

**TWSE 1789** 

#### **ScinoPharm Management Presentation**

**Fourth Quarter 2015 Investor Conference** 

February 18, 2016



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# **Overview of ScinoPharm**

An API + ANDA Company

Active Pharmaceutical Ingredients
Abbreviated New Drug Application

#### **Business Overview**

- Established in 1997 in Taiwan, listed on TWSE in 2011, and honored as the top 5% TWSE issuer in info disclosure & corporate governance
- Specialized in high potency (cytotoxic/steroid) APIs and integrating to injectable formulations
- Facility built in Taiwan and expanding in China with a marketing base in Shanghai and a newly US FDA approved plant in Changshu
- 80 generic APIs developed with 27 APIs launched; 55 US DMFs filed (734 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
- Fully Complied with world-class cGMP and regulatory requirements;
   Certified by US FDA, EMA, Australian TGA, Japanese PMDA, Korean FDA, Mexican COFEPRIS, etc.



## **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 oncology medical needs of high prevalence in Asia

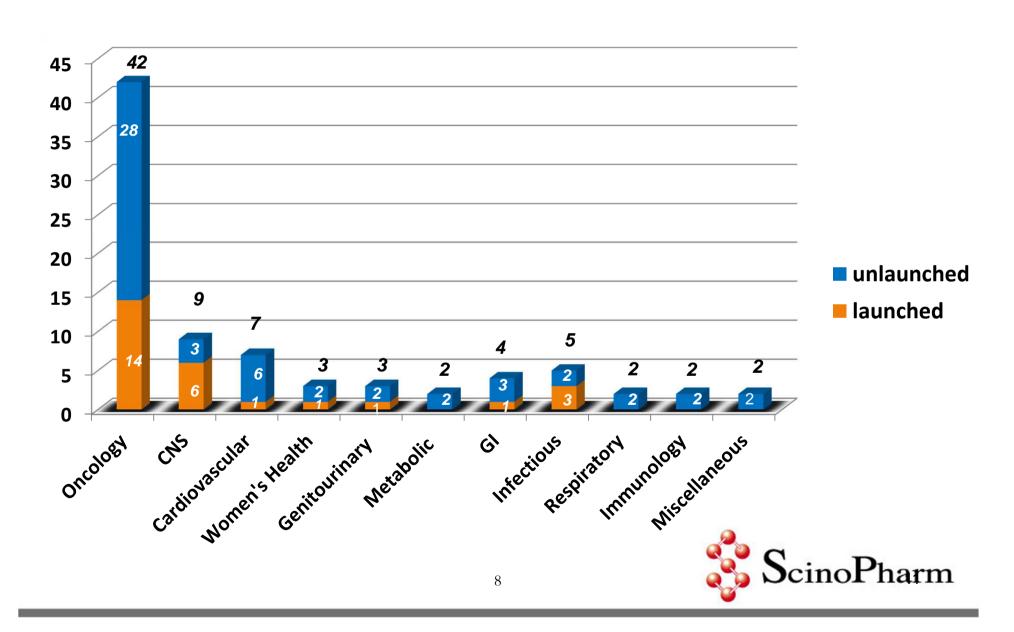


## **Keys to Generic Formulation Business**

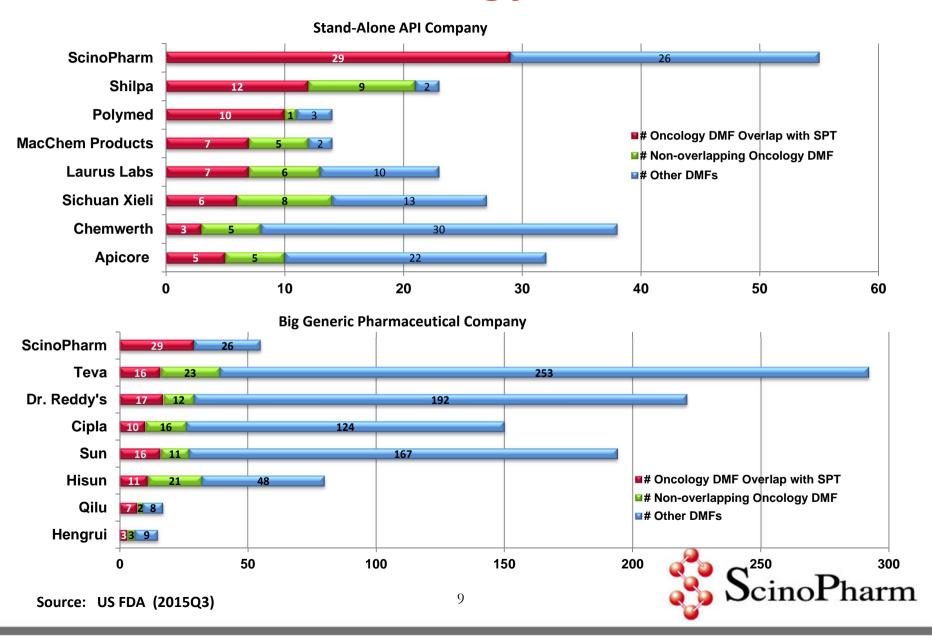
- Expanding formulation portfolio
- Building on-site injectable facility and forming a complete supply chain of drug products
- Promoting our formulations via strategic alliance, especially in China, US, & EU
- Acquiring critical resources via M&A



