

# ScinoPharm Management Presentation

May 9, 2017



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# Overview of ScinoPharm

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# Business Overview

- Company specializes in high potency (steroid/cytotoxic) APIs and is expanding into sterile/aseptic injectable formulations
- Facility & organization established in Taiwan and expanding in China with a new GMP plant in Changshu & marketing base in Shanghai
- 72 generic APIs in current portfolio with 25 APIs launched; 53 US DMFs filed (759 DMFs WW), 32 US DMFs in oncology APIs. 100+ NCE CRAM projects, with 5 APIs launched and 5 in phase III for NDA filing in 1-3 years
- Fully compliant with world-class cGMPs and international regulatory requirements; Certified by US FDA, EMA, EDQM, Australian TGA, Japanese PMDA

# World Class API Facilities

## Taiwan

- 6.6 hectares of land, 330K sq.ft. facilities with  $>200\text{M}^3$  reactor volume
- 5 of 16 production lines equipped with high potency capabilities for cytotoxic/steroids
- Passed US FDA, EMA, EDQM, Australian TGA, Japanese PMDA inspections, & 300+ cGMP customer audits
- Provides comprehensive contract research & manufacturing services for brand drug companies
- Global Market

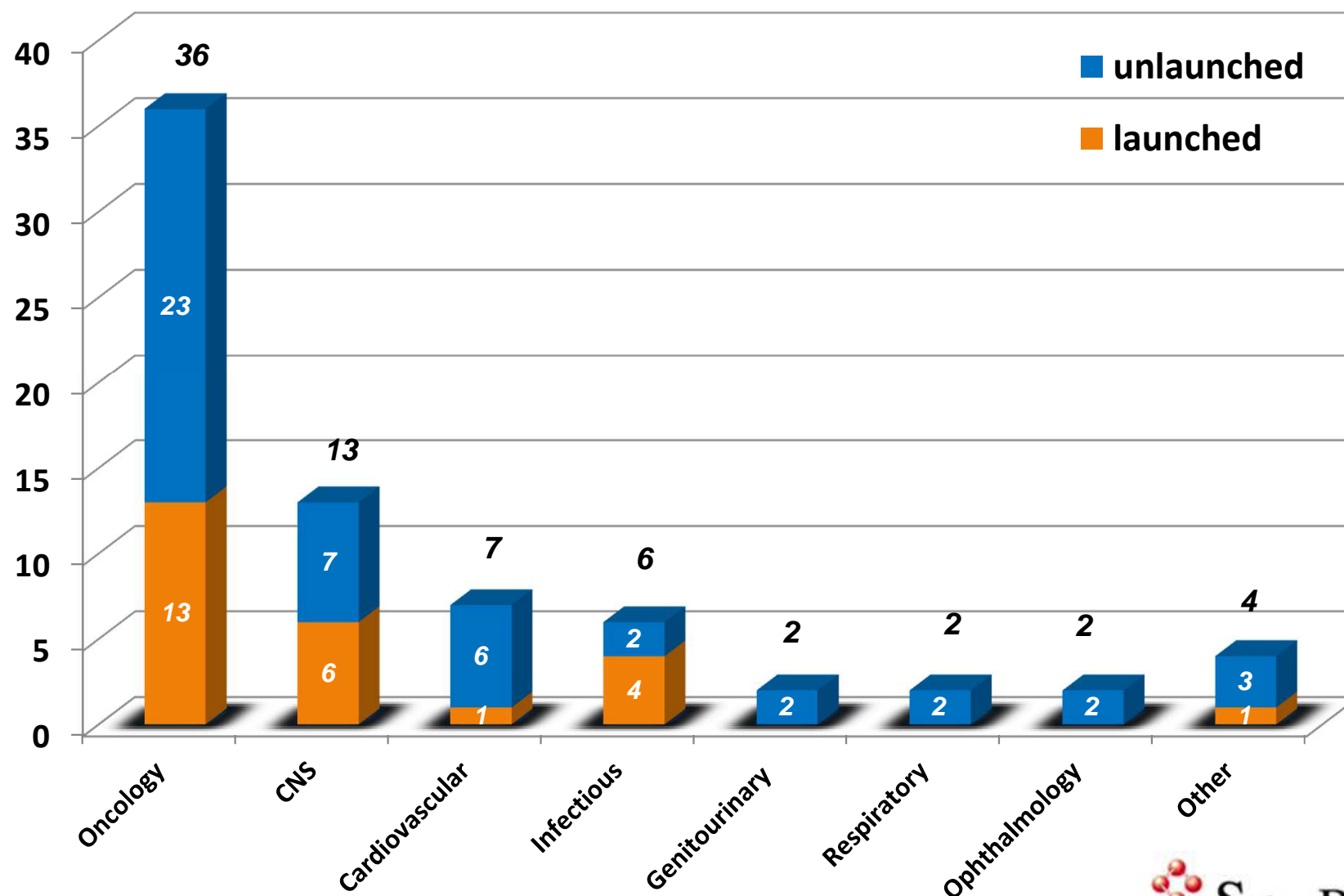


## China

- 6.7 hectares of land with  $> 250\text{M}^3$  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 the development and production of APIs on small to large scales for generic & CRAM markets
- Global market including China



# Strong Generics Product Portfolio



Note: Other (Women's Health, Gastrointestinal, Immunology and Metabolic)

