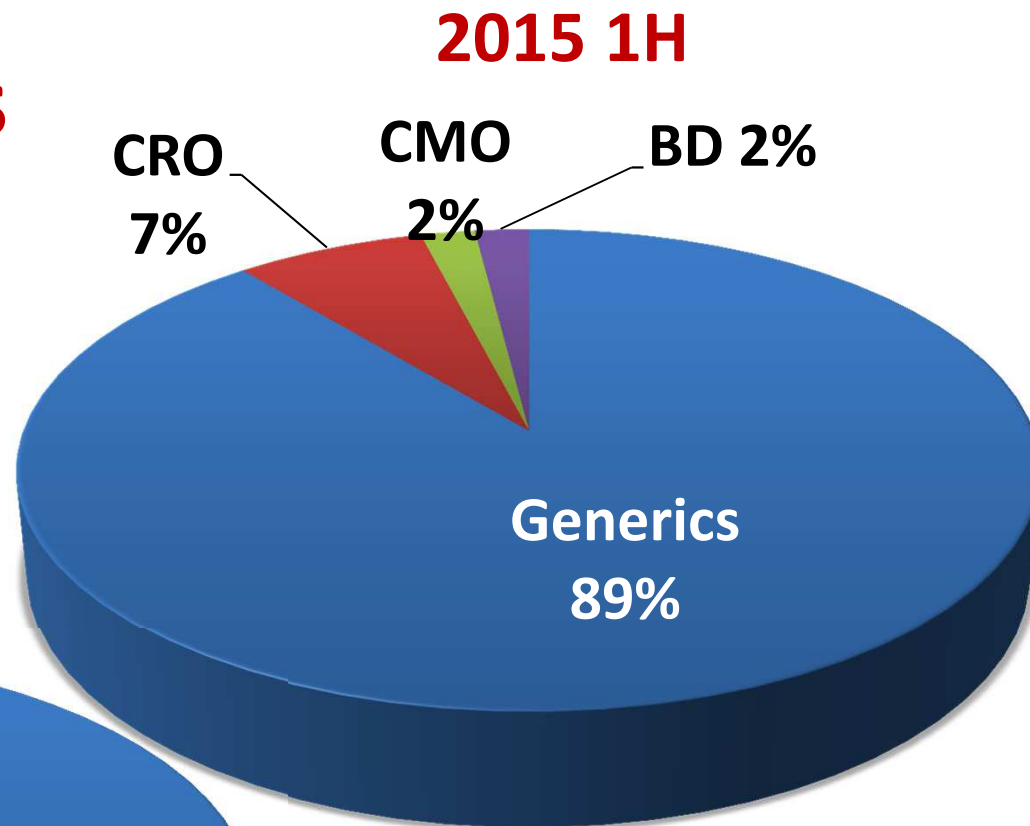
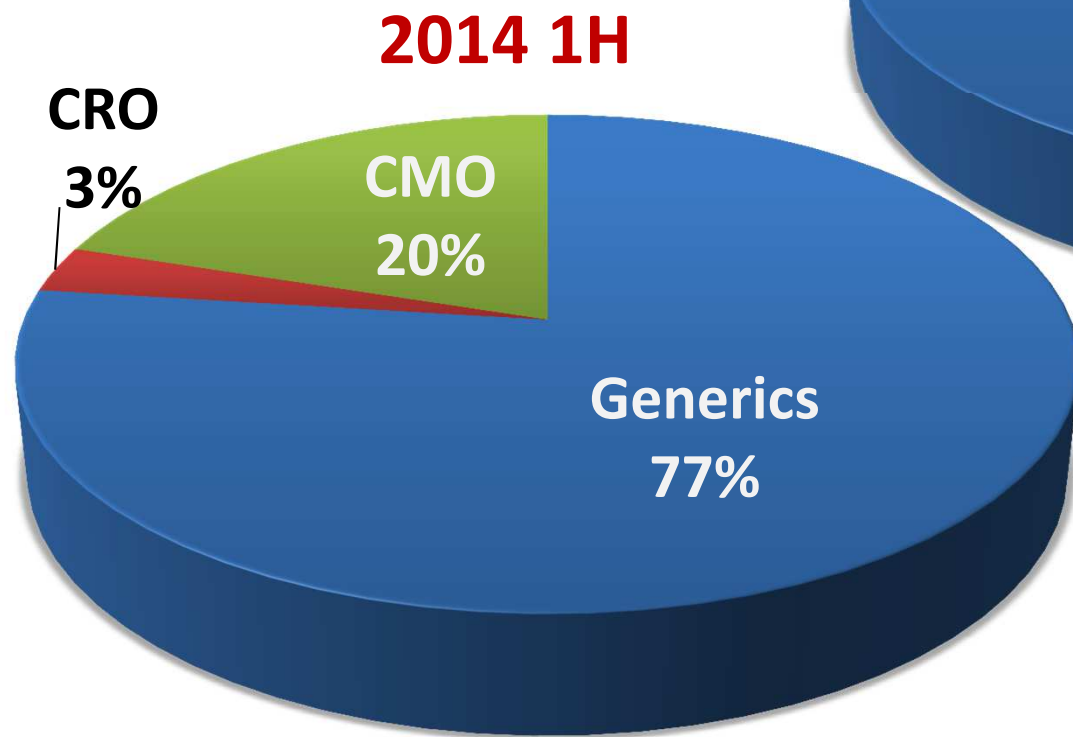
# Balance Sheet - Consolidated

