



TWSE 1789

# ScinoPharm Management Presentation

2016/05/11



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# Overview of ScinoPharm

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# Background

- Established in 1997 in Taiwan and listed on TWSE in 2011
- Major shareholders include Uni-President Group, National Development Fund, & Taiwan Sugar
- Facility & organization built in Taiwan by experienced Syntex team, received multiple regulatory inspections from US FDA, Australia, EU, Japan, etc.
- Specializes in high potent/cytotoxic APIs & moves to injectable formulations
- Expanding in China with a marketing base in Shanghai & new GMP plant in Changshu, just inspected by US FDA with zero 483



# World Class API Facilities

## Taiwan

- 6.6 hectares of land, 330K sqft facilities with >200M<sup>3</sup> reactor volume
- 6 of 16 production lines equipped with high potency capabilities for cytotoxic/steroids
- Passed US FDA, EMA, Australian TGA, Japanese PMDA inspections & 300+ cGMP customer audits
- Provides comprehensive contract research & manufacturing services for brand drug companies
- Global Market



## China

- 6.5 hectares of land with > 250M<sup>3</sup> reactor volume
- 3 of 7 production lines equipped with high potency capabilities for cytotoxics
- US FDA approved cGMP facility for intermediates & high potency API
- Full scope capabilities in developing and producing APIs from small to large scale for generic & CRAM markets
- Global market including China



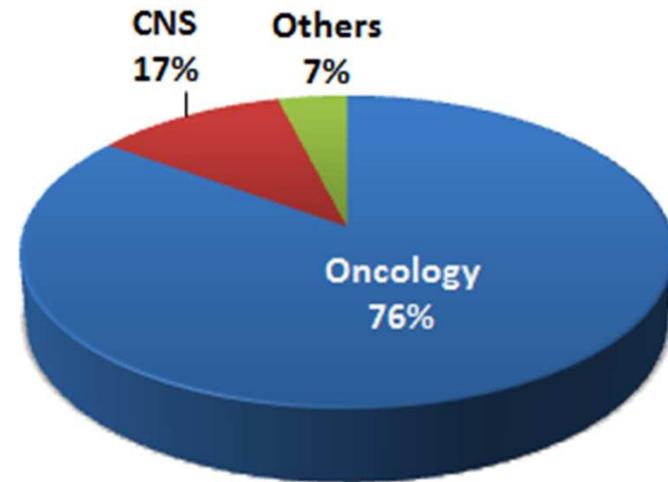
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# Business Overview

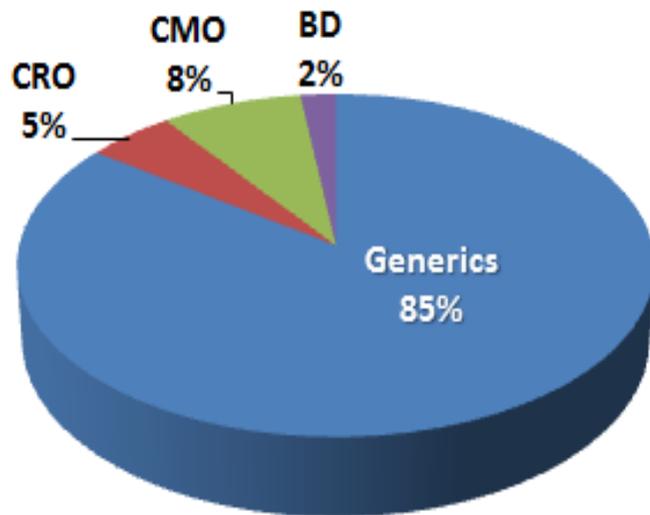
- Risk & return balanced model to offer APIs and sterile filling capability for both generic and new drugs
- 80+ generic APIs developed with 27 APIs launched; 56 US DMFs filed (738 DMFs WW), 29 US DMFs in oncology APIs
- 100+ NCE CRAM projects, with 5 launched and 5 in phase III for NDA filing in 2-3 years; The Qualified Asian supplier to provide APIs to global market for multiple commercial NCEs