# **Strong Generics Product Portfolio**



## ScinoPharm - Oncology API Leader



# **Strategic Alliance Highlights**

\* Launched already

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, 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	1st 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	Strategic alliance collaboration in formulation	
	Travoprost Bimatoprost	Glaucoma	China	2022	Strategic alliance collaboration in 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 & Chinese partners	Project B	imaging agent	US	2019	Paragraph IV filing	

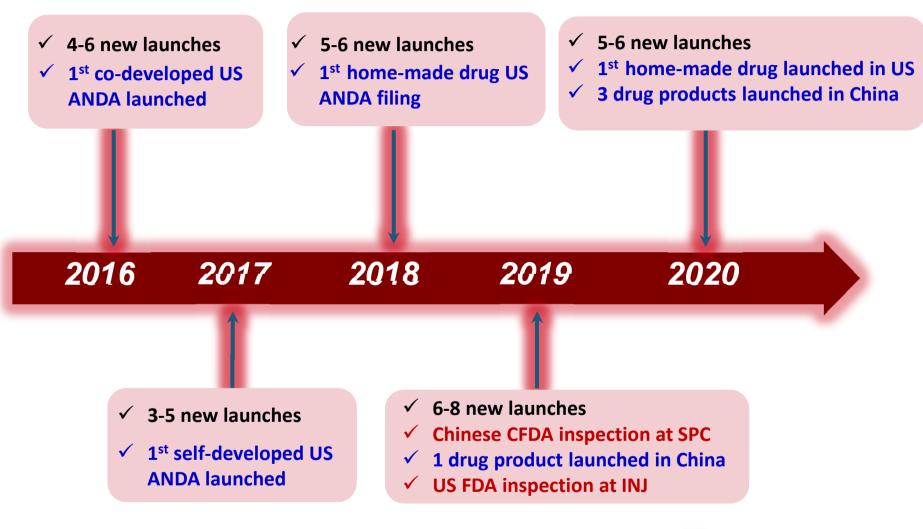
## **2016 API Product Launch Plan**

Product Name	Region	Indications	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 HCI	Middle East	Pancreas, Lung, Ovary, Breast Cancers.	Eli Lilly	N/A	US\$547.9M
Tamsulosin HCI	USA	Benign Prostatic Hyperplasia (BPH)	Boehringer Ingelheim	US\$410.0M	US\$1,818.4M

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



## **Pipeline Outlook**





# **Financial & Operating Results**

## **Profit & Loss - Consolidated**

In NT\$ million, except for EPS	FY 2015 (Unaudited)	FY 2014 (Audited)	YoY
Operating Revenue	3,955	4,098	-3%
Gross Profit	1,677	1,600	5%
Gross margin	42%	39%	
Operating Expenses	(927)	(1,041)	-11%
Operating Income	750	559	34%
Operating margin	19%	14%	
Other Rev. (Exp.)	53	43	23%
Net Income before Tax	803	602	33%
Net Income after Tax	635	484	31%
Net margin after tax	16%	12%	
EPS (after tax)	0.87	0.66	32%

## **Balance Sheet- Consolidated**

In NT\$ million	2015/12/31 (Unaudited)		2014/12/31 (Audited)	
Cash and Cash Equivalents	2,336	19%	1,928	17%
Accounts Receivable	867	7%	523	5%
Inventories	2,169	18%	2,449	22%
Long-Term Investments	339	3%	248	2%
Property, Plant & Equipment	5,171	42%	5,065	44%
Other Current/Non-Current Assets	1,340	11%	1,159	10%
Total Assets	12,222	100%	11,372	100%
Current Liabilities	2,275	18%	1,918	17%
Long-Term & Other Liabilities	90	1%	74	1%
Stockholders' Equities	9,857	81%	9,380	82%