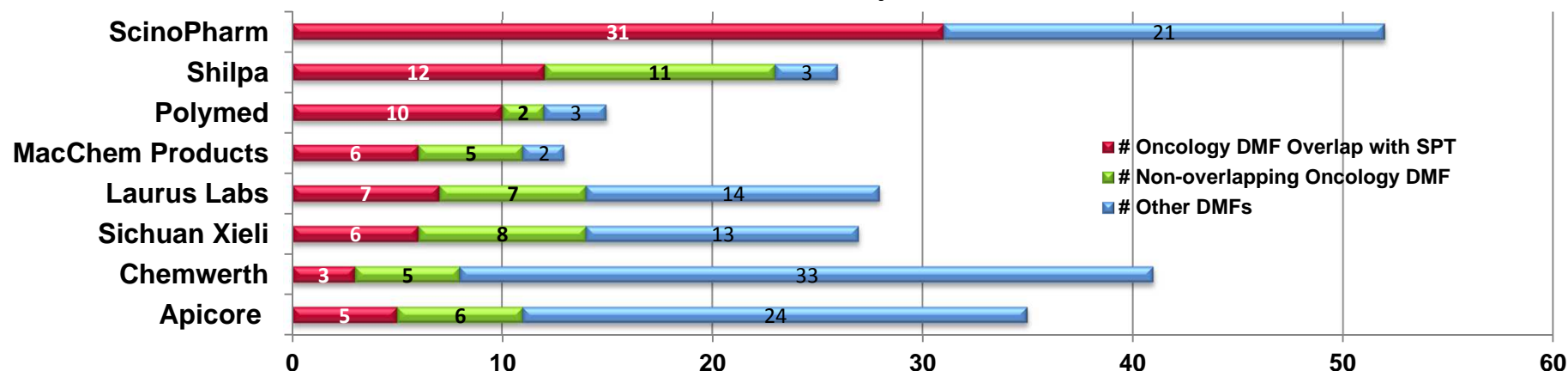


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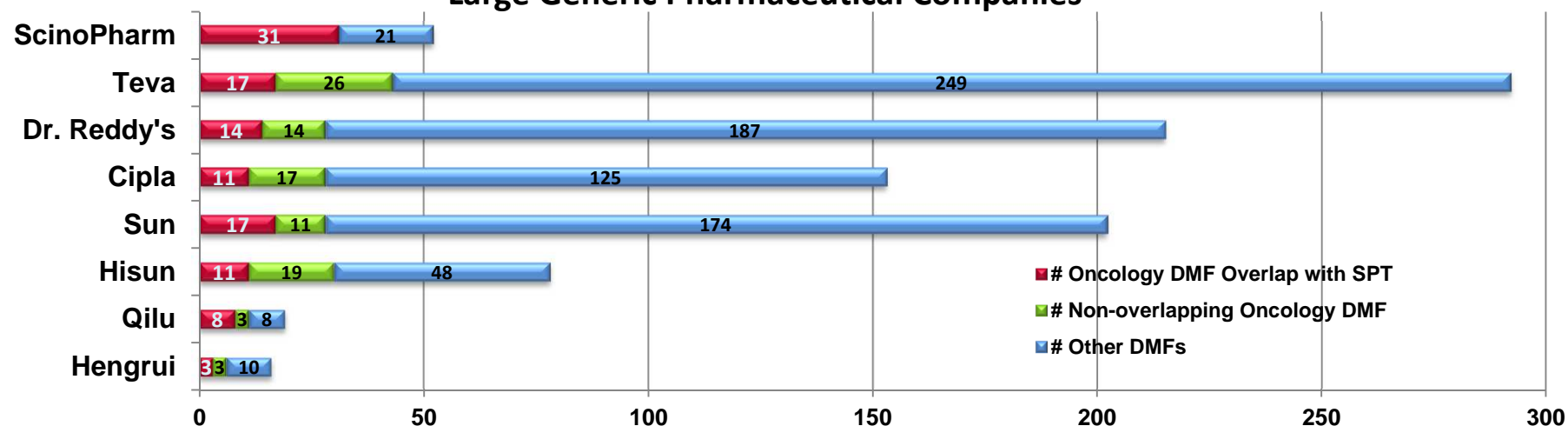
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# ScinoPharm - Oncology API Leader

