ScinoPharm Taiwan, Ltd.

TWSE 1789

# ScinoPharm Management Presentation

## First Quarter 2016 On-Line Investor Meeting

May 10, 2016

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# Table of Content





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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; 56 US DMFs filed (738 DMFs WW), 29 US DMFs in oncology APIs. 100+ NCE CRAM projects, with 5 launched and 5 in phase III for NDA filing in 1-3 years
- Fully Complied with world-class cGMP and regulatory requirements; Certified by US FDA, EMA, Australian TGA, Japanese PMDA, Korean FDA, Mexican COFEPRIS, etc.



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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**

# ScinoPharm Changshu Operating Update

# Short-Term Goal

- To provide API contract development and manufacturing services for both multinational and China domestic pharmas
- Major base for large volume API with regulatory supports
- To be able to produce high value added intermediates for SPT



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# The Completive Advantages

## Process Development Capability

Collaborating with a partner specialized in enzymatic technology to integrate with ScinoPharm in-house strong chemical synthesis capabilities for providing services to develop greener, safer, and more cost-effective API manufacturing processes

## GMP Production Capability

Knowledge to design, develop, and test parameters of spray drying process for APIs which are difficult-to-dry, are sensitive to long drying residence time, or require uniform particle size distribution

## Regulatory Compliance Capability

Fully compliant with the most advanced guideline published by EMA in 2014 to set the standards for production line segregation and equipment cleaning criteria



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# Operating Progress

- Actively implementing more than 20 contract research or manufacturing projects every year
- 9 US/EU customers and 3 of them are top 10 big pharmas
- Strategically partnership with Lee's Pharma in China to provide API process development and manufacturing services for more than 15 projects
- Successfully passed 14 GMP and 2 EHS audits conducted by customers



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# Selected List of CRAM Projects at SPC

| No | Customer | Project Type | Product Indication/stage | Product Type | Remarks/ Market |
|---|---|---|---|---|---|
| 1 | Top 10 global pharma | CMO | Approved antidepressant drug in US | GMP Intermediate | Passed Mexican authority (APIF) GMP inspection |
| 2 | Top 5 global pharma | CMO | Approved African sleeping disease drug | API | Site transfer from SPT |
| 3 | Lee's Pharma | CRO+CMO | +15 items including topical anesthetic, brain tumor, antibiotic, hypertension, eye drop, etc. | API | China |
| 4 | China pharm company | CRO | Phase II/ III clinical trial for cancer | API | China |
| 5 | China pharