



TWSE 1789

# ScinoPharm Management Presentation

## 2016 JP Morgan Healthcare Conference

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# Overview of ScinoPharm

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# Background

- Established in 1997 in Taiwan and listed on TWSE in 2011, current market cap around US\$1.2 billion
- 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
- 8 of 18 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

- 6.6 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

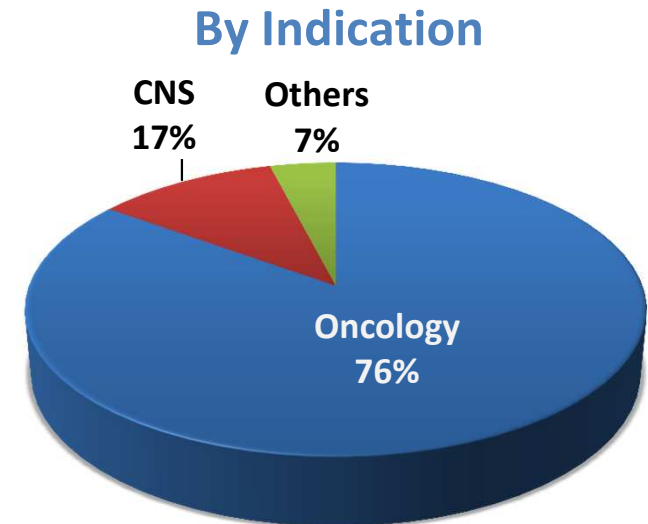
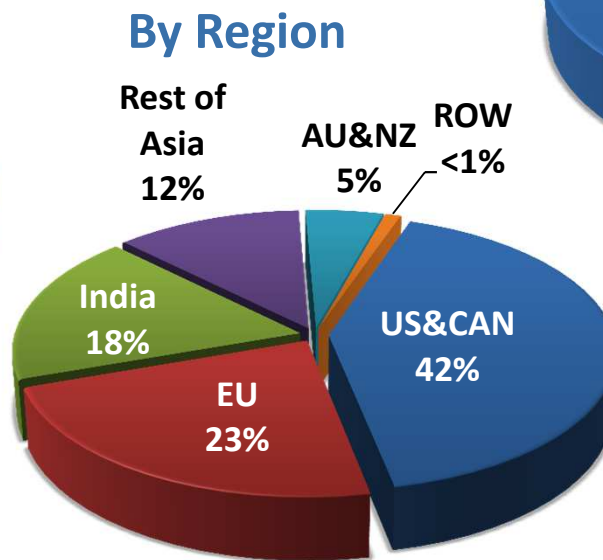
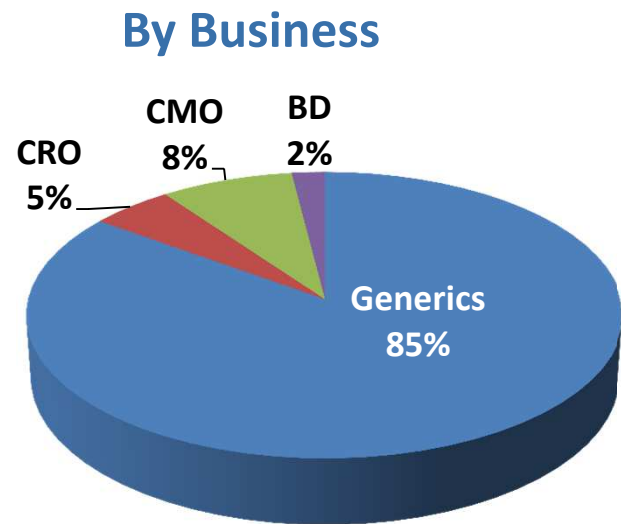