## Stand-Alone API Companies



## Large Generic Pharmaceutical Companies



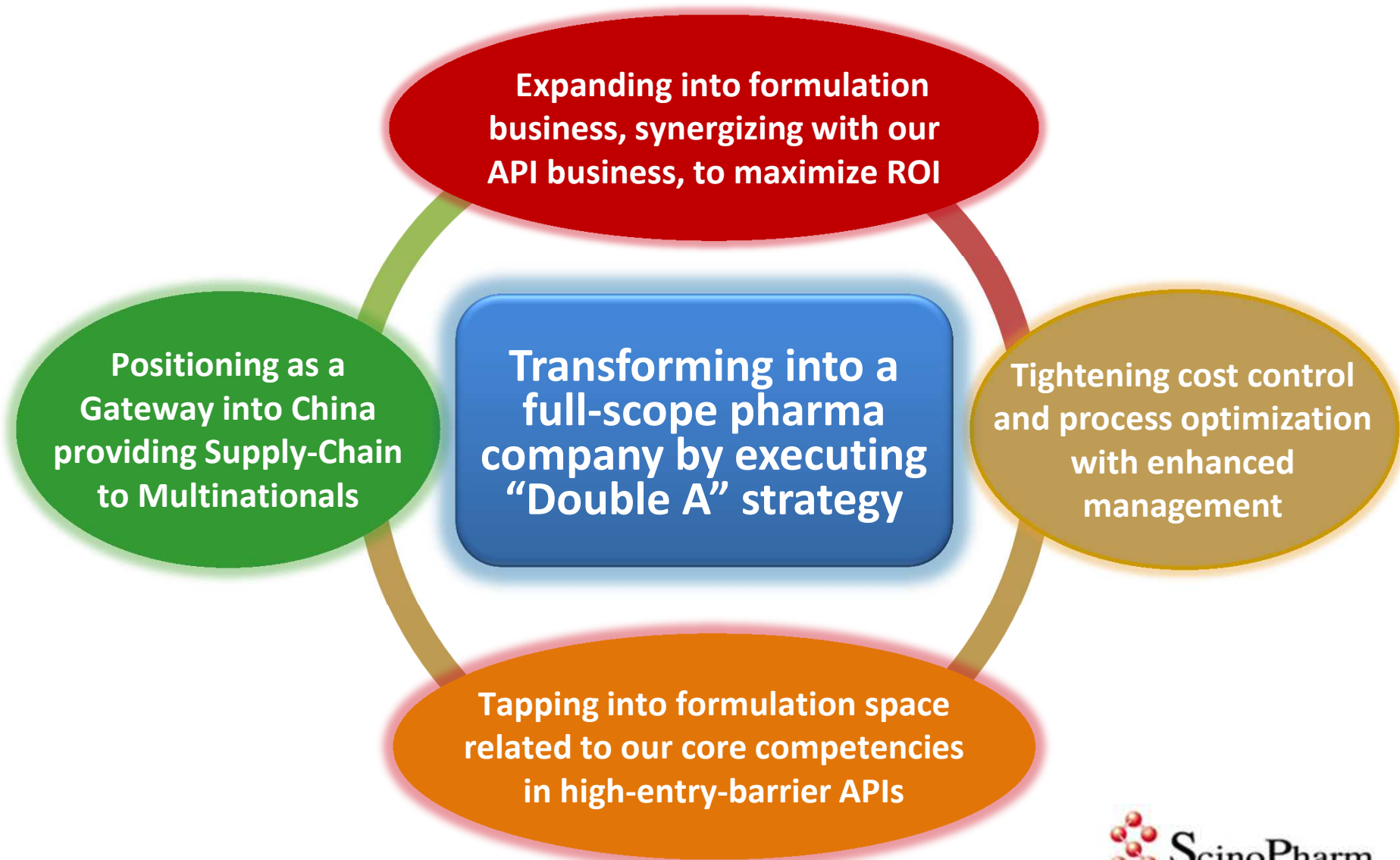
Source: US FDA DMF Q3 2016 database



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# We are Transforming our Company



# Keys to Generic Formulation Business

Opportunity	Strategy	Tactics
<ul style="list-style-type: none"><li>✓ Already the leader in providing oncology APIs to regulated markets worldwide</li><li>✓ Injectable CMOs are in short supply.</li><li>✓ Can be customer's injectables provider by developing formulations using our own oncology APIs or others' APIs, up to and including ANDA filing with FDA</li></ul>	<ul style="list-style-type: none"><li>✓ Developing dossiers per our difficult-to-make APIs to increase value proposition in the supply chain</li><li>✓ Targeted delivery &amp; extended release of proven APIs via 505(b)(2) fast track</li><li>✓ Collaborating with start-ups &amp; research institutes, focusing on un-met oncology medical needs of high prevalence in Asia</li></ul>	<ul style="list-style-type: none"><li>✓ Expanding formulation portfolio</li><li>✓ Establishing on-site oncology injectable facility and providing an integrated supply chain</li><li>✓ Promoting our formulations via strategic alliances, especially in China and US/EU</li></ul>



# **Financial & Operating Results in Q1,2017**

# Quarterly P&L - Consolidated

In NT\$ million, except for EPS	Q1, 2017 (Reviewed)	Q1, 2016 (Reviewed)	YoY
Operating Revenue *	919	1,022	-10%
Gross Profit	470	431	9%
<i>Gross margin</i>	<i>51%</i>	<i>42%</i>	
Operating Expenses	(249)	(236)	6%
Operating Income	221	195	13%
<i>Operating margin</i>	<i>24%</i>	<i>19%</i>	
Other Rev. (Exp.)	(29)	(4)	
Net Income before Tax	192	191	1%
Net Income after Tax	170	172	-1%
<i>Net margin after tax</i>	<i>19%</i>	<i>17%</i>	
EPS (after tax)	0.22	0.23	

\* Taiwan New Dollar per 1 US Dollar quarterly average:  
2017Q1: 30.93, 2016Q1: 33.16

# Balance Sheet- Consolidated

In NT\$ million	2017/03/31 (Reviewed)		2016/03/31 (Reviewed)	
Cash and Cash Equivalents	3,715	29%	2,560	21%
Accounts Receivable	635	5%	645	5%
Inventories	1,941	15%	2,167	17%
Long-Term Investments	364	3%	364	3%
Property, Plant & Equipment	5,155	40%	5,361	43%
Other Current/Non-Current Assets	1,043	8%	1,394	11%
<b>Total Assets</b>	<b>12,853</b>	<b>100%</b>	<b>12,491</b>	<b>100%</b>
Current Liabilities	1,692	13%	2,374	19%
Long-Term & Other Liabilities	803	6%	90	1%
<b>Stockholders' Equities</b>	<b>10,358</b>	<b>81%</b>	<b>10,027</b>	<b>80%</b>

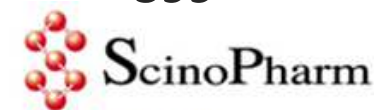
# Cash Flows- Consolidated

In NT\$ million	Q1, 2017 (Reviewed)	Q1, 2016 (Reviewed)
Cash and cash equivalents at beginning of period	3,707	2,336
<b>Cash flows from operating activities</b>	<b>304</b>	<b>663</b>
CAPEX	(203)	(264)
Short-term borrowings	(51)	(16)
Long-term borrowings	(41)	-
Others	(1)	(159)
Cash and cash equivalents at end of period	3,715	2,560