# 2015 Sales Distribution

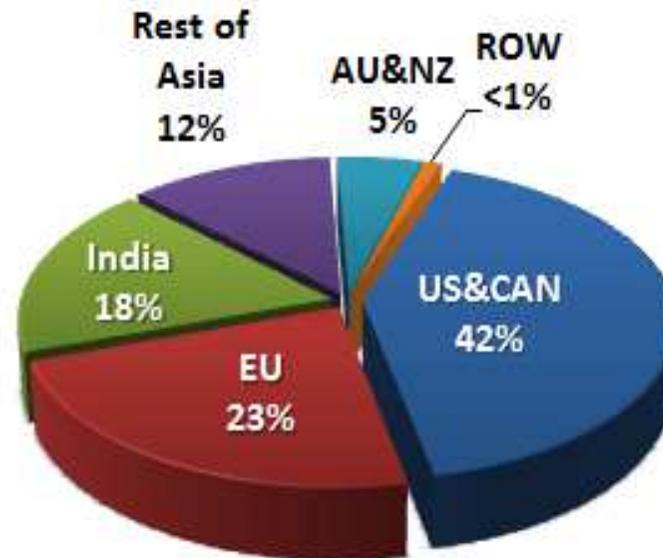
## By Indication



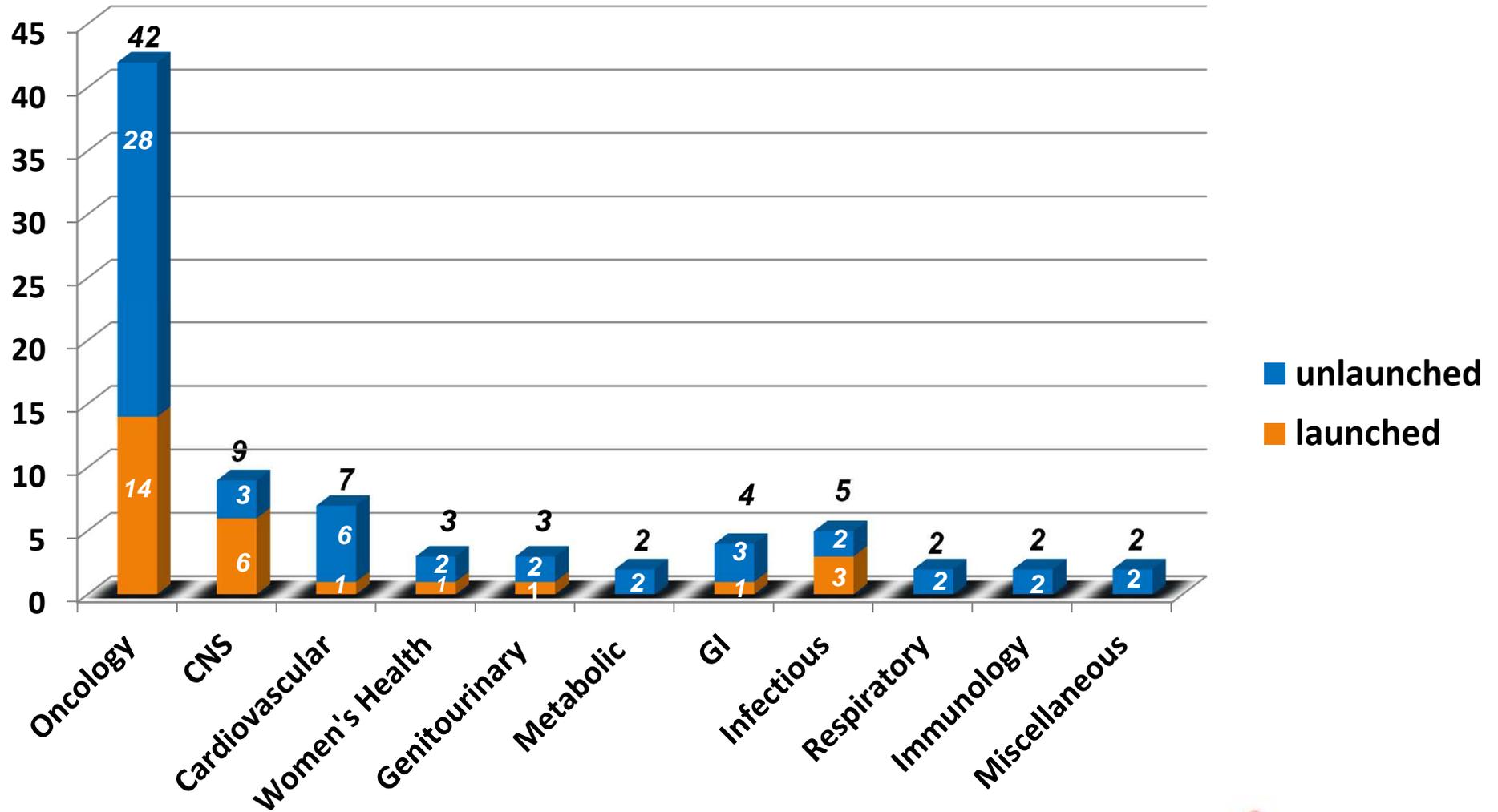
## By Business



## By Region



# Strong Generics Product Portfolio



# Diversified CRAM Portfolio

Stage	First Launch Year	Indication	Location
Commercial	2005	Eluting Stent	US
Commercial	2009/2013	Skin Infection/HAP	US/EU
Commercial	2011	Depression	US
Commercial	2012	Obesity	US
Commercial	2013	Seizure	US
Stage	Est. NDA Filing Year	Indication	Location
Phase III	2016	Infections	US / EU / Asia
Phase III	2017	Ovarian Cancer	US / EU
Phase III	2017	Prostate Cancer	US
Phase III	2017	Ovarian Cancer	CN
Phase III	2017	Parkinson's Disease	US





# **ScinoPharm's Strategies and Opportunities**

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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 start-ups & research institutes, focusing on un-met oncology medical needs of high prevalence in Asia

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# Keys to Generic Formulation Business