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## Business Overview

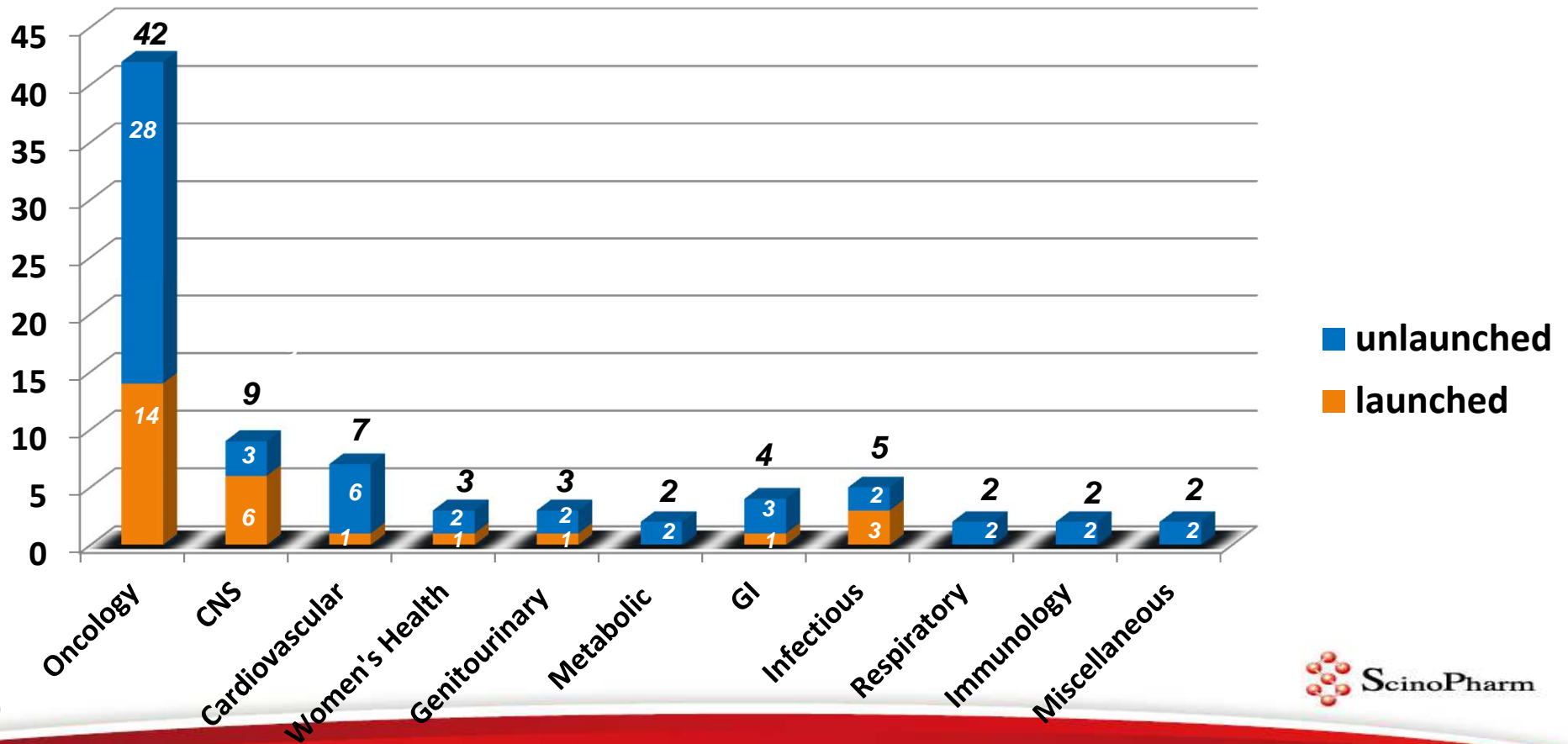
- Risk & return balanced model to offer APIs and sterile filling capability for both generic and new drugs
- 80+ generic APIs developed with 27 APIs launched; 55 US DMFs filed (733 DMFs WW), 29 US DMFs in oncology APIs
- 100+ NCE CRAM projects, with 5 launched and 6 in phase III for NDA filing in 2-3 years; The Qualified Asian supplier to provide APIs to global market for multiple commercial NCEs