In NT\$ million	2015/6/30 (Reviewed)		2014/6/30 (Reviewed)	
Cash and Cash Equivalents	2,410	20%	2,184	18%
Accounts Receivable	568	5%	793	7%
Inventories	2,315	19%	2,676	23%
Long-Term Investments	339	3%	255	2%
Property, plant & equipment	5,142	43%	4,658	40%
Other assets	1,100	10%	1,229	10%
Total Assets	11,874	100%	11,795	100%
Current Liabilities	2,333	19%	2,569	22%
L-T Liabilities and Others	91	1%	66	0%
Stockholders' Equities	9,450	80%	9,160	78%

# Cash Flows - Consolidated

In NT\$ million	1H 2015 (Reviewed)	1H 2014 (Reviewed)
Cash and cash equivalents at beginning of period	1,928	2,289
Cash flows from operating activities	589	248
CAPEX	(345)	(694)
Short-term borrowings	212	317
Others	26	24
Cash and cash equivalents at end of period	2,410	2,184

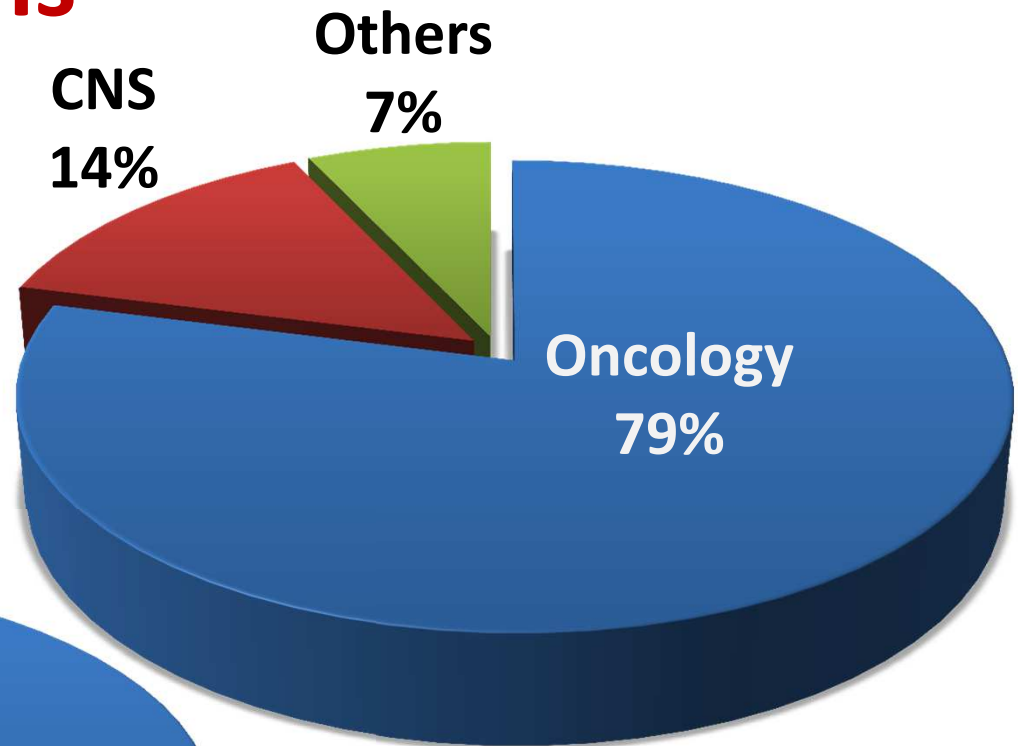
# Sales by Business



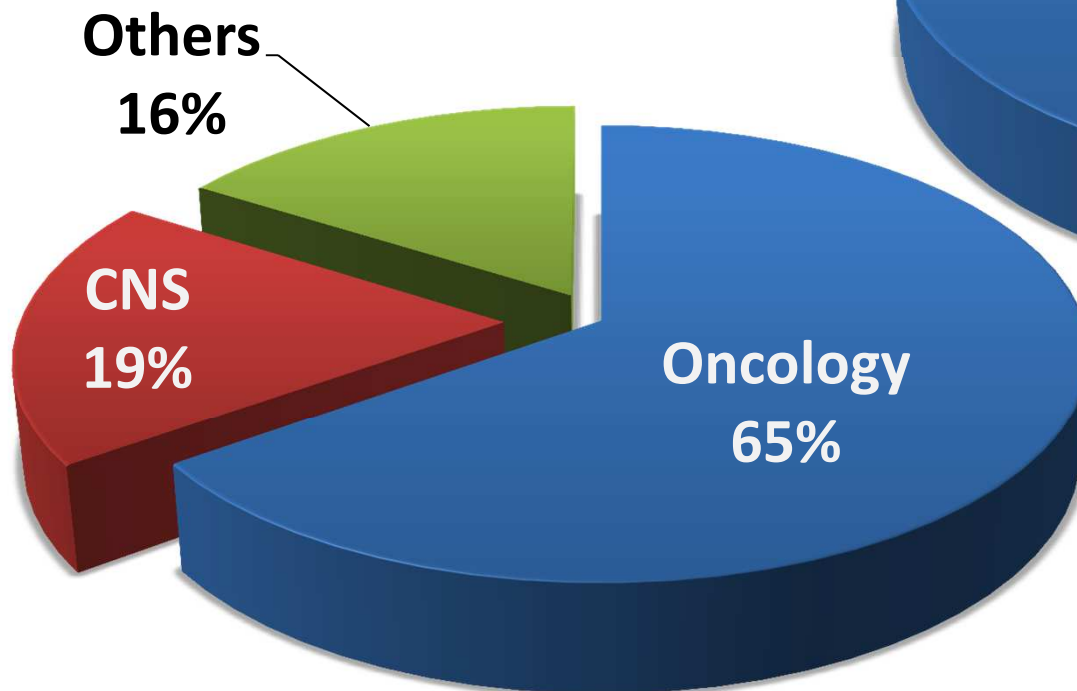


# Sales by Indications

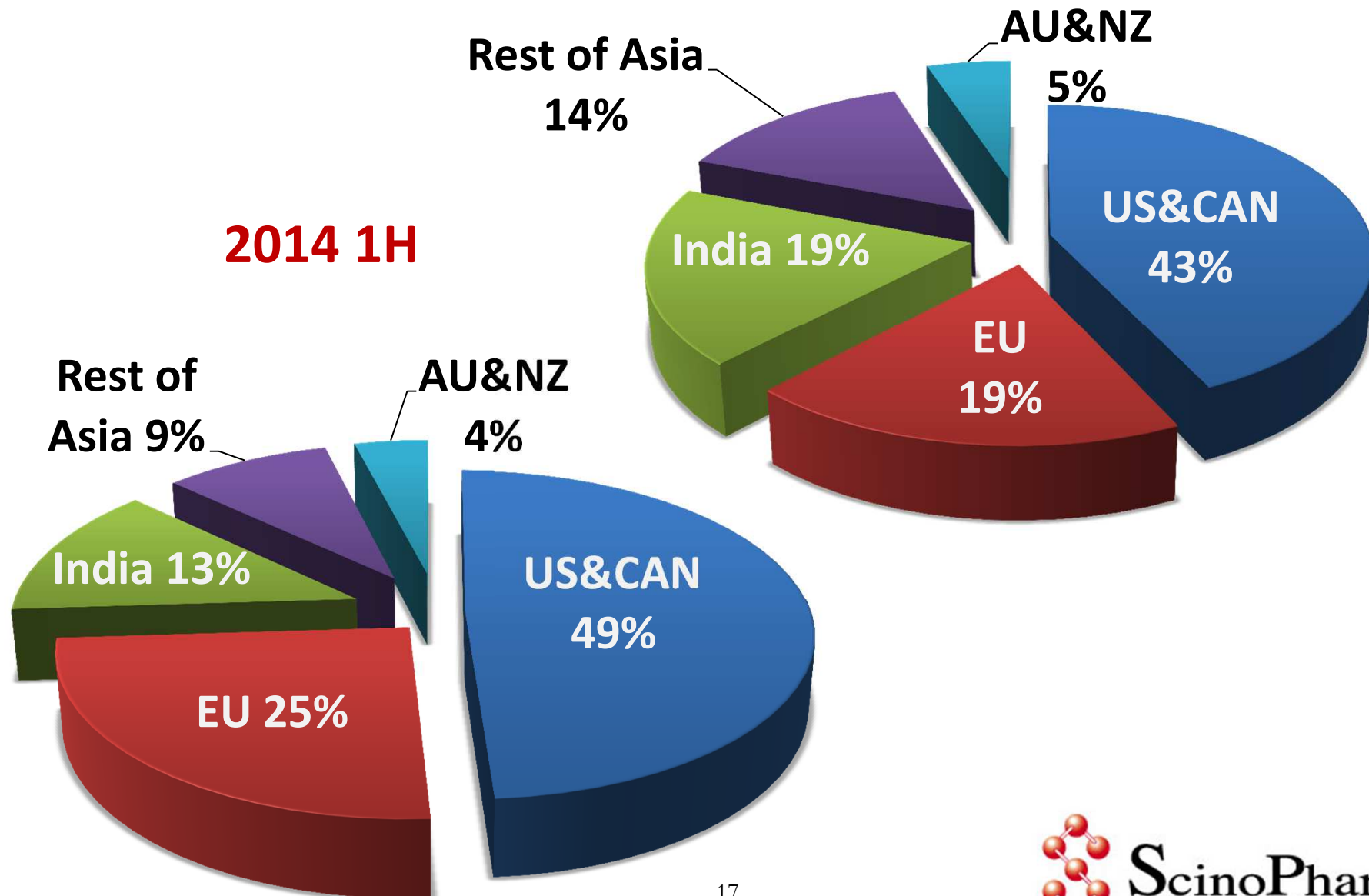
2015 1H



2014 1H