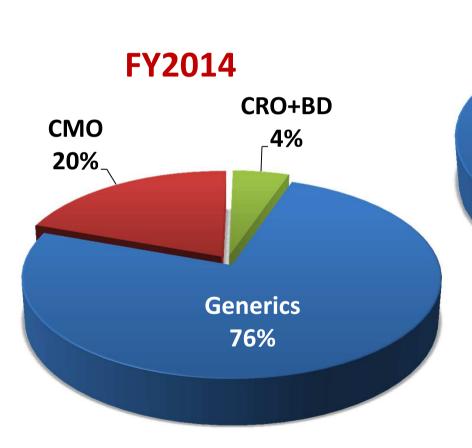
## **Cash Flows- Consolidated**

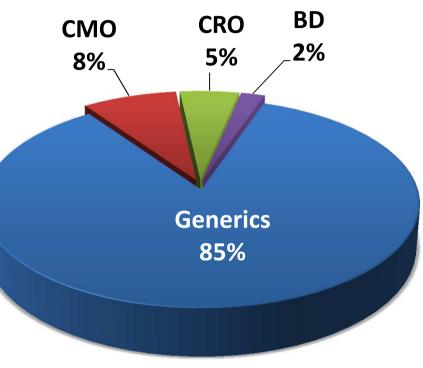
In NT\$ million	FY 2015 (Unaudited)	FY 2014 (Audited)
Cash and cash equivalents at beginning of period	1,928	2,289
Cash flows from operating activities	1,045	888
CAPEX	(657)	(1,018)
Short-term borrowings	425	588
Cash Dividends	(141)	(811)
Others	(264)	(8)
Cash and cash equivalents at end of period	2,336	1,928



# **Sales by Business**

#### FY2015

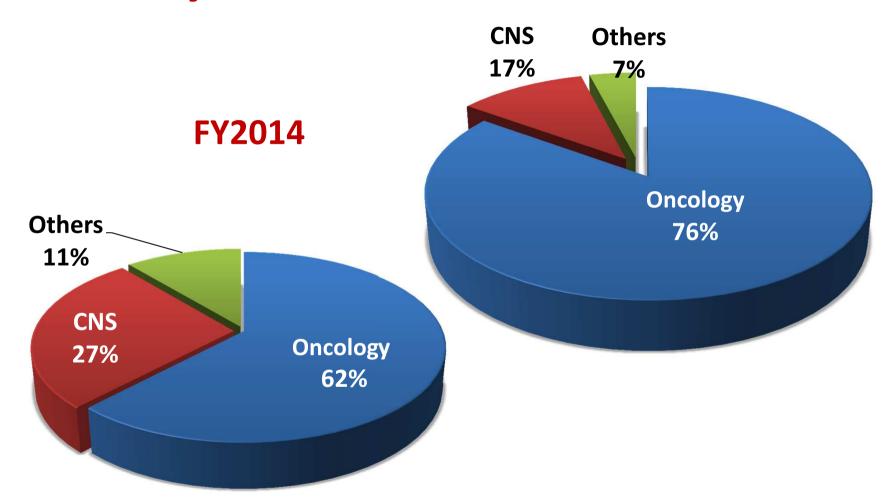






# **Sales by Indications**

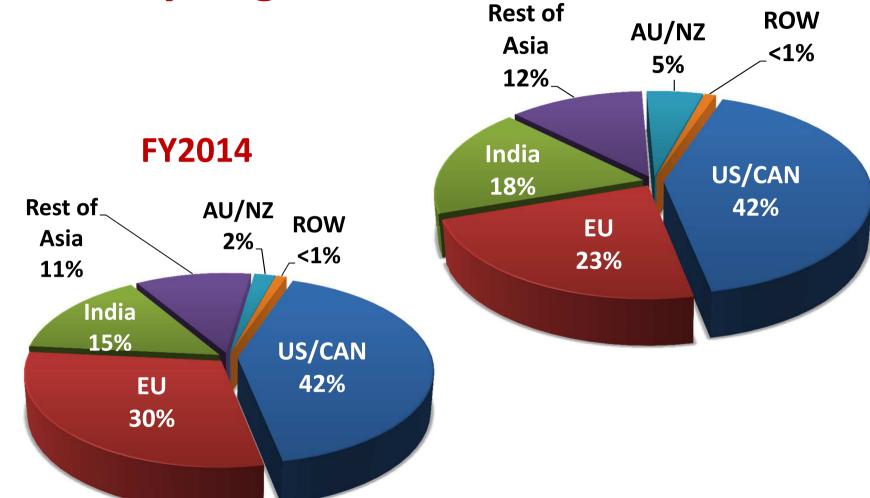
#### FY2015





## Sales by Region

#### FY2015





# Perspectives in Latin American Market

## **Pharmerging Markets**

- IMS Health identified 21 countries as the "Pharmerging" markets per their macroeconomics and pharma market forecasts
- <u>Tier 1:</u> China -- accounts for half of Pharmerging market growth;
  <u>Tier 2:</u> Brazil, India, & Russia;
  <u>Tier 3:</u> Argentina, Colombia, Mexico, Poland, Turkey, Venezuela
- Governments in Pharmerging markets promote generics to expand healthcare coverage cost effectively
- Branded generics are popular in Pharmerging markets as quality assurance
- Big Pharmas tap M&A for local expansion and market presence