# 2015 Sales Distribution





# 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	Seizure	US
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

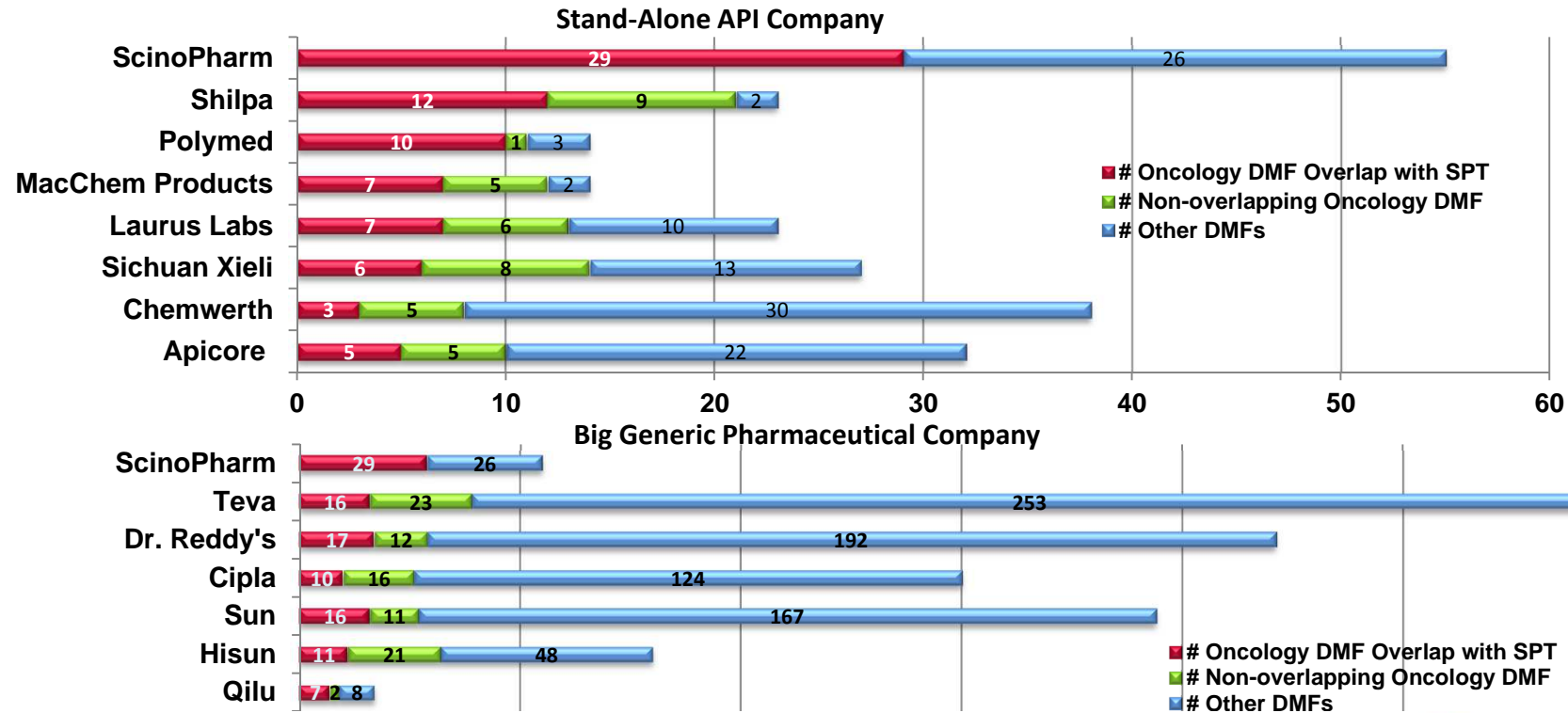
# Strategic Alliance Highlights

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	2021	Co-developed formulation
Lee's Pharma	Fondaparinux	Anti-thrombotic	China	2022	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	2021	1 <sup>st</sup> type 3.1 co-developed new drug in China
US partner	Project A	non-small cell lung cancer	US	2018	US NDA 505(b)2 & Paragraph IV filing
US & China partners	Project B	imaging agent	US	2018	Paragraph IV filing