Free Cash flow

101

399

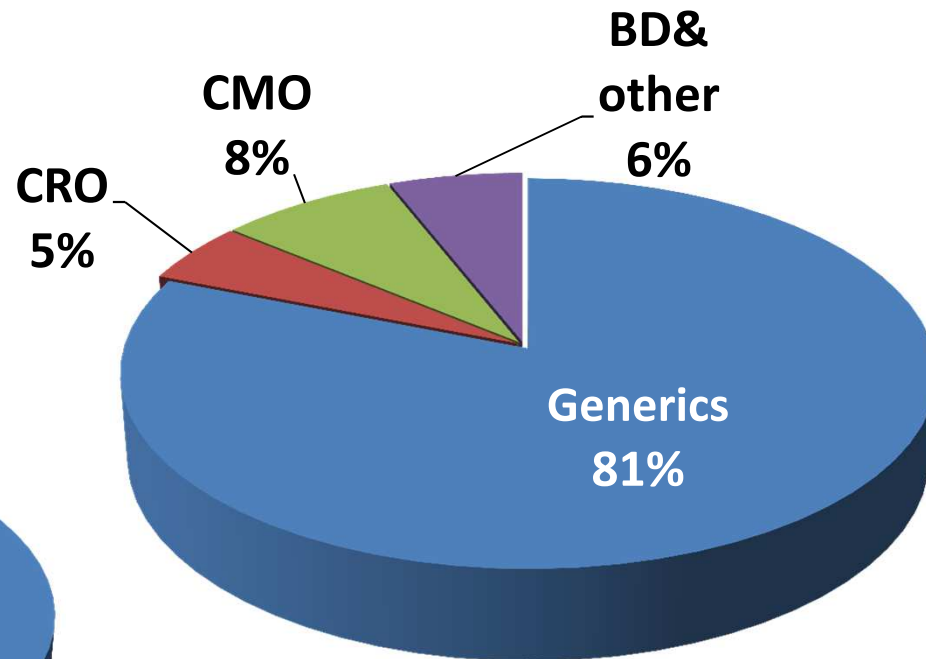
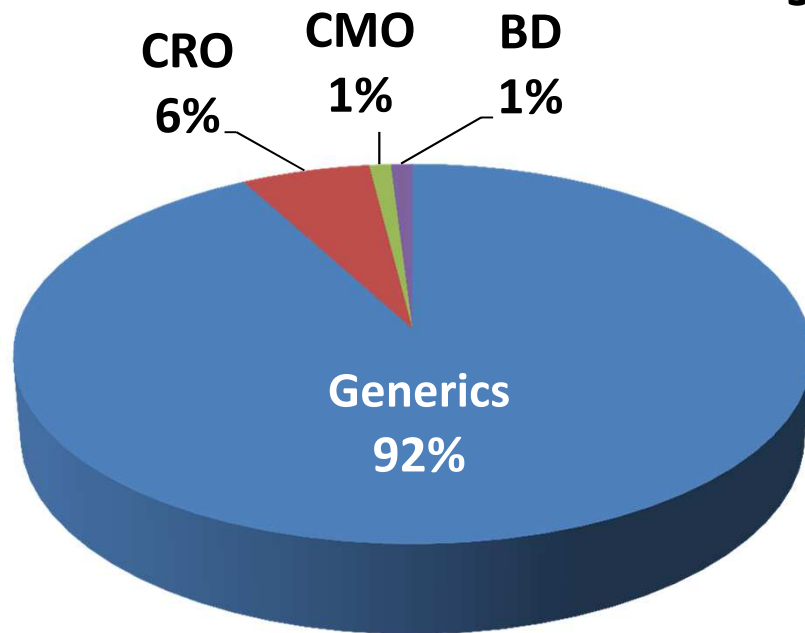


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# Sales by Business

2017 Q1

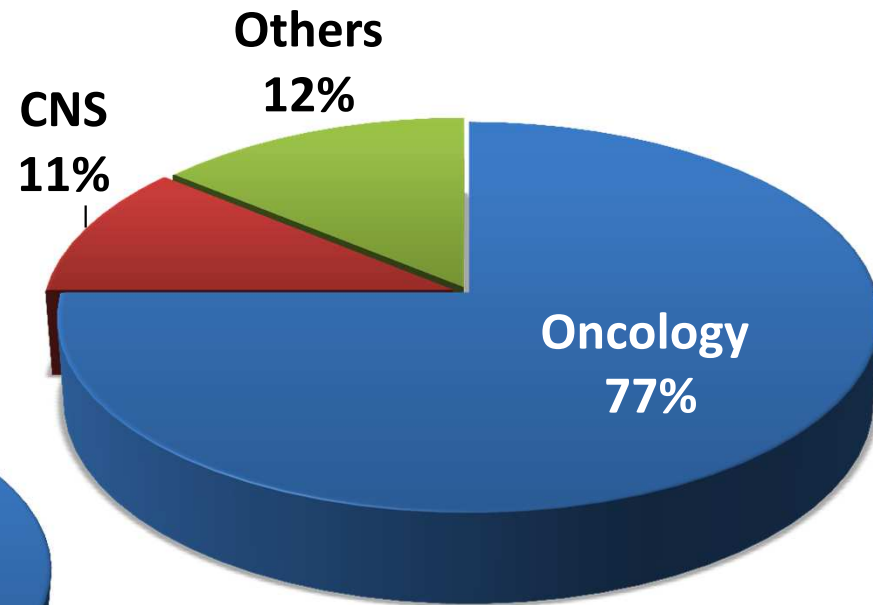
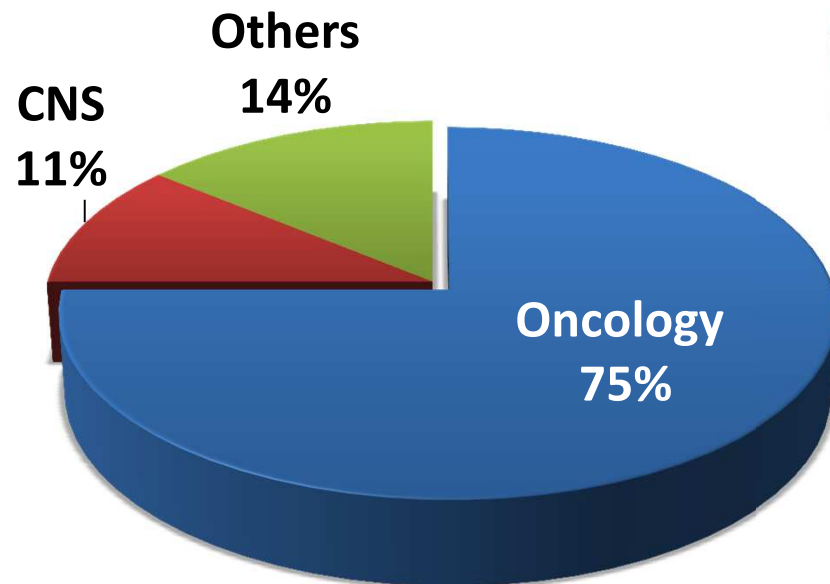
2016 Q1