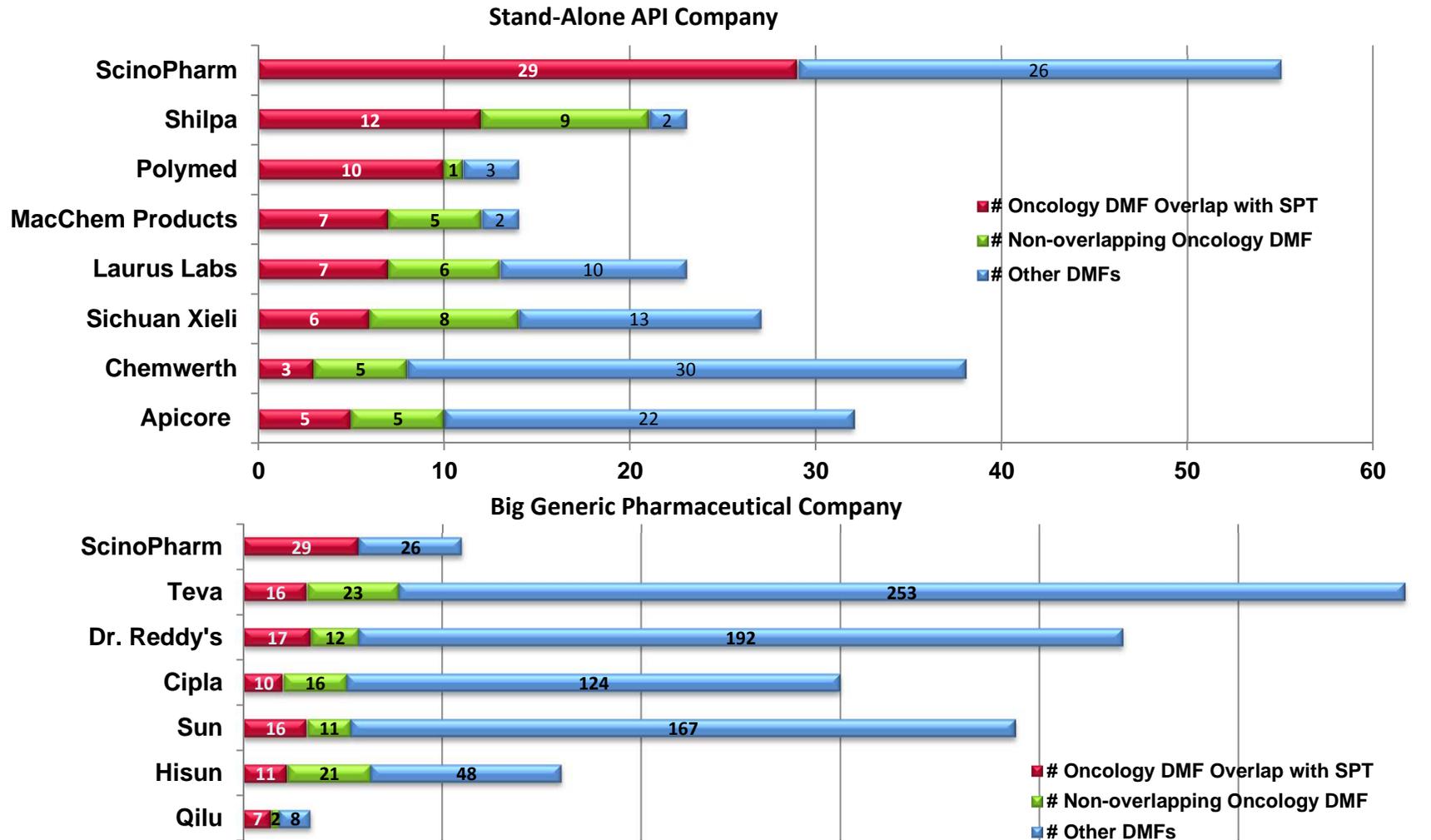
- Expanding formulation portfolio
- Building on-site oncology injectable facility and establishing a complete supply chain
- Sustaining B2B model, promoting our formulations via strategic alliance, especially in China and US/EU
- Acquiring critical resources via M&A

# Strategic Alliance Highlights

\* Already launched

Partner	Product	Indications	Region	Launch Year(E)	Remarks
Genovate	Entecavir	Hepatitis B Viral	Taiwan	2013*	1 <sup>st</sup> co-developed formulation product launch
Sagent	Oncology Injectable	Myeloid Leukemia	US	2016	1 <sup>st</sup> US ANDA filing, triggered US FDA inspection in Changshu site
Foresee	Leuprolide	Prostate cancer	US	2018	505(b)2 NDA CRAM + Equity
Coland	Bortezomib	Multiple Myeloma	China	2019	1 <sup>st</sup> co-developed drug in China to trigger CFDA inspection in Changshu site
	Azacitidine	MDS	China	2020	Co-developed formulation
Lee's Pharma	Fondaparinux	Anti-thrombotic	China	2020	1 <sup>st</sup> self-developed drug in China
	Travoprost Bimatoprost	Glaucoma	China	2022	Co-developed formulations
Nanjing King Friend	Regadenoson	Stress agent for heart scan	China	2020	1 <sup>st</sup> type 3.1 co-developed new drug in China
US partner	Project A	non-small cell lung cancer	US	2019	US NDA 505(b)2 & Paragraph IV filing
US & China partners	Project B	imaging agent	US	2019	Paragraph IV filing

