



TWSE 1789

# ScinoPharm Management Presentation

## 2015 Morgan Stanley Asia Pacific Healthcare Day



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# Overview of ScinoPharm

- an **API + ANDA** Company

Active Pharmaceutical Ingredients

Abbreviated New Drug Application

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# Background

- Established in 1997 in Taiwan and listed on TWSE in 2011, current market cap around US\$830 million
- Major shareholders include Uni-President Group, National Development Fund, Taiwan Sugar, etc.
- Facility & organization built in Taiwan by experienced Syntex team, received multiple regulatory inspections from US FDA, EU, Australia, Japan, etc.
- Specializes in high potency (steroid/cytotoxic) APIs and expands to injectable formulations
- Expanding in China with a new GMP plant in Changshu & marketing base in Shanghai



# 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 cytotoxics/steroids
- US FDA approved & 250+ CGMP audits by customers
- 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
- 2 of 8 production lines equipped with high potency capabilities for cytotoxics
- cGMP designed facility for intermediates & high potency API
- Full scope capabilities in developing and manufacturing APIs from small to large scale for generic & CRAM
- Global market including China

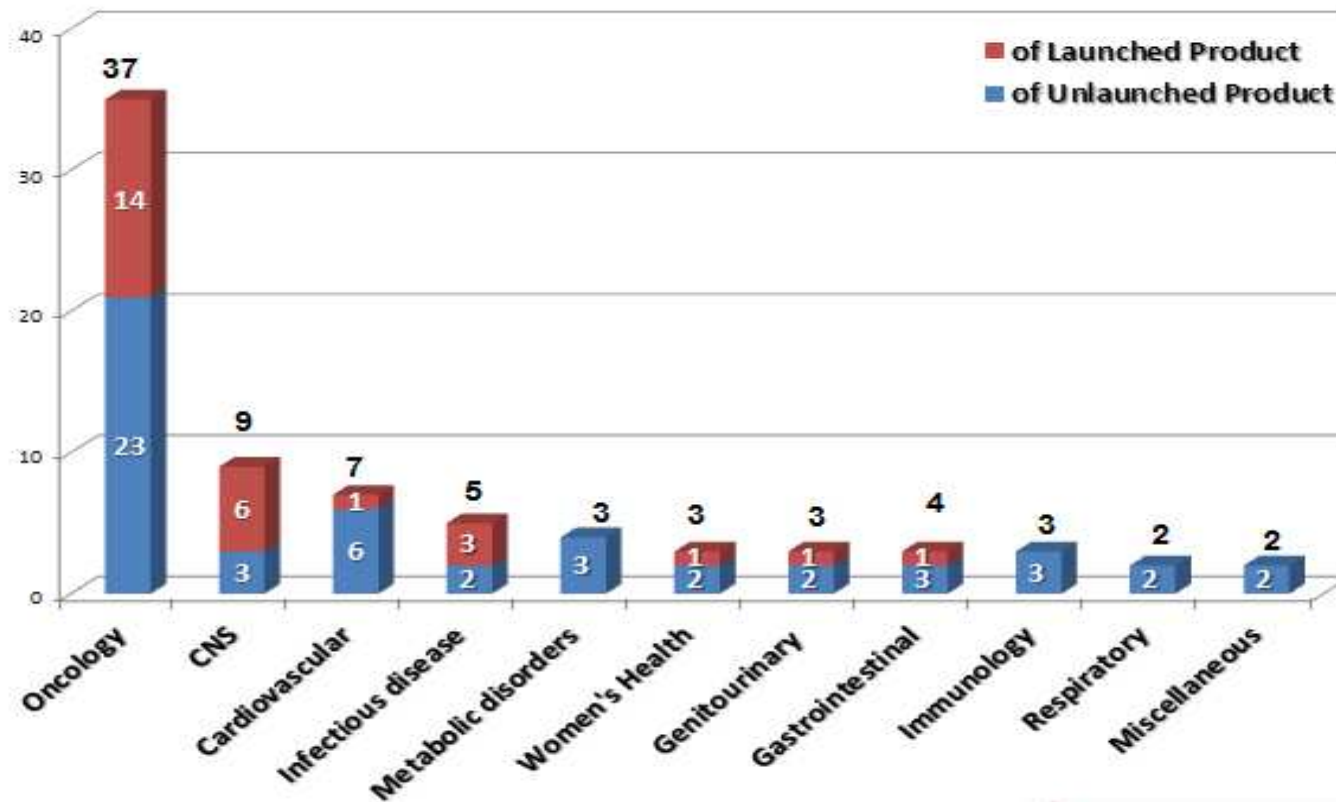


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## Business Overview

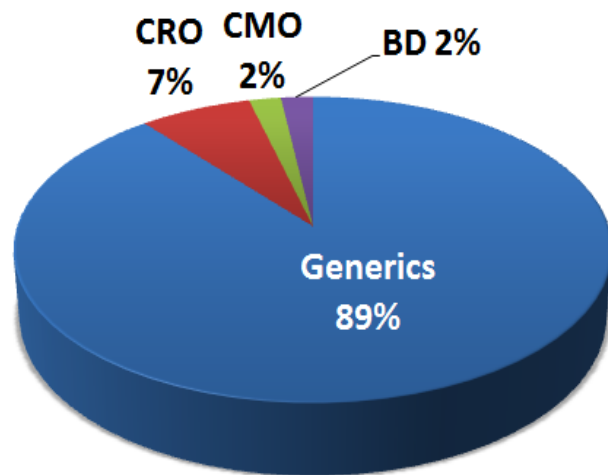
- Risk & return balanced model to offer APIs and fill/finish capability for both generic and new drugs
- 70 generic APIs developed with 27 APIs launched; 50 US DMFs filed (711 DMFs WW), 24 US DMFs in oncological APIs
- 80+ NCE CRAM projects, with 5 launched and 7 in phase III for NDA filing in 2-3 years; Qualified Asian supplier to provide APIs to global market for multiple commercial NCEs