# Sales by Indications

2017 Q1

2016 Q1



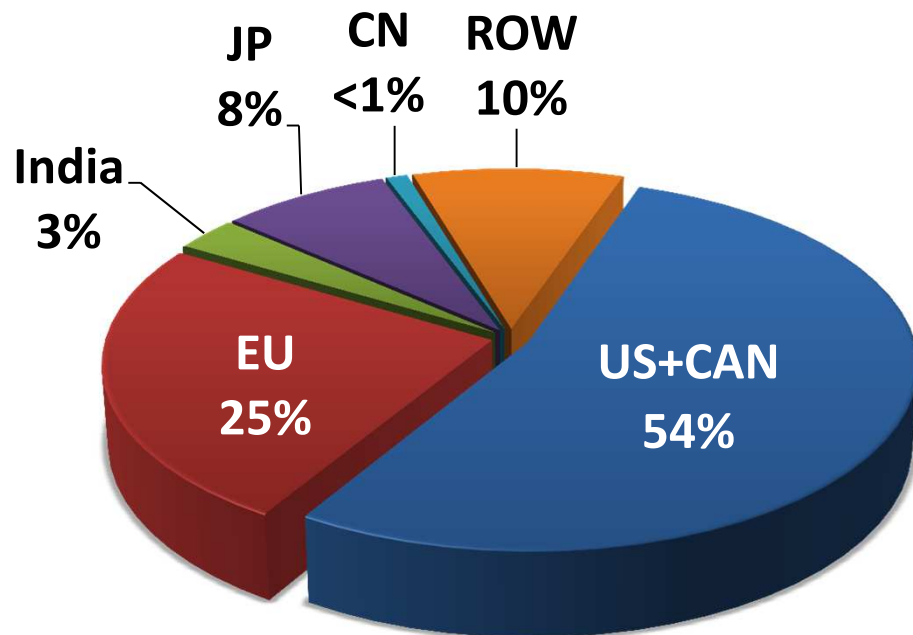
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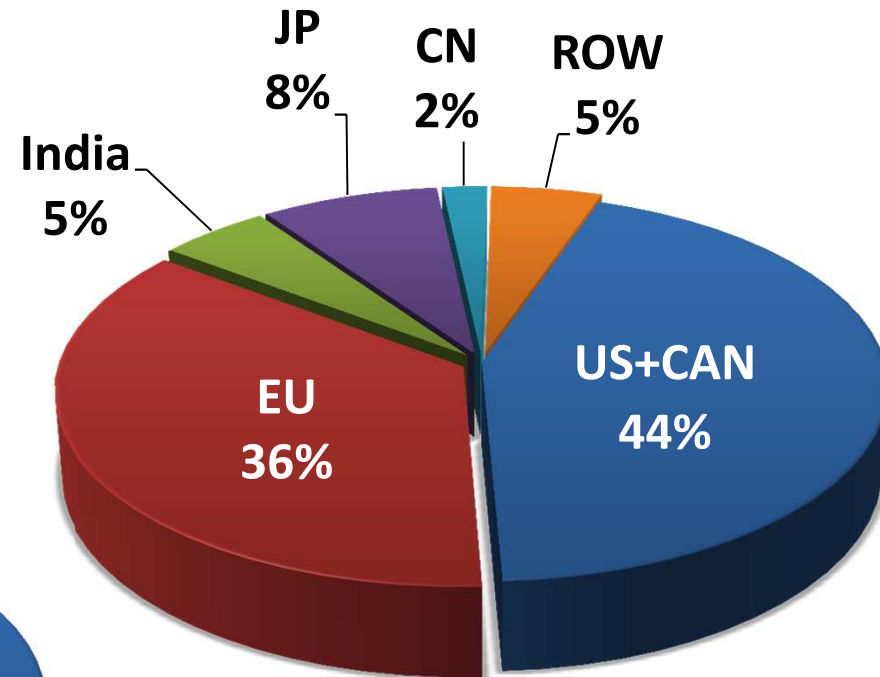


# Sales by Region

2016 Q1



2017 Q1



# **Business Updates**

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# Business Growth Drivers

- **CRAM has promising development potential in the next three years**
  - Focus on small-molecule targeted therapies and CNS agents based on new mode of action
  - Provide integrated service from API to formulation for niche injectables
- **Active development of Chinese and Japanese market**
  - Target projects to utilize capacity and accelerate growth for Changshu site
  - Develop partnership with major Japanese pharmaceutical companies and international pharmaceutical groups with Japan-based operation site
- **Deploying the network of development, production and distribution of injectable products**
  - Build partnerships to speed up the momentum of vertical integration
  - Achieve critical mass workforce for in-house injectable plant facility
- **Continue optimizing existing generic APIs**
  - Maintain the market share and profit of the top 5 marketed products