# Sales by Region



# **Business Updates**

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# First Self-developed US ANDA Filing

- Fondaparinux, an anticoagulant, is the first self-developed and filed ANDA under “API+ANDA” strategy
- The chemical synthesis of this carbohydrate-based drug is extremely complicated with 50+ steps
- ScinoPharm is one of the few firms worldwide with a complete technical and commercial scale supply chain from API through injectable
- Discussing with global pharmas for executive right and profit sharing in the US and EU; Partnering with Lee’s Pharma for profit sharing from drug sales in China

# Portfolio for Aging Society

- As a result of China's “single-child” policy and low mortality, China's population has been aging rapidly
- Popular in China are age-related diseases, e.g., cancer, glaucoma, cardiovascular, hypertension, dementia and Alzheimer's disease

## Oncology

- \*Anastrozole
- \*Capecitabine
- \*Docetaxel
- \*Gemcitabine
- \*Irinotecan
- \*Paclitaxel
- \*\*Azacitidine
- \*\*Bortezomib

## CVD

- \*Benazepril
- \*Bivalirudin
- \*\*Fondaparinux
- \*\*Regadenoson

## Urology

- \*Tamsulosin

## Glaucoma

- \*\*Bimatoprost
- \*\*Travoprost

## Alzheimer

- \*Galantamine

## Others

- \*\*Lubiprostone

\* Submit drug import license applications or production permits

\*\*Co-developed product targeted for Chinese market

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# License-in Celecoxib to Expedite Ramping

- To accelerate the momentum and growth of the Changshu plant, ScinoPharm licenses in APIs paired with self-development
- Celecoxib is powerful in treating several common acute pains, including acute tissue injury and postoperative pain
- Raffles is responsible for the R&D, while ScinoPharm Changshu for the production and marketing in the US/EU. Both parties will share the profits after its launch in the US
- DMF filing expected in 2016 and API launch expected in the US by 2018

