



# ScinoPharm Management Presentation

**TWSE 1789**

**February 3, 2015**



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# Table of Content

- Overview of ScinoPharm
- Financial & Operating Results in Q4, 2014
- Progress Made in China
- Business Updates

# Overview of ScinoPharm

- An API + ANDA Company

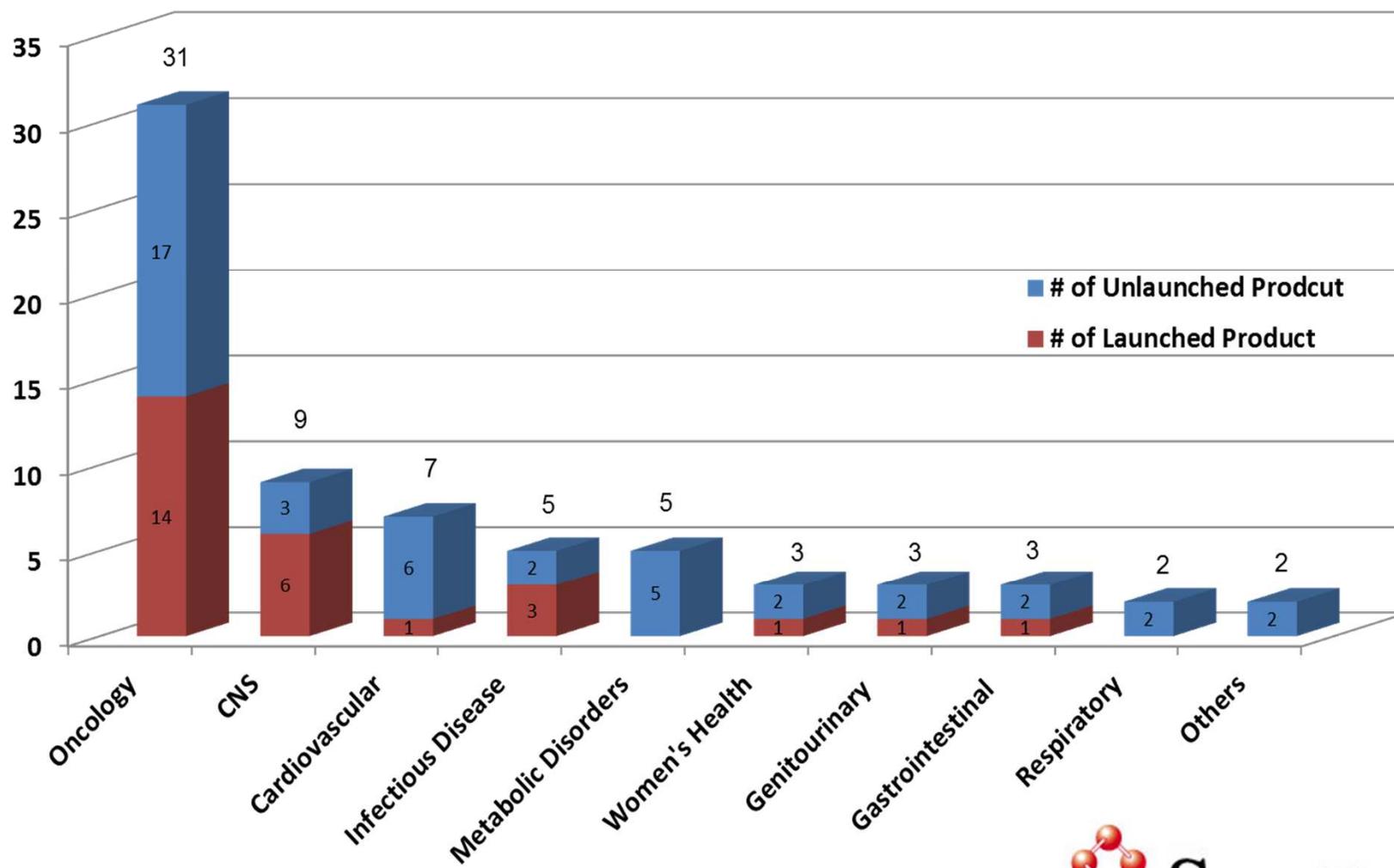
Active Pharmaceutical Ingredients  
Abbreviated New Drug Application