# Strong Generics Product Portfolio



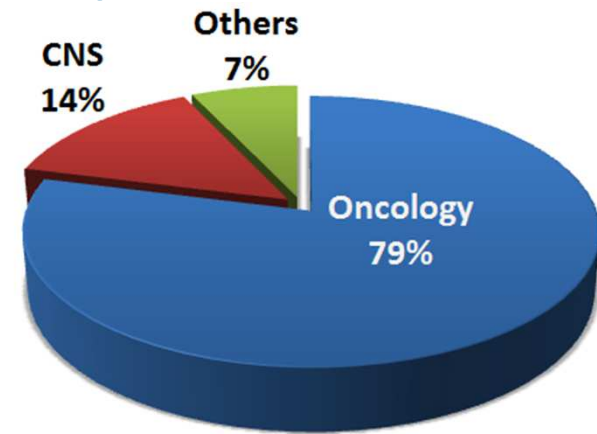
# Sales Breakdowns

## By Business

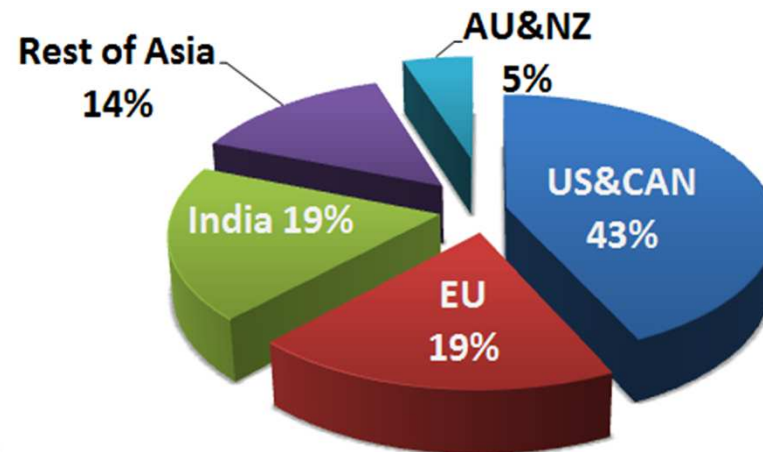


1H 2015

## By Indication

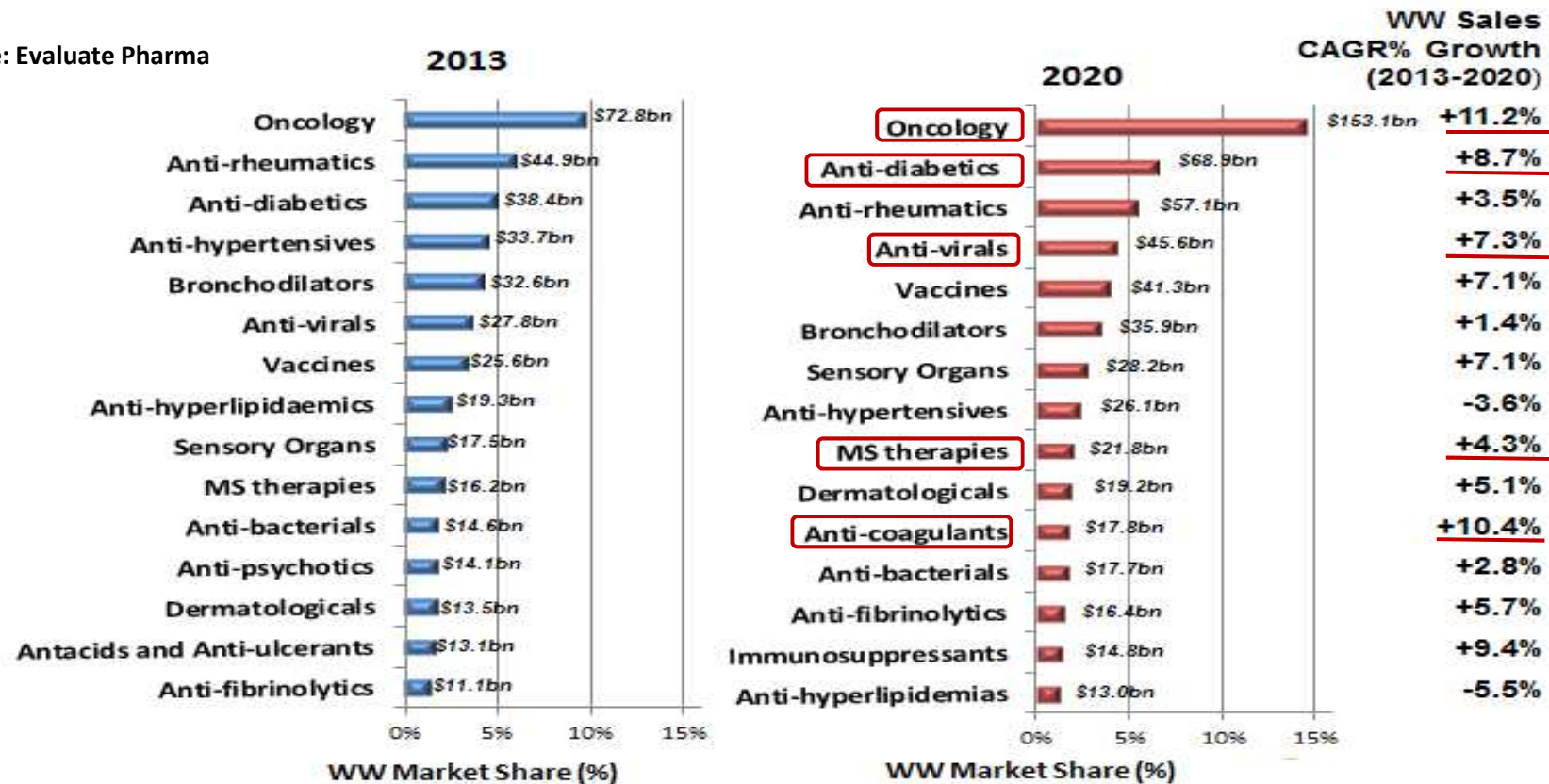


## By Region

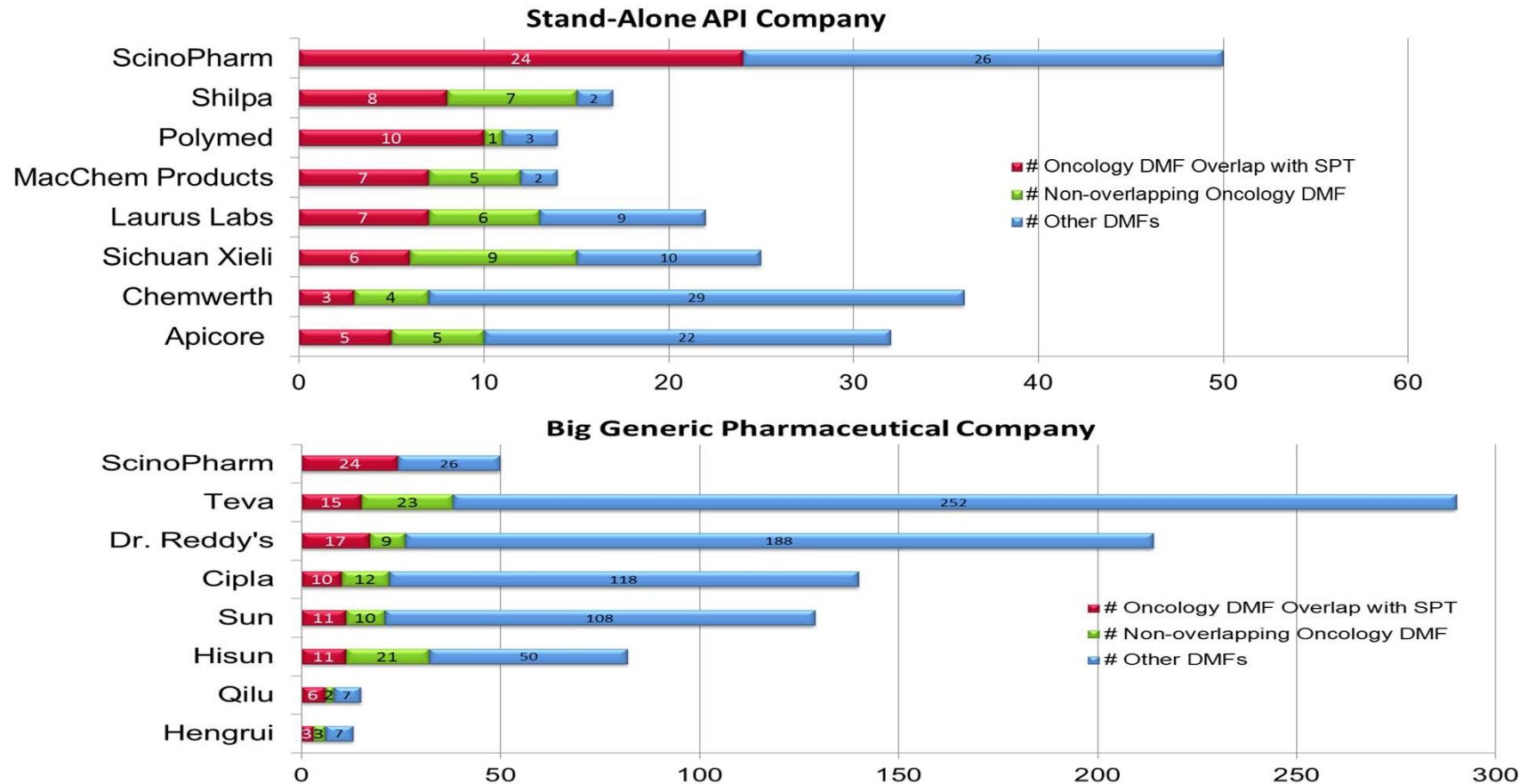


# Oncology as Worldwide Top 1 Therapy

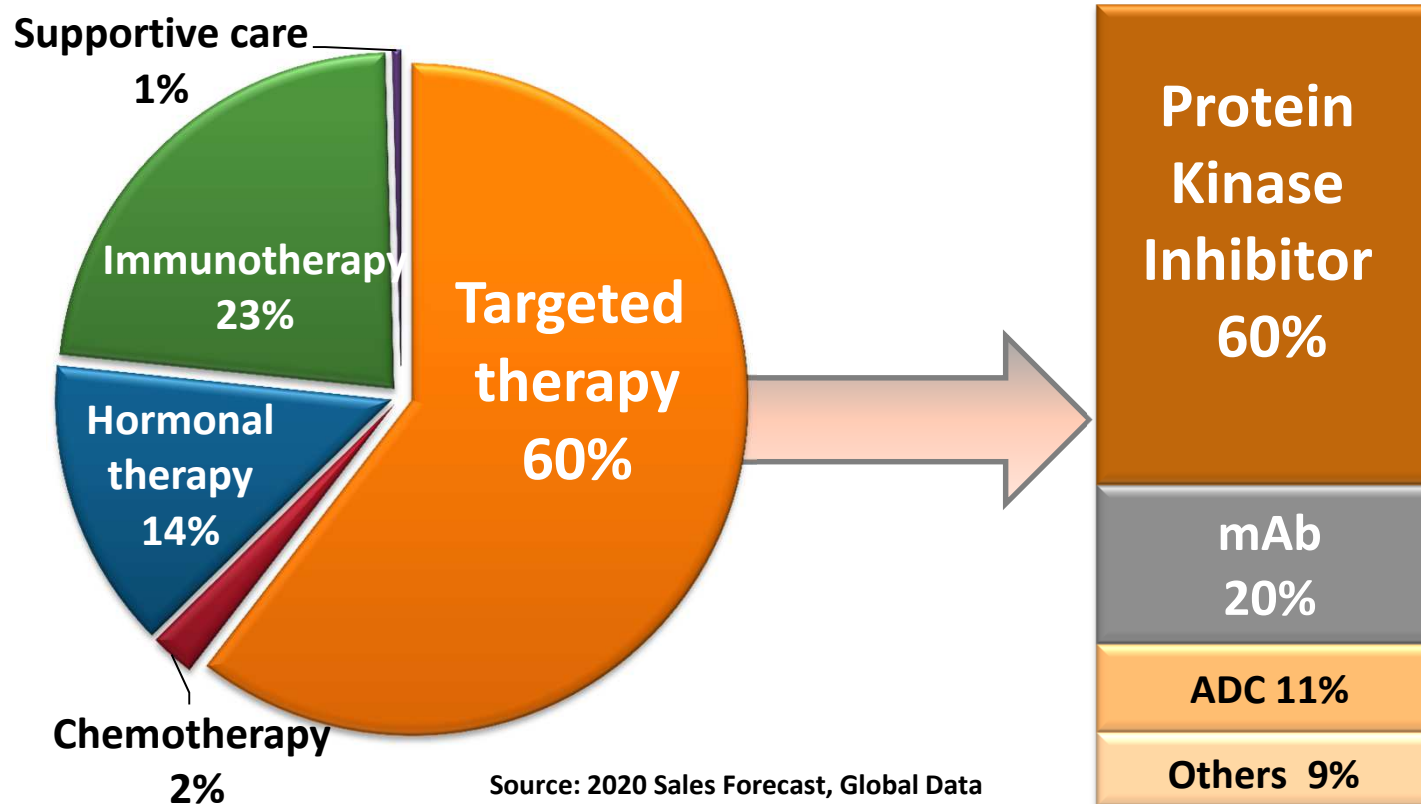
Source: Evaluate Pharma



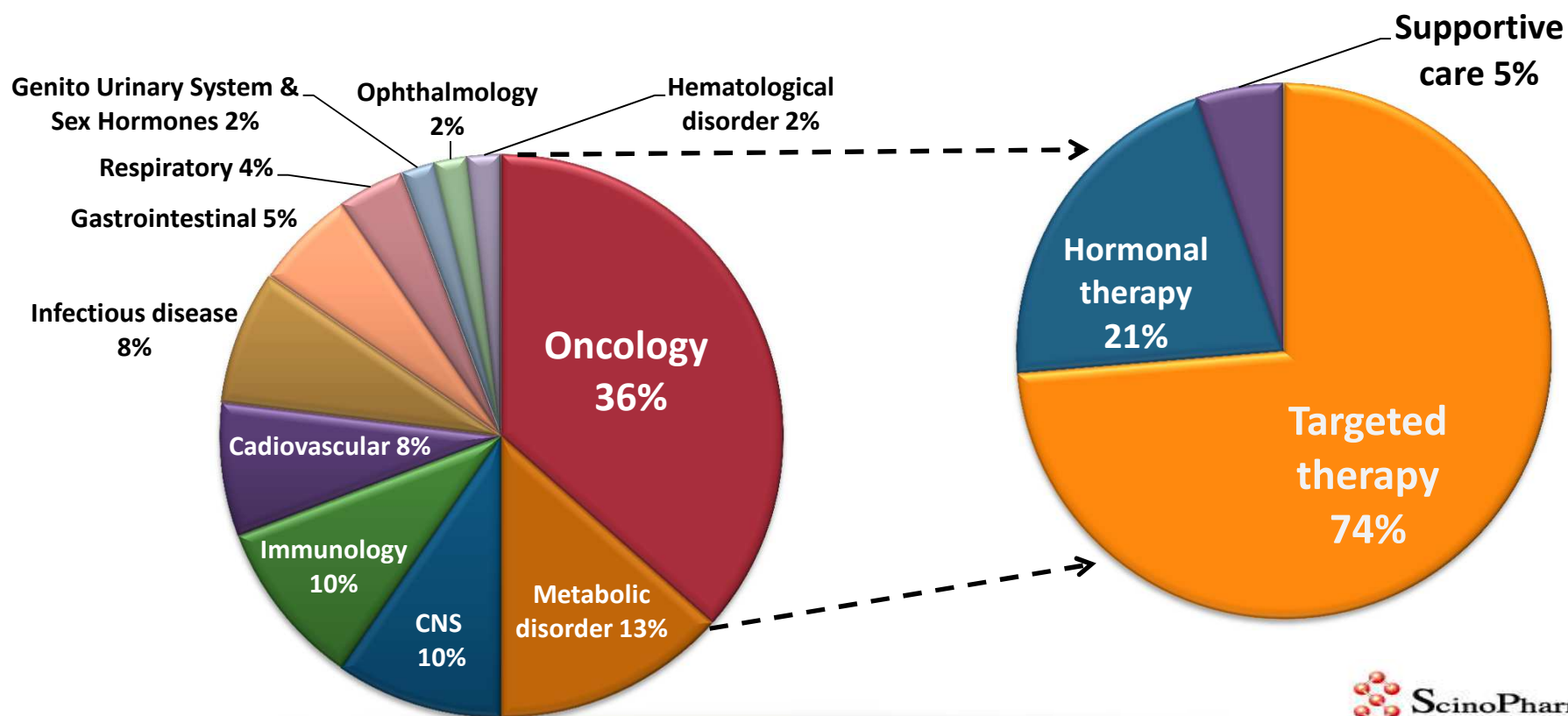