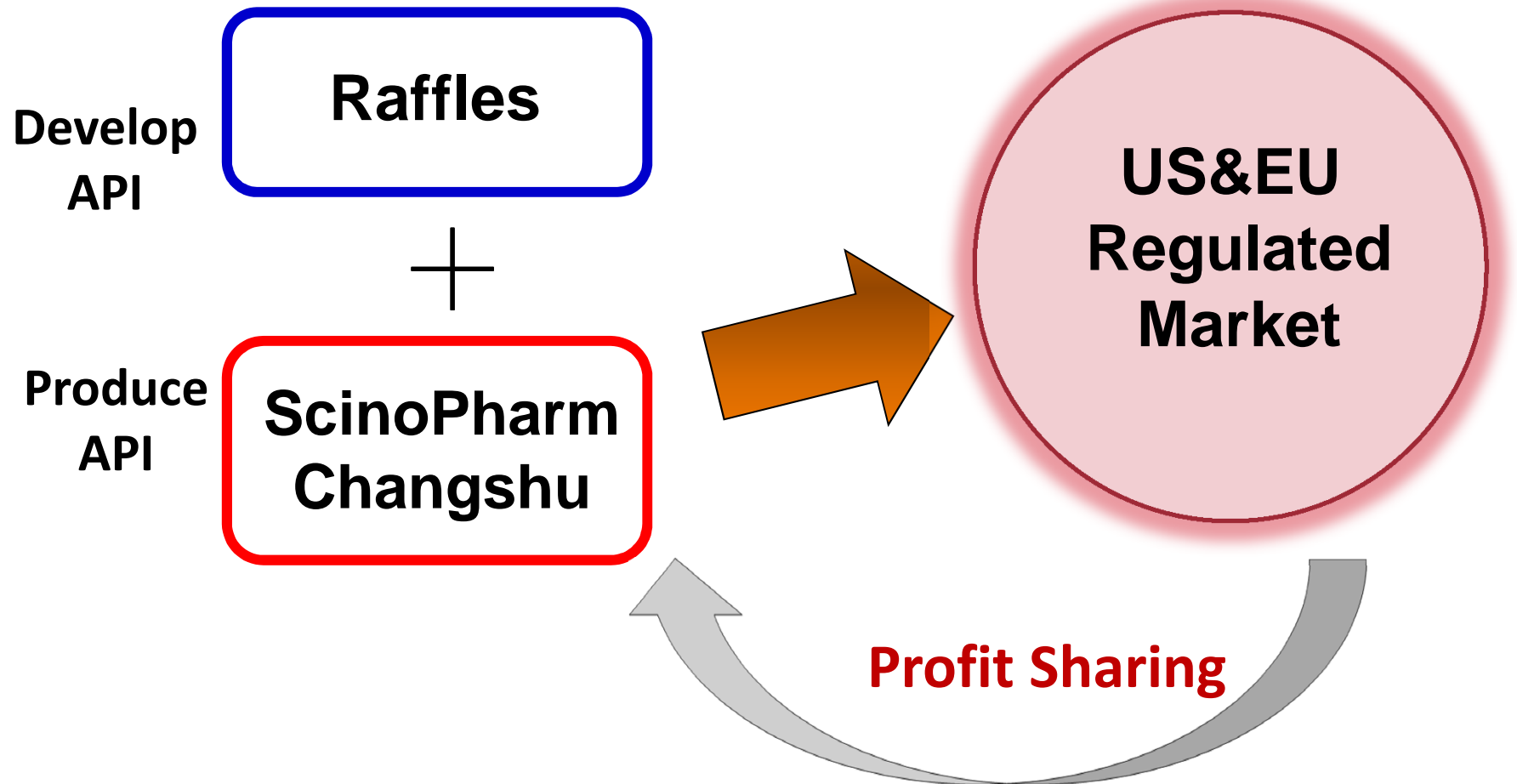
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# Background on Raffles

- Located in Huizhou, Guangdong, China. Focused on organic macromolecule catalysts, value-added pharmaceutical intermediates and APIs
- Its customer base includes well-known international pharmaceutical companies



# Collaboration Flow Chart





# 2015 Product Launch Plan

API	Region	Indications	Brand Marketer	Regional Sales	WW Sales
Azacitidine	US	MDS Oncology	Celgene	US\$323MM*	US\$815MM*
Benazepril	CN	Hypertension, CV	Novartis	US\$65MM**	US\$480MM*
Desmopressin	US	Polyuria	Ferring	US\$131MM*	US\$395MM*
✔ Letrozole	JP	Breast Cancer	Novartis	US\$51MM**	US\$581MM*
Tamsulosin	US	Benign prostatic hyperplasia (BPH)	Boehringer Ingelheim	US\$335MM*	US\$1,829MM*



Launched

Source: \* IMS Data (2013Q3-2014Q2) \*\* In-house research

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# *Questions*

# *&*

# *Answers*



## Brand Quality with Asian Advantages

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