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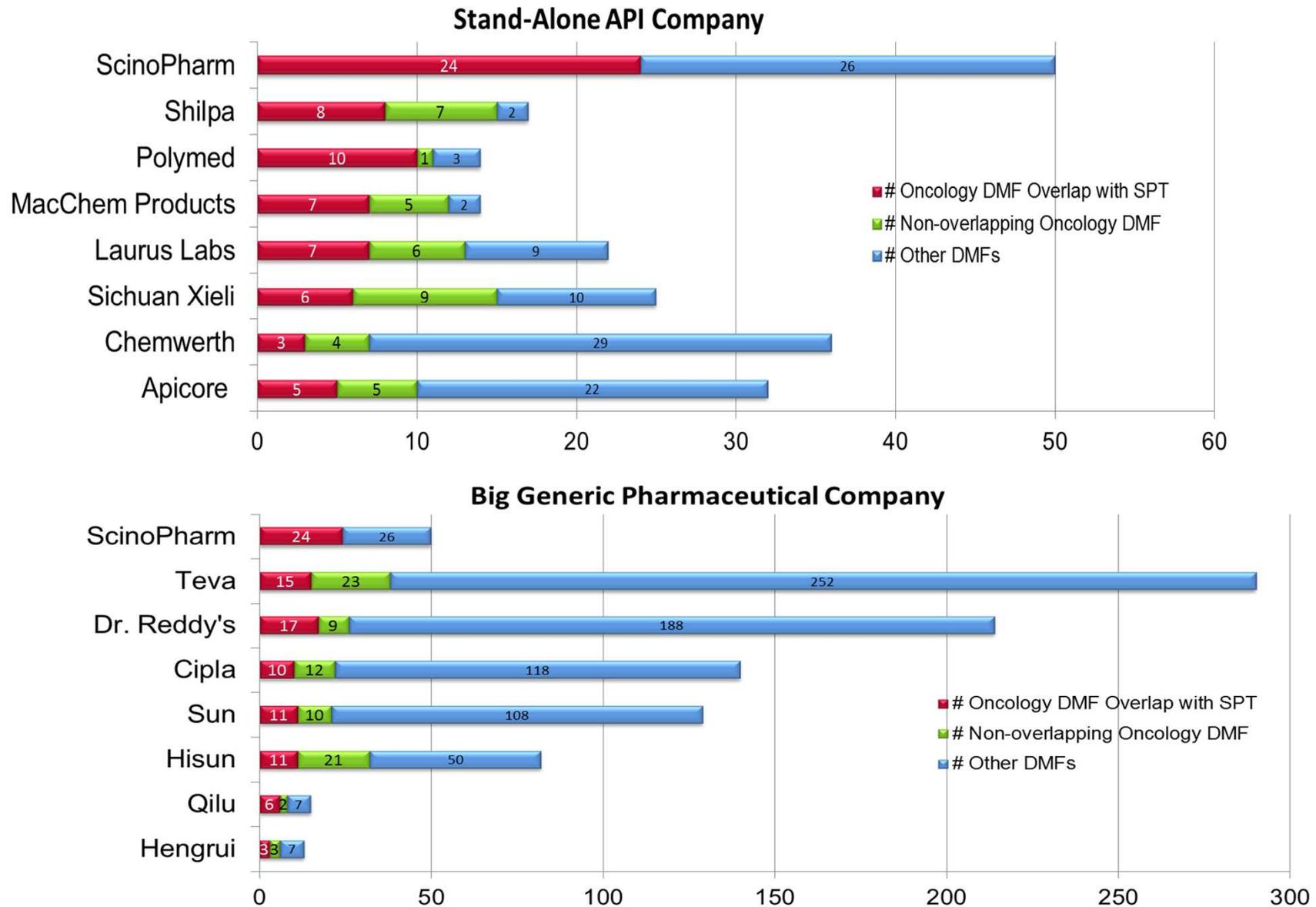
# Business Overview

- Established in 1997 in Taiwan and listed on TWSE in 2011, current market cap around US\$1.2 billion
- 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 (694 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; The Qualified Asian supplier to provide APIs to global market for multiple commercial NCEs