# CRO Phase III Product Portfolio

\* Already Filed

Code	Est. NDA Filing Year	Indication	Region	*Regional Sales	Remarks
A	2016*	Infectious Disease	US / EU / Asia	\$1.4 bn	Completed process validation. Anticipated launch in 2017 with demand in tons. Expected revenue of several million USD per year
B	2018	Type I,II Diabetes	US/ EU	\$2.4 bn	Intermediate project made in Changshu site. Expected revenue of several million USD per year after launch
C	2018	Advanced Hepatocellular Carcinoma, Myelofibrosis, Autoimmune disease, etc.	CN	N/A	API project made in Changshu site. CFDA granted accelerated review under its category 1.1 innovative drug. Anticipated launch in 2019 with demand in tons
D	2018	Prostate Cancer	US / EU	\$2.4 bn	Started process validation. Anticipated launch in 2019 and revenue of several million USD per year
E	2018	Parkinson's Disease	US	\$1.0 bn	Novel mechanism with promising demand. Anticipated launch in 2019 with demand in tons. Expected revenue of several million USD per year

\* Source: BioMedTracker, GlobalData and DataMonitor

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# China and Japan Market Development

## China

- Accelerate progress to create positive cash flow
- Focus on mid- to late-phase CRO projects. Current portfolio includes agents for oncology, anti-hypertension, and diabetes
- Seek generic APIs/intermediates with large demand to increase production utilization
- Develop partnerships with downstream formulation for collaborative development and registration, realizing shared profit creation

## Japan

- Among 20 customers, 6 are top 10 drug firms. Less established players have exited the more concentrated market
- Encourage local generic customers to engage more in direct business
- Support Japanese companies and foreign pharmaceutical companies to enable and extend business outreach
- With the resources in Taiwan and Changshu, API supply is more flexible and can be incorporated to injectable drug product via integrated services

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# Capturing Chinese Growth on Multiple Fronts

- MNCs and emerging virtual-model players create a sizable demand in high quality API contract manufacturing in China for compliance.
- The review and approval system significantly raises the cost structure & entry barrier in Chinese drug market, with dedication to quality and innovation.
- We have domestic presence plus world-class strengths in:
  - \* Global, first-tier customer base
  - \* High-technical-barrier oncology APIs
  - \* Quality and EHS/GMP compliance

# Selected List of CRAM Projects at Changshu

Customer	Project Type	Product Indication/stage	Product Type	Remarks/ Market
Top 10 global pharma	CMO	Approved antidepressant drug in US	GMP Intermediate	Passed Mexican authority (APIF) GMP inspection
Top 5 global pharma	CMO	Approved African sleeping disease drug	API	Site transfer from Taiwan
Lee's Pharma	CRO / CMO	>15 projects for brain tumors, antibiotic, hypertension, ophthalmology, etc.	API	China
China pharm company	CRO	Phase II/ III clinical trial for cancer	API	China
China pharm company	CRO	Phase IIb for age-related macular degeneration	API	US/China
Taigen Biotech	CRO	Phase II clinical trial for myocardial infarction	API	China/Taiwan
US-based new drug company	CRO	Phase II clinical trial for prevention of HIV infection	API	US
Aslan Pharmaceuticals	CRO	Phase II clinical trial for cancer	API	China/Global
Top 5 global pharma	CRO	Phase III clinical trial for diabetes	Intermediate	US
Top 5 global pharma	CRO	Phase I clinical trial	API	NA
US NASDAQ listed pharma	CRO	Phase III clinical trial for opioid-induced constipation	Crude API	US
US-based new drug company	CRO	Phase I clinical trial for sickle cell disease	API	US

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# Formulation Business Progress

## In-house injectable plant

- On schedule to complete equipment assembly and verification, sterility verification, organization, personnel deployment and training, and cGMP system deployment for both vial and cartridge production lines
- Planned kick-off registration batch production by 2017. Expected submission of 1st in-house ANDA in 2018 and subsequent US FDA inspection approval in 2019.