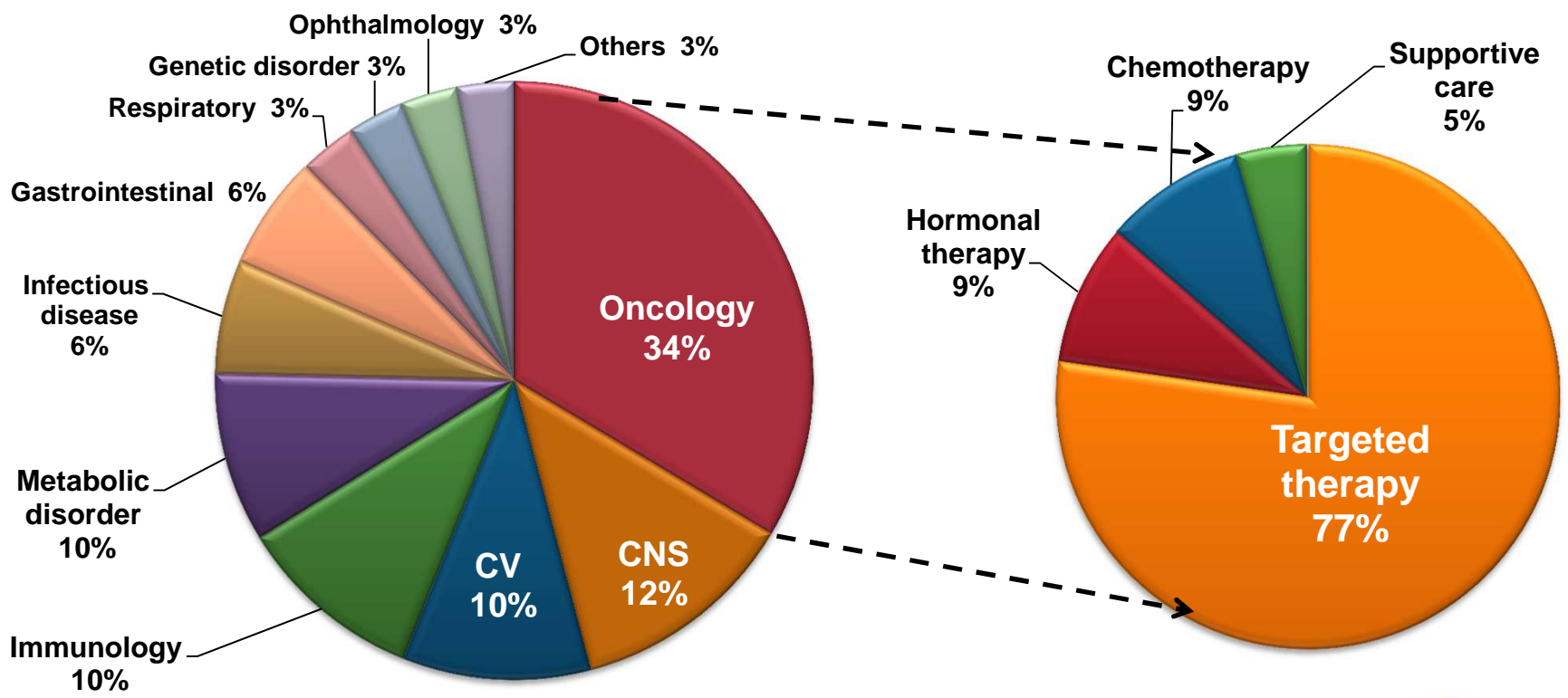
\* Already launched



# ScinoPharm - Oncology API Leader



# ScinoPharm Pipeline Echoes Therapy Trend





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# Forces Reshaping Chinese Pharma Market

- Policy reform expediting drug approvals, allowing new drug developers to own drug licenses without manufacturing sites
- Significantly lifting the cost structure & entry barrier in Chinese drug market, with a heavy focus on quality and innovation
- Motivating drug makers to improve quality by applying for US ANDAs, which need SPT's world class APIs
- MNCs and emerging virtual-model players creating huge needs in API contract manufacturing in China for global compliance