# Strong Generics Product Portfolio



# ScinoPharm - Oncological API Leader



# Diversified CRAM Portfolio

Stage	MFG Site	First Launch Year	Indication	Location
Commercial	SPT	2005	Eluting Stent	US
Commercial	SPT	2009/2013	Skin Infection/HAP	US/EU
Commercial	SPT	2011	Depression	US
Commercial	SPT	2012	Obesity	US
Commercial	SPT	2013	Seizure	US
Stage	MFG Site	Est. NDA Filing Year	Indication	Location
Phase III	SPT	2014*	Infections	US
Phase III	SPT	2016	Prostate & Ovarian Cancer	EU
Phase III	SPT	2016	Prostate Cancer	US
Phase III	SPT	2017	Seizure	US
Phase III	SPT	2017	Parkinson's Disease	US
Phase III	SPT	2017	Opioid-Induced Constipation	US
Phase III	SPC	2016-2017	Ovarian Cancer	CN
Phase III	SPC	2016	Hypogonadism	US
Phase III	SPC	2017	Cancer	CN

\* Filed

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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

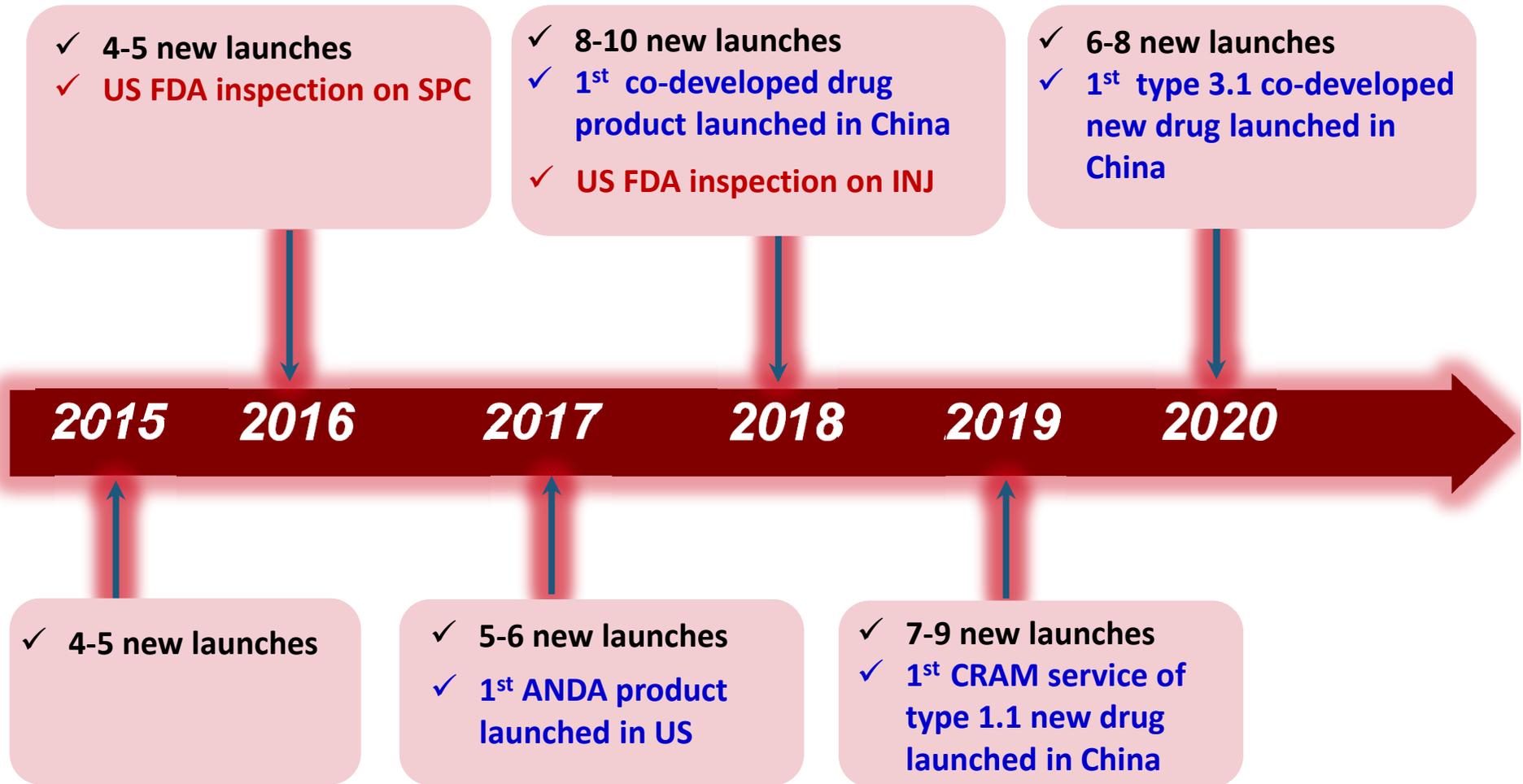
- Expanding formulation portfolio
- Building on-site oncological injectable facility and establishing a complete supply chain of oral products
- Promoting our formulations via strategic alliance, especially in China and US
- Acquiring critical resources via M&A