# ScinoPharm – Global Oncological API Leader



# Targeted Therapy Dominates Oncology



# ScinoPharm Pipeline Echoes Therapy Trend



# 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	2014	Infections	US
Phase III	2016	Prostate & Ovarian Cancer	EU
Phase III	2017	Prostate Cancer	US
Phase III	2016-2017	Ovarian Cancer	CN
Phase III	2017	Seizure	US
Phase III	2017	Parkinson's Disease	US
Phase III	2017	Opioid-Induced Constipation	US

# Strategic Alliances for Formulation

\* 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	Oncological Injectable	Myeloid Leukemia	US	2016	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	China	2019	1 <sup>st</sup> co-developed drug in China to trigger CFDA inspection in Changshu
	Azacitidine	MDS	China	2019	Co-developed formulation
Lee's Pharma	Fondaparinux	Anti-thrombotic	China	2019	1 <sup>st</sup> self-developed drug in China
	Travoprost Bimatoprost	Glaucoma	China	2020	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



# **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 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: Two US ANDA filed
- Building on-site oncological injectable facility and establishing a complete supply chain
- Acquiring critical resources via M&A
- Sustaining B2B model, promoting our formulations via strategic alliance, especially in China and US

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# Golden Opportunities in China

- Government's strong support carrying into 13<sup>th</sup> five-year plan to encourage pharma industry's 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

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# Policy Reforms to Expedite Drug Approvals

- Redefine new drugs and generics in China
- Elevate the overall quality and efficacy requirements of submissions
- Encourage innovative drugs via fast track approval
- Allow new drug developers to own drug licenses without manufacturing sites
- Clear the application backlog by discouraging redundant filings and fee raises
- Impose severe penalties on fraudulent data/activities on research & trials