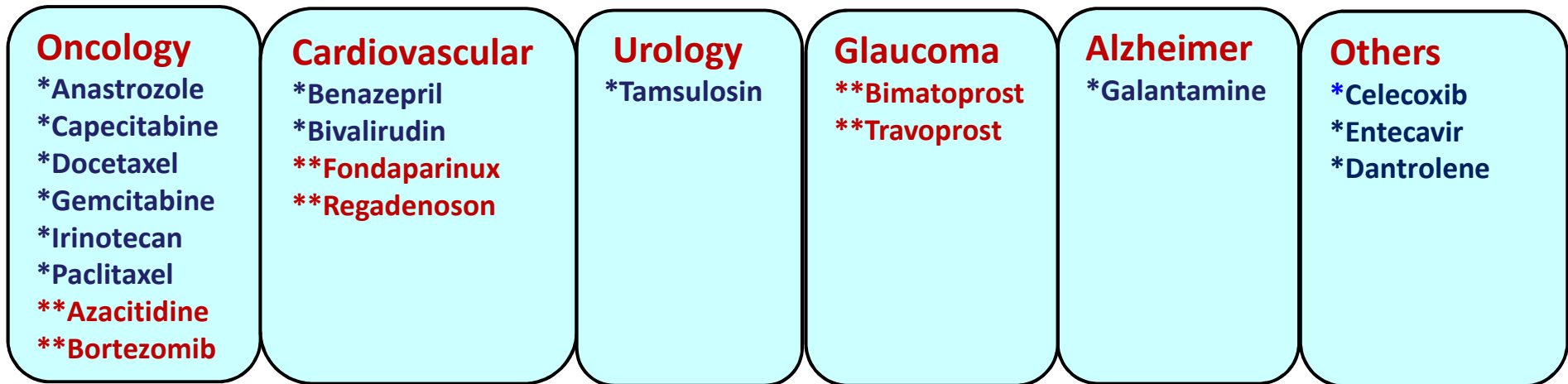
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# Advantages in Growing Chinese Market

- **Direct benefit from the new GMP standards and policy reform**
- **Tailor-made product portfolio for Chinese market**
- **Domestic presence plus world-class strengths in:**
  - \* **High-technical-barrier oncology APIs**
  - \* **Global first tier customer base**
  - \* **Quality and EHS/GMP compliance**
- **Bridge between Chinese and global markets**

# Portfolio for Chinese Aging Society

- 14 drug licenses applied and 6 collaborated with local marketers for popular age-related diseases in China
- **Benazepril as the first granted import drug license**