# ScinoPharm - Oncology API Leader

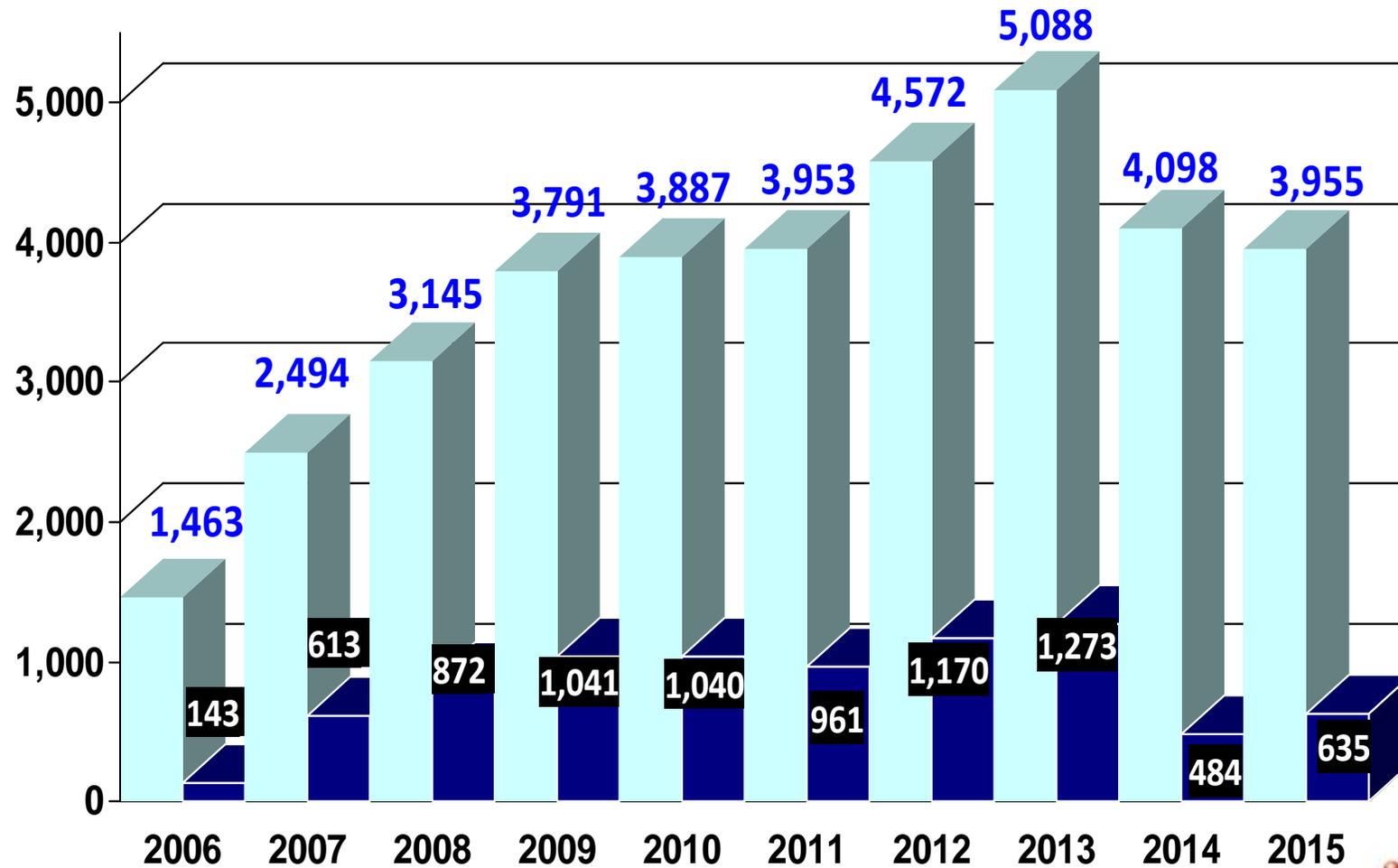


# Operating Results & Outlook

# Historical Performance

■ Sales  
■ Net Income

Unit: In NT\$ million



# Recent Financial

\* In NT\$

Year	2013	2014	2015
Total assets*	11,484 M	11,372 M	12,222 M
Shareholders' equity*	9,643 M	9,380 M	9,857 M
Sales*	5,088 M	4,098 M	3,955 M
Net profit after tax*	1,273 M	484 M	635 M
Earnings per share	1.88	0.69	0.87
Cash dividends (NT\$/share)	1.2	0.2	0.3
Stock dividends (NT\$/share)	0.4	0.4	0.4
Pay-out ratio	85%	87%	80%