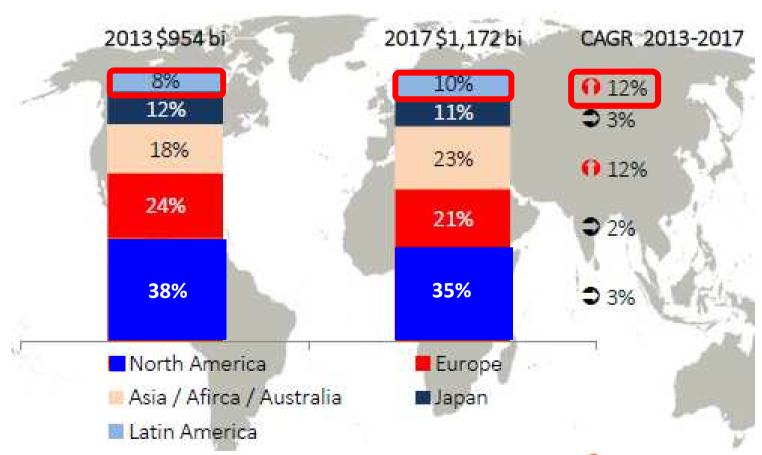
## **Opportunities in Latin America**

- The main consumers aged 20-50 account for 44% of 600Mn people. Latin America as a key growth region of 14% CAGR in 2008 thru 2012 and expected to keep outgrowing after 2016
- Governments encourage generic drugs, manage drug pricing affordable in the domestic market, and elevate generic drug penetration rate to 30% 50%
- A high level of imported drugs pushes local governments to support domestic firms via favorable policies
- Argentina, Brazil, and Colombia upgrading into regulated markets and cultivating regional trading via continual GMP regulatory tightening and harmonization



### **Latin American Markets Fuel the Growth**

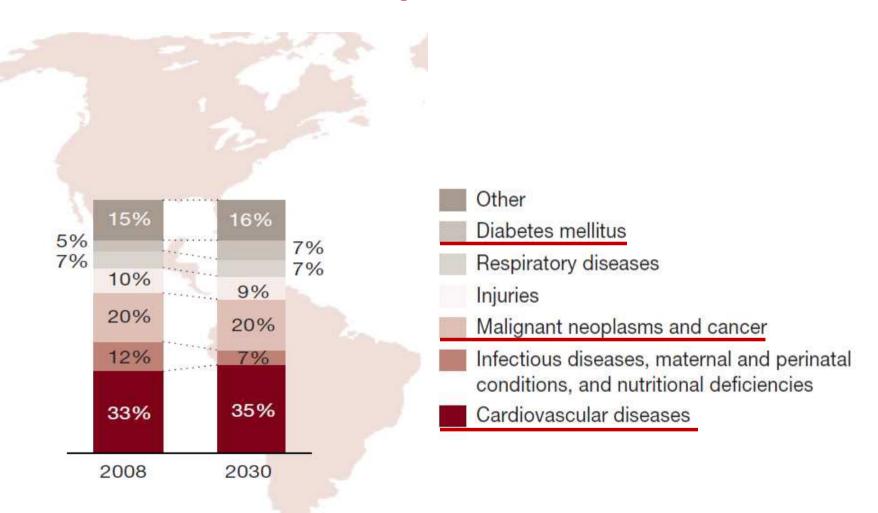
Share of pharmaceutical spending by region 2013-2017



**Source: Americas Market Intelligence** 



## **Product Mix Fits Key Needs in Americas**



Source: WHO; PWC strategy & analysis



## **Market Size**



## Major Latin American Landscape

- Brazil keeps lifting its healthcare expenditure, accounting for Latin American pharma sales of 45% and expected to become the global 5<sup>th</sup> largest pharm market soon
- Mexico, as the region's 2<sup>nd</sup> largest market, bridges the well-established and emerging markets in Americas. Mexico's expansion in healthcare coverage triggers the demand for generic drugs, with 70% penetration
- Argentina actively promotes its pharmaceutical industry, which exports finished and semi-finished drugs to over 115 countries, mainly to the US, EU and Brazil



## **Growing Customer Base in Latin America**

- ScinoPharm reaching out new business along with big pharma customers' M&As, cultivating over 10 domestic customers by 2015
- Sales in Latin America has grown 90% in 2015 from 2014 and is expecting a significant growth continuously
- Both Tainan and Changshu sites passed GMP inspection by Mexican regulatory agency COFEPRIS
- Aim to be a vital API supplier to the high-end oncology generic and brand name drugs in Latin America







Brand Quality with Asian Advantages

www.scinopharm.com