## Formulation and collaboration development

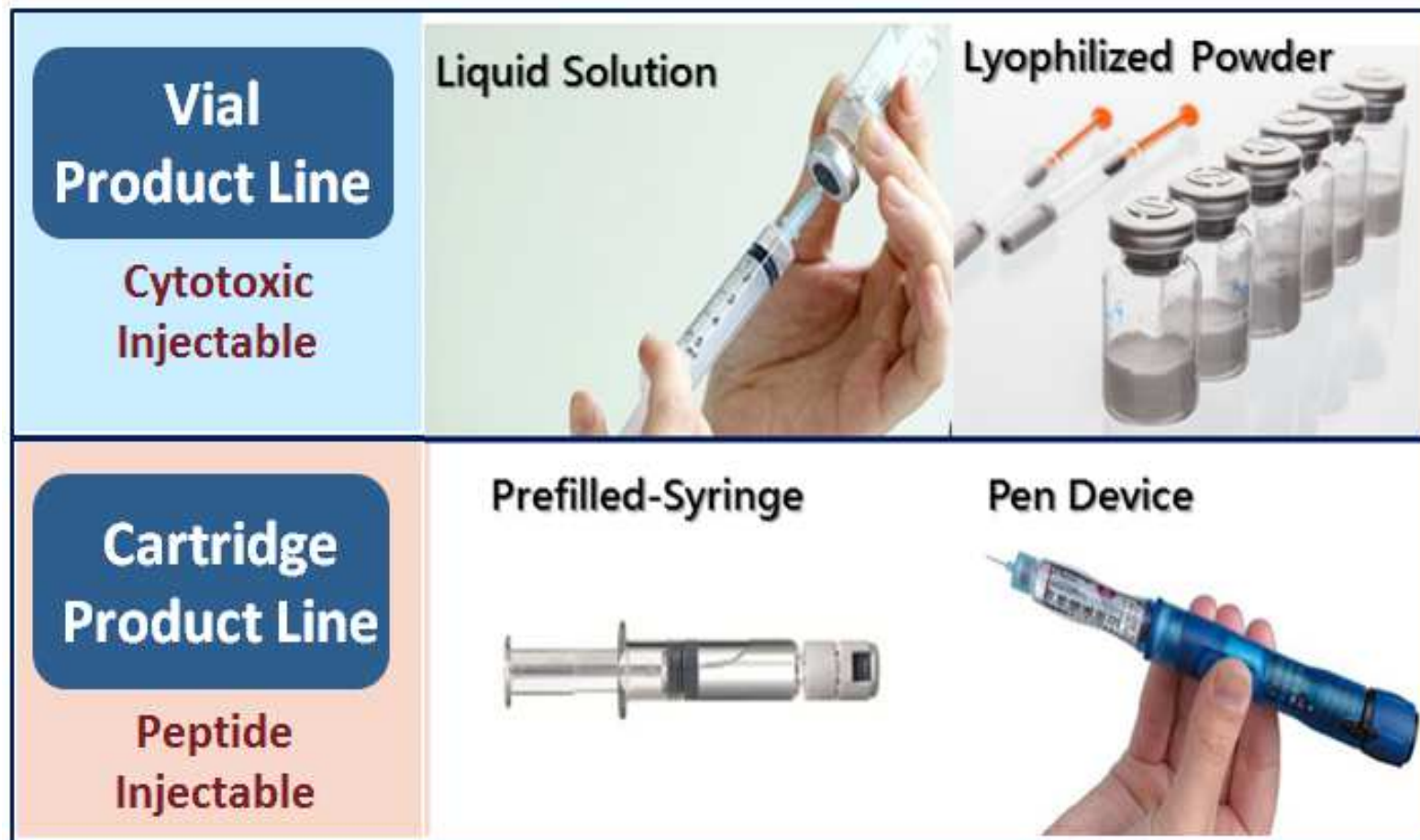
- 2 US ANDAs: Oncology product partnership with SAGENT, and ScinoPharm-developed Fondaparinux
- 16 co-developed and cost/profit sharing products with various partners
- Niche drugs planned with the indications of cancer, diabetes, osteoporosis and multiple sclerosis. Continue to develop strategic alliances, including ongoing discussions with international major companies for exclusive rights of distribution



# Injectable Plant



# Aseptic Fill & Finish Service



# Strategic Alliance Highlights

\* Already launched

Partner	Product	Indications	Region	Launch Year(E)	Remarks
Genovate	Entecavir	Hepatitis B Virus	Taiwan	2013*	1 <sup>st</sup> co-developed formulation product launch
Sagent	Oncology Injectable	Myeloid Leukemia	US	2017	1 <sup>st</sup> US ANDA filing, triggering US FDA inspection in Changshu, China site
Foresee	Leuprolide	Prostate cancer	US	2019	505(b)(2) NDA CRAM + Equity
Coland	Bortezomib	Multiple Myeloma	China	2020	1 <sup>st</sup> co-developed drug in China to trigger CFDA inspection in Changshu site
	Azacitidine	MDS	China	2021	Co-developed formulation in China
Lee's Pharma	Fondaparinux	Anti-thrombotic	China	2021	Co-development collaboration
	Travoprost & Bimatoprost	Glaucoma	China	2021	
Nanjing King Friend	Regadenoson	Stress agent for heart scan	China	2020	Co-developed formulation in China
US partner	Project A	Non-small cell lung cancer	US	2017	US NDA 505(b)(2) / The estimated launch year is subject to US FDA review
US & China partners	Project B	Imaging agent	US	2021	ANDA with Paragraph IV filing / The estimated launch year is subject to litigation results
Baxter	5 niche injectables	Anti-cancer & antinauseant	US/EU	2020& continuing thereafter	Baxter has the right to add up to 15 additional injectable products for collaboration
Indian Int'l partner	Niche injectable	Anti-thrombotic	US/EU	2018	1st self-developed US ANDA launched. Executive right for marketing & sales

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# Injectable Products Allied with Baxter

- ScinoPharm and Baxter Healthcare establish worldwide partnerships to co-develop and commercialize five niche generic injectable products at the initial stage
- ScinoPharm develops all APIs and injectable formulations. Baxter leads regulatory submissions in the US/EU and eventually market & sell the injectable products via its extensive presence in the hospital channel
- Both parties work on a cost-and-profit-sharing collaboration model
- Baxter has the right to add up to 15 additional injectable products for collaboration with ScinoPharm