\* Submit drug import license applications or production permits

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

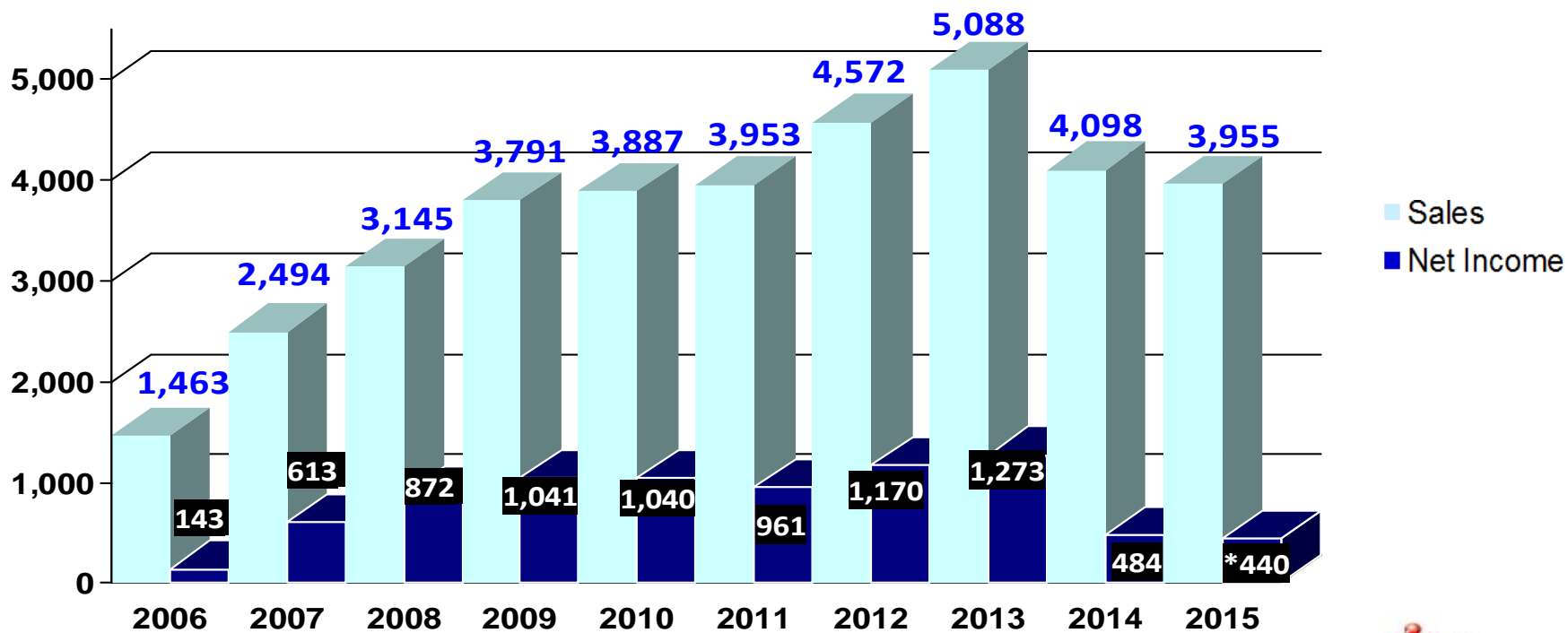


# Operating Results & Outlook

# Historical Performance

Unit: In NT\$ million

\* For Q1-Q3 only

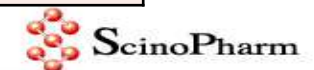


# Recent Financial

\* In NT\$ million

Year	2013	2014	Q1-Q3 or 9/30 2015
Total assets*	11,484M	11,372M	11,995M
Shareholders' equity*	9,643M	9,380M	9,701M
Sales*	5,088M	4,098M	2,925M
Net profit after tax*	1,273M	484M	440M
Earnings per share (NT\$)	1.88	0.69	0.60
Cash dividends (NT\$/share)	1.2	0.2	-
Stock dividends (NT\$/share)	0.4	0.4	-
Pay-out ratio	85%	87%	-

Note : All of the above figures represent consolidated information



# 2016 API Product Launches

Product Name	Region	Indications	Brand Marketer	Regional Sales*	WW Sales*
Azacitidine	USA	Myelodysplastic syndromes (MDS)	Celgene	US\$257.2M	US\$771.9M
Desmopressin Acetate	USA	Polyuria	Ferring	US\$140.1M	US\$393.3M
Entecavir	USA, Singapore, Australia	Hepatitis B Virus (HBV)	Bristol-Myers	US\$286M (USA only)	US\$1591.6M
Flumazenil	Korea	Reversal of the sedative effects of benzodiazepines	Roche	N/A	US\$86.2M
Gemcitabine HCl	Middle East	Pancreas, Lung, Ovary, Breast Cancers.	Eli Lilly	N/A	US\$583.4M
Tamsulosin	USA	Benign Prostatic Hyperplasia (BPH)	Boehringer Ingelheim	US\$411.1M	US\$1853.2M

Source \*IMS Data (2014Q3-2015Q2)



# 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
- ✓ 3 drug products launched in China
- ✓ 1<sup>st</sup> home-made drug launched in US

2016

2017

2018

2019

2020

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

- ✓ 6-8 new launches
- ✓ SPC China FDA inspection
- ✓ 3 drug products launched in China
- ✓ US FDA inspection at INJ







# Brand Quality with Asian Advantages

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