# Strategic Alliances

\* Already launched

Partner	Product	Indications	Region	Launch Year(E)	Remarks
Genovate	Entecavir	Hepatitis B Viral	TW*/ CN	2013*/ 2019	1 <sup>st</sup> co-developed formulation product launch
Sagent	Oncological Injectable	Myeloid Leukemia	US	2017	1 <sup>st</sup> US ANDA filing to trigger US FDA inspection in Changshu site
Foresee	Leuprolide	Prostate cancer	US	2018	505(b)2 NDA CRAM + Equity
Coland	Bortezomib	Multiple Myeloma	CN	2018	1 <sup>st</sup> co-developed drug in China to trigger CFDA inspection in Changshu
	Azacitidine	MDS	CN	2019	Co-developed formulation
Lee's Pharma	Fondaparinux	Anti-thrombotic	CN	2019	Co-developed formulation
	Travoprost Bimatoprost	Glaucoma	CN	2020	Co-developed formulation
Nanjing King Friend	Regadenoson	Stress agent for heart scan	CN	2020	1 <sup>st</sup> type 3.1 co-developed new drug in China

# Pipeline Outlook



# **Financial & Operating Results**

# Cumulative P&L - Consolidated

In NT\$ million, except for EPS	1Q~4Q,'14 (Unaudited)	1Q~4Q,'13 (Audited)	YoY
Net Sales	4,098	5,088	-19%
Gross Profit	1,600	2,543	-37%
<i>Gross margin</i>	<i>39%</i>	<i>50%</i>	
Operating Expenses	(1,041)	(1,145)	-9%
Operating Income	559	1,398	-60%
<i>Operating margin</i>	<i>14%</i>	<i>27%</i>	
Other Rev.(Exp.)	43	11	291%
Net Income before Tax	602	1,409	-57%
Net Income after Tax	484	1,273	-62%
<i>Net margin after tax</i>	<i>12%</i>	<i>25%</i>	
EPS (after tax)	0.69	1.81	-62%