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# Collaboration Framework

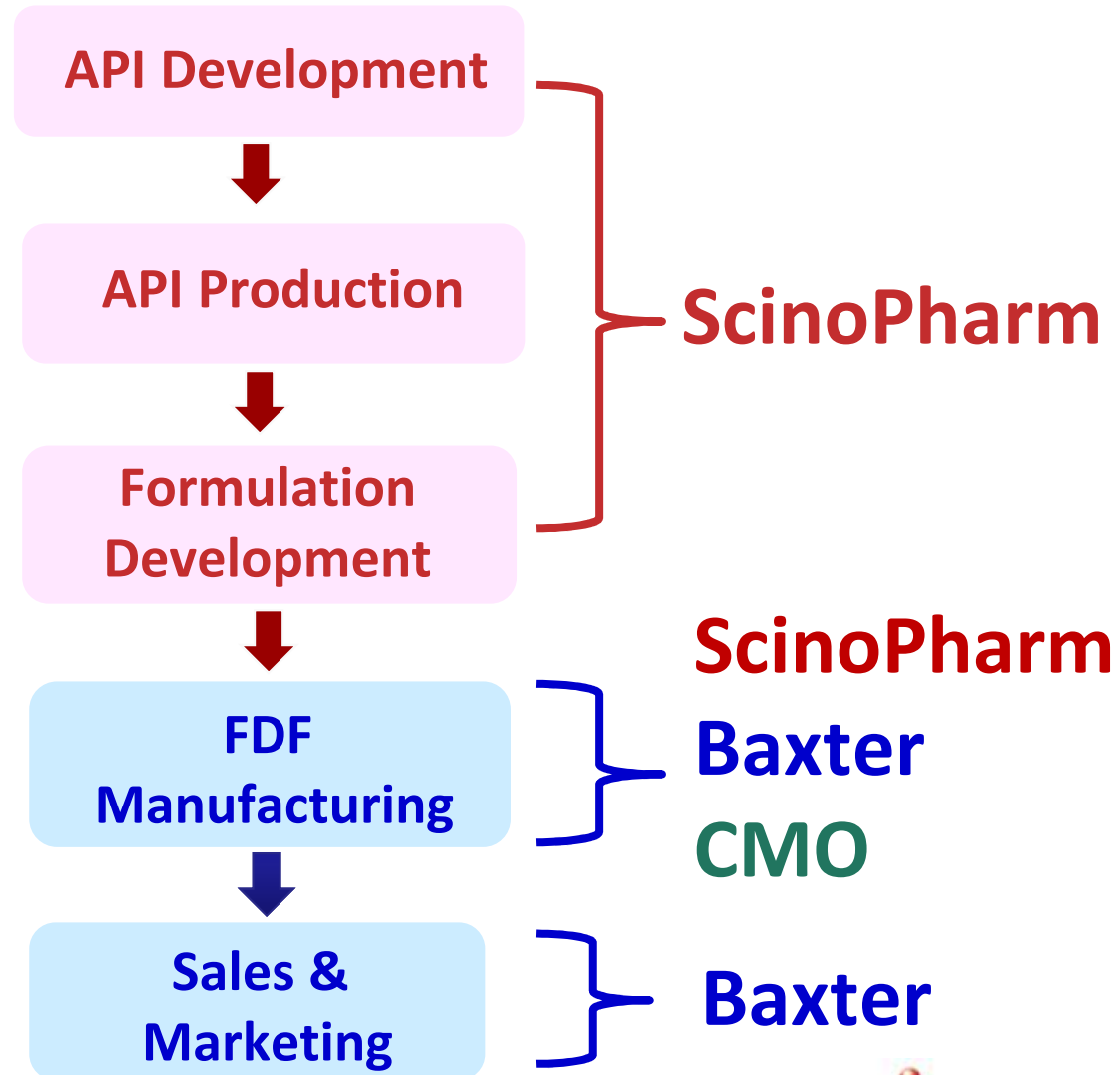
- Initial product portfolio including the generic injectables for breast cancer, lung cancer, multiple myeloma and antinauseant. Targeting US/EU markets first and expect to expand to other territories
- This exclusive partnership will utilize each other's strengths and expertise in order to achieve large scale of synergies in providing niche and affordable generic injectable products
- Commercial launch for the first 5 products upon FDA approval, with product launches beginning in 2020 and continuing thereafter
- Current branded sales of the initial five products included in this partnership total more than \$4 billion annually



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# Responsibilities by ScinoPharm and Baxter



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# Benefits of the Collaboration

- Aggressively expanding our “Double A” strategy for in-house developed/produced APIs and formulations. Providing an outlet for our injectable plant capacity
- A win-win solution and collaboration. ScinoPharm provides comprehensive APIs and formulation portfolio, while Baxter operates strong injectable product marketing channels throughout the US and worldwide
- Accelerate the momentum of our downstream integration strategy by establishing alliance with an world-renowned partner

# Maintain Market Share of Existing APIs

2016 Major Products account for 65% of total sales

API	Indication	2016 MKT share*	# of US DMF/EDMF & other filings
Irinotecan HCl	Antineoplastic	42%	63
Paclitaxel	Antineoplastic	34%	57
Gemcitabine	Antineoplastic	24%	76
Exemestane	Antineoplastic	22%	44
Galantamine HBr	Antipsychotic	17%	38
Docetaxel Anhydrous	Antineoplastic	15%	69

\*Source: IMS data from Newport



# 2017 Product Launch Plan

Type	Product	Region	Indication	Brand Marketer	Regional Sales	WW Sales
Generic API	Desmopressin Acetate	USA	Polyuria	Ferring	US\$166M	US\$405M
Generic API	Tamsulosin HCl	USA	Benign Prostatic Hyperplasia (BPH)	Boehringer Ingelheim	US\$333M	US\$1706M
New Drug API	Oncology Product	US	Non-Small Cell Lung Cancer	N/A	N/A	N/A
New Drug API	Oral Product	USA EU	Antibiotics	N/A	N/A	N/A
Generic Drug	Oncology Injectable	US	Myeloid Leukemia	MDS	US\$183M	US\$278M

Source: IMS Data (2015Q3-2016Q2)

# Pipeline Outlook

- ✓ 2 generic API launches
- ✓ 1<sup>st</sup> co-developed US ANDA launched

- ✓ 5-6 new launches
- ✓ 1 drug products launched in US
- ✓ Chinese (CFDA) inspection at Changshu site
- ✓ US FDA inspection at Injectable plant

2017

2018

2019

2020

- ✓ 3-5 generic API launches
- ✓ 1<sup>st</sup> in-house drug US ANDA filing
- ✓ 1<sup>st</sup> self-developed US ANDA launched
- ✓ 1 co-developed US ANDA launched

- ✓ 4-5 new launches
- ✓ 2 co-developed China ANDAs and 1 co-developed US ANDA launched



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## Brand Quality with Asian Advantages

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