*This reform will significantly lift the cost structure & entry barrier to Chinese market, with a heavy focus on quality and innovation*



# **Operating Results & Outlook**

# 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%

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# 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

# 2015 Product Launch Plan

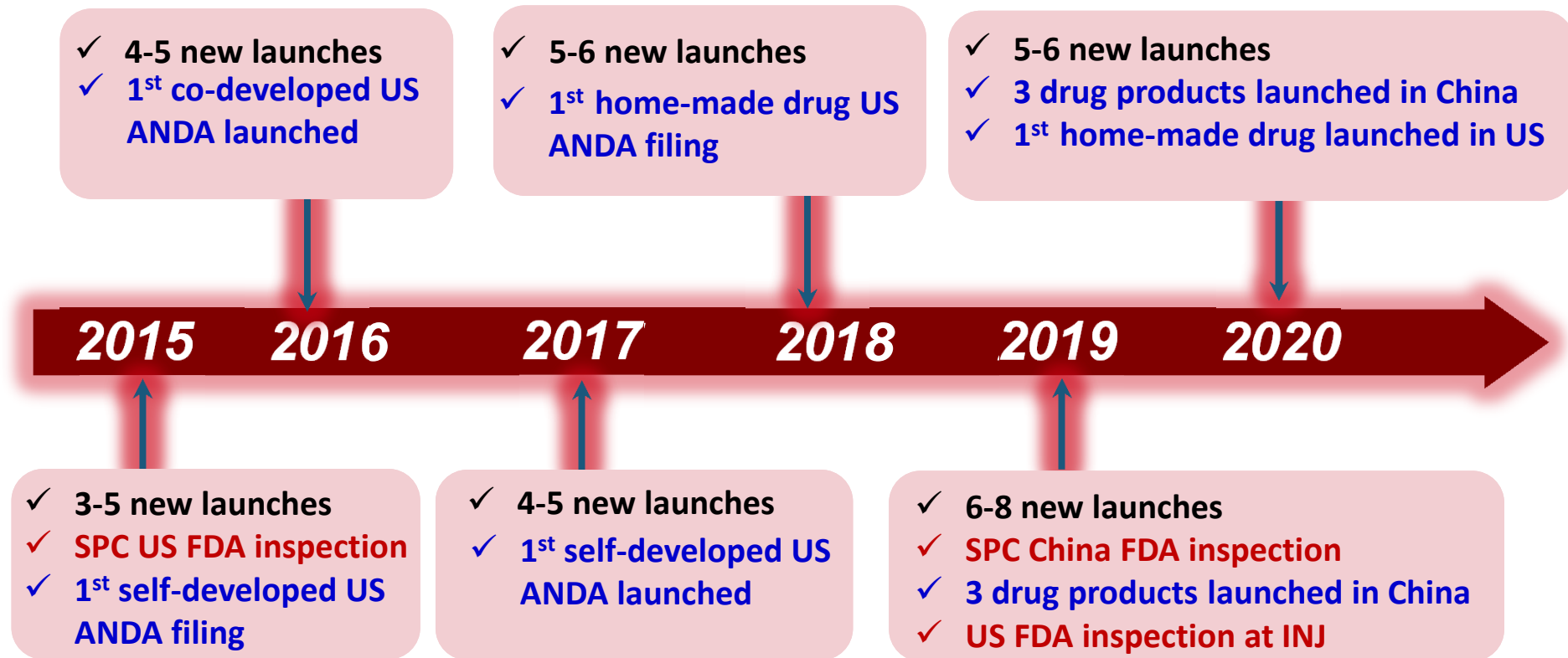
API	Region	Indications	Brand Marketer	Regional Sales	WW Sales
Azacitidine	US	MDS Oncology	Celgene	US\$323MM*	US\$815MM*
Benazepril	CN	Hypertension, CV	Novartis	US\$65MM**	US\$480MM*
Desmopressin	US	Polyuria	Ferring	US\$131MM*	US\$395MM*
✔ Letrozole	JP	Breast Cancer	Novartis	US\$51MM**	US\$581MM*
Tamsulosin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

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

✔ Launched



# Pipeline Outlook





## Brand Quality with Asian Advantages

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