# Balance Sheet- Consolidated

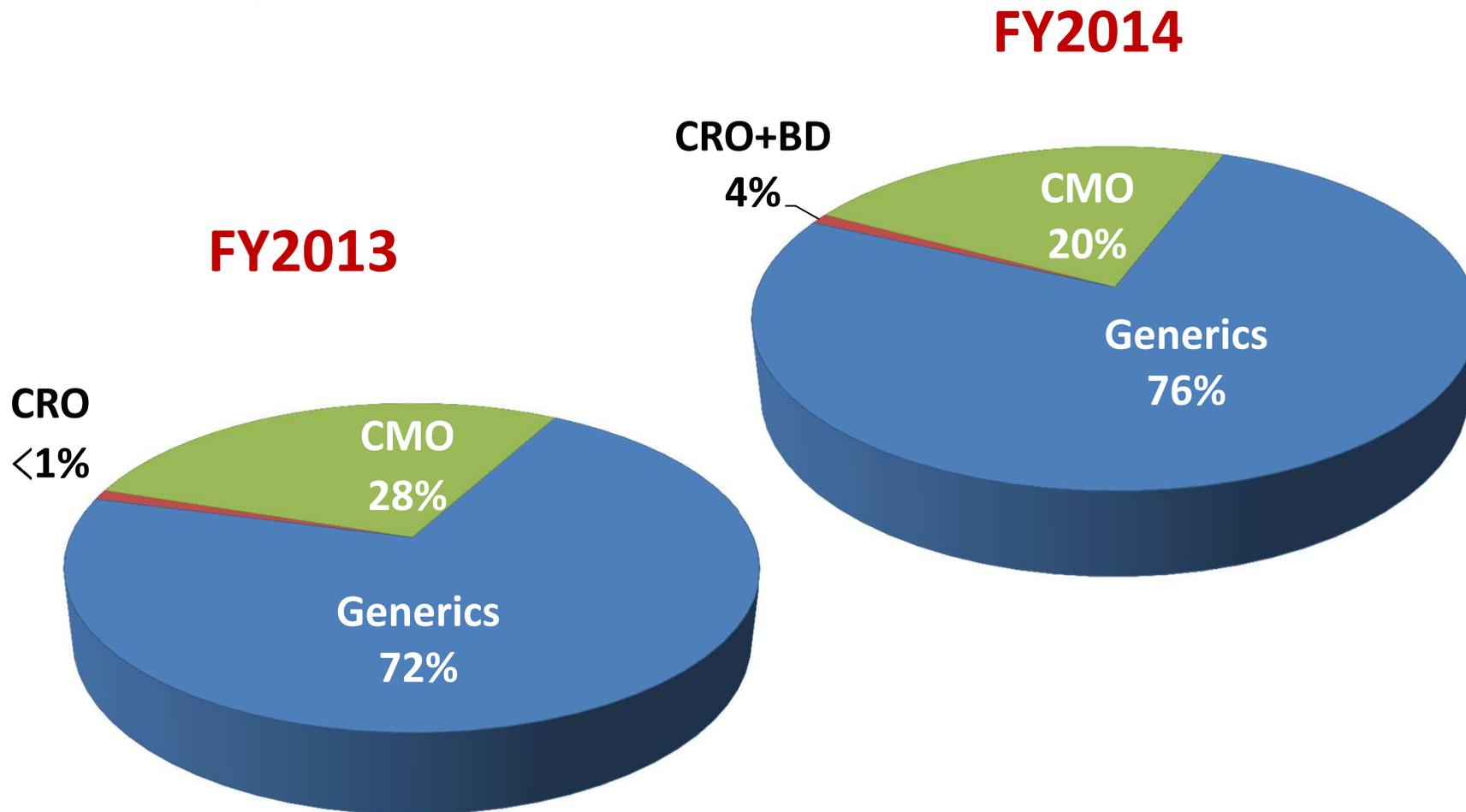
In NT\$ million	2014/12/31 (Unaudited)		2013/12/31 (Audited)	
Cash and Cash Equivalents	1,928	17%	2,289	20%
Accounts Receivable	523	5%	971	8%
Inventories	2,449	22%	2,512	22%
Long-Term Investments	248	2%	258	2%
Property, plant and equipment	5,065	44%	4,214	37%
Others	1,159	10%	1,240	11%
<b>Total Assets</b>	<b>11,372</b>	<b>100%</b>	<b>11,484</b>	<b>100%</b>
Current Liabilities	1,918	17%	1,775	15%
L-T Liabilities and Others	74	1%	66	1%
<b>Stockholders' Equities</b>	<b>9,380</b>	<b>82%</b>	<b>9,643</b>	<b>84%</b>



# Cash Flows- Consolidated

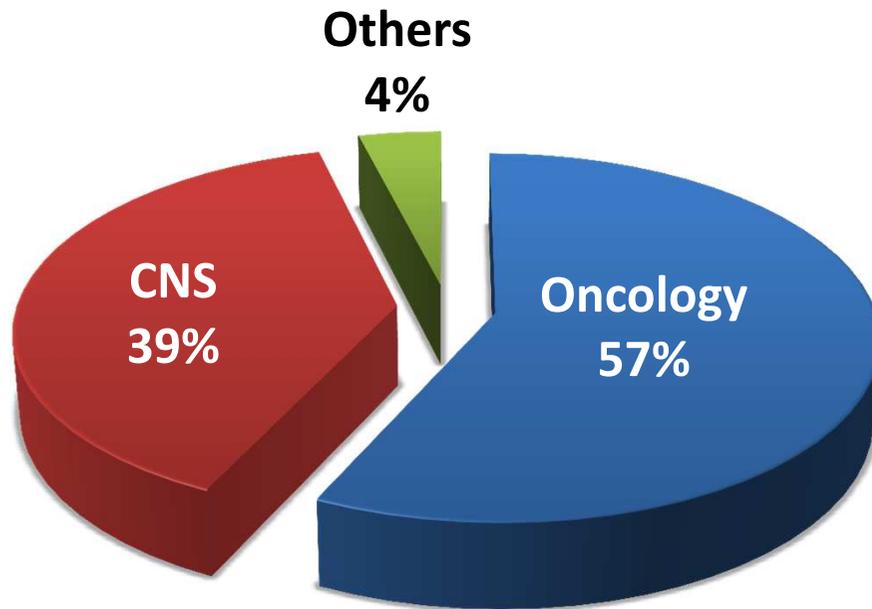
In NT\$ million	1Q~4Q 2014 (Unaudited)	1Q~4Q 2014 (Audited)
Cash and cash equivalents at beginning of period	2,289	3,035
Cash flows from operating activities	888	939
CAPEX	(1,018)	(1,226)
Long-term Investment	0	(107)
Short-term borrowings	588	426
Cash Dividends	(811)	(780)
Others	(8)	2
Cash and cash equivalents at end of period	1,928	2,289