Note : All of the above figures represent consolidated information



# Quarterly P&L - Consolidated

In NT\$ million, except for EPS	1Q 2016 (Reviewed)	1Q 2015 (Reviewed)	YoY
Net Sales	1,022	979	4%
Gross Profit	431	344	25%
<i>Gross margin</i>	<i>42%</i>	<i>35%</i>	
Operating Expenses	(236)	(203)	16%
Operating Income	195	141	39%
<i>Operating margin</i>	<i>19%</i>	<i>15%</i>	
Other Rev.(Exp.)	(4)	(7)	-35%
Net Income before Tax	191	134	42%
Net Income after Tax	172	113	52%
<i>Net margin after tax</i>	<i>17%</i>	<i>12%</i>	
EPS (after tax)	0.24	0.15	60%

# Balance Sheet- Consolidated

In NT\$ million	2016/3/31 (Reviewed)		2015/3/31 (Reviewed)	
Cash and Cash Equivalents	2,560	21%	2,008	17%
Accounts Receivable	645	5%	653	6%
Inventories	2,167	17%	2,402	21%
Long-Term Investments	364	3%	244	2%
Property, plant & equipment	5,361	43%	5,109	44%
Other assets	1,394	11%	1,155	10%
<b>Total Assets</b>	<b>12,491</b>	<b>100%</b>	<b>11,571</b>	<b>100%</b>
Current Liabilities	2,374	19%	2,004	17%
L-T Liabilities and Others	90	1%	91	1%
<b>Stockholders' Equities</b>	<b>10,027</b>	<b>80%</b>	<b>9,476</b>	<b>82%</b>

# Cash Flows- Consolidated

In NT\$ million	1Q 2016 (Reviewed)	1Q 2015 (Reviewed)
Cash and cash equivalents at beginning of period	2,336	1,928
Cash flows from operating activities	663	241
CAPEX	(263)	(269)
Short-term borrowings	(16)	86
Others	(160)	22
Cash and cash equivalents at end of period	2,560	2,008

# 2016 Product Launch Plan

API	Region	Indication	Brand Marketer	Regional Sales	WW Sales
Azacitidine	USA	Myelodysplastic syndromes (MDS)	Celgene	US\$248.1M	US\$751.6M
Desmopressin Acetate	USA	Polyuria	Ferring	US\$150.1M	US\$395.8M
Entecavir	USA Singapore Australia	Hepatitis B Virus (HBV)	Bristol-Myers	US\$262.5M (USA only)	US\$1,576.6M
Flumazenil	Korea	Reversal of the sedative effects of benzodiazepines	Roche	N/A	US\$84.0M
Gemcitabine HCl	Middle East	Pancreas, Lung, Ovary, Breast Cancers.	Eli Lilly	N/A	US\$547.9M
Tamsulosin HCl	USA	Benign Prostatic Hyperplasia (BPH)	Boehringer Ingelheim	US\$410.0M	US\$1,818.4M

Source: : IMS Data (2014Q4-2015Q3)

 Launched



# Pipeline Outlook

- ✓ 4-6 new launches
- ✓ 1<sup>st</sup> co-developed US ANDA launched

- ✓ 5-6 new launches
- ✓ 1<sup>st</sup> home-made drug US ANDA filing

- ✓ 5-6 new launches
- ✓ 1<sup>st</sup> home-made drug launched in US
- ✓ 3 drug products launched in China

2016

2017

2018

2019

2020

- ✓ 3-5 new launches
- ✓ 1<sup>st</sup> self-developed US ANDA launched

- ✓ 6-8 new launches
- ✓ 1 drug product launched in China
- ✓ Chinese CFDA inspection at SPC
- ✓ US FDA inspection at INJ



## Brand Quality with Asian Advantages

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