# Sales by Business

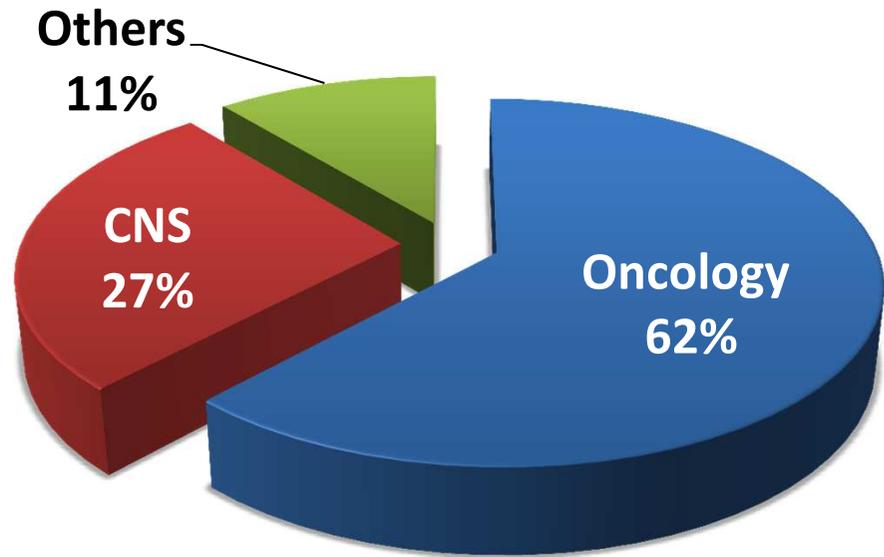


# Sales by Indications

**FY2013**



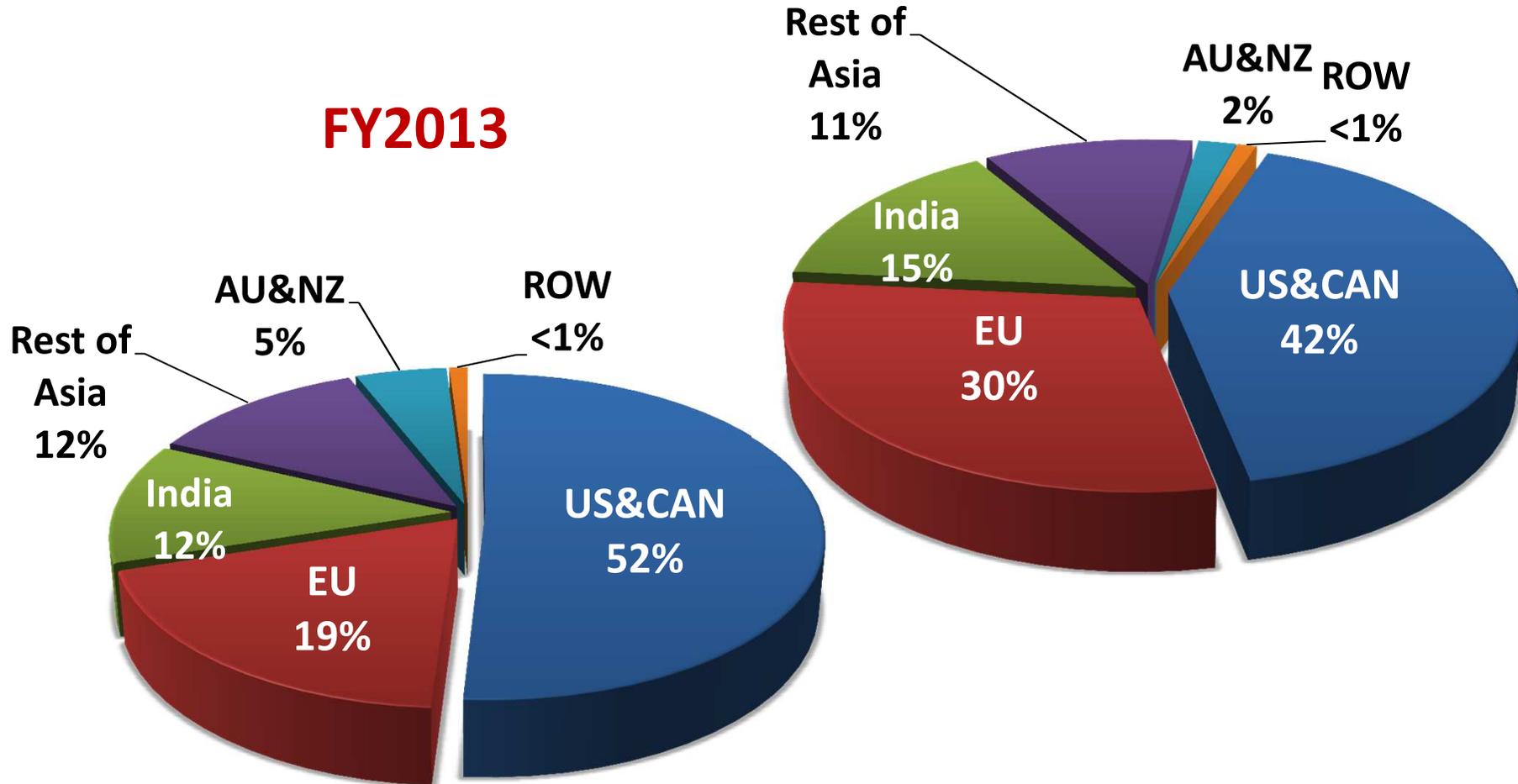
**FY2014**

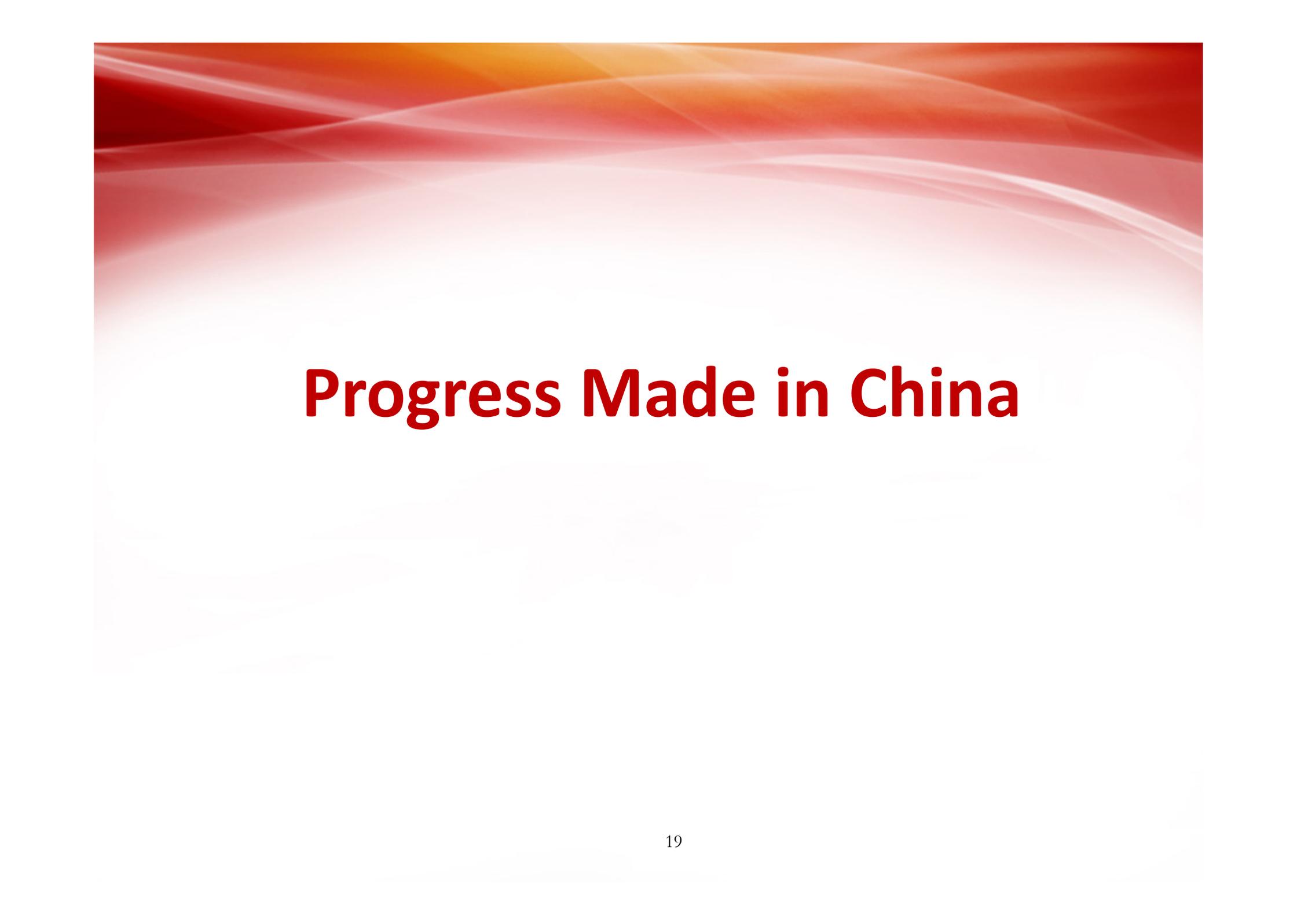


# Sales by Region

FY2014

FY2013





# **Progress Made in China**

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# Golden Opportunities in China

- Government's 12<sup>th</sup> five-year plan encourages pharma industry to grow at a CAGR of 20%
- **Tighten GMP requirements to align with US/EU**
- Motivate drug makers to improve quality by applying for US ANDAs, which need SPT's world class APIs
- **MNCs and emerging virtual-model players create huge needs in API contract manufacturing in China for compliance**
- ScinoPharm timely captures oncological API needs via importing from Taiwan and local made in Changshu sites

# Portfolio Fits China's Demands

Rank	Therapeutic indication	2012 China Market Share	# of SP's API candidates
1	Anti-cancer	18.9%	31
2	Anti infective	15.3%	5
3	Cardiovascular	14.5%	7
4	Metabolic	14.1%	5
5	Blood & Blood-Forming	11.8%	0
6	CNS	10.9%	9

Source: Blue Book on 6 major drugs of Chinese pharmaceutical industry , 2013

# Provide 6 of Top 10 Oncological Drugs

Rank	Drug	2012 Sales*	% of market	% of growth	SP's Pipeline
1	Paclitaxel	1144	9.15%	19.01%	V
2	Docetaxel	1049	8.39%	7.81%	V
3	Pemetrexed	688	5.50%	44.32%	V
4	Oxaliplatin	662	5.30%	5.51%	
5	Kangai	570	4.56%	31.94%	
6	Capecitabine	568	4.54%	15.45%	V
7	Rituximab	535	4.28%	18.69%	
8	Gemcitabine	454	3.69%	6.51%	V
9	Tegafur	446	3.57%	87.77%	V
10	Herceptin	387	3.09%	17.31%	

\* Unit: RMB Million

Source: Analysis Report of Anti-Cancer Drugs, 2014

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# Key Progress for China Market

## ScinoPharm Taiwan

Submitted drug import license applications for 10 APIs (5 for anti-cancer, 2 for cardiovascular, 1 for Alzheimer's disease, 1 for benign prostatic hyperplasia and 1 for Hepatitis B )

## ScinoPharm Changshu

- Obtained drug production permits for 9 APIs (6 for anti-cancer, 1 for anti-viral and 2 for glaucoma )
- Submitted 2 drug license applications for anti-cancer APIs

## Strategic Alliance

5 formulation development and 1 new drug projects smoothly undergoing. Expected to be commercially available in 2018-2020

# **Business Updates**

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# Injectable Plant Progress

- To be completed by Q2'15 and start registration batch production for liquid vial line by Q4'15. Expected to submit the 1<sup>st</sup> home-made ANDA in 2017 and pass US FDA inspection in 2018
- Target on biologics, high potent new drugs and small-volume, complicated and high unit-priced generics
- Offer CMO services for brand drugs and self-developed drug products in the initial stage
- Flexible in capacity expansion and capable for producing liquid/lyophilized vials and prefilled syringes

# 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*

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

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**Q***uestions*

**&**

**A***nswers*



## Brand Quality with Asian Advantages

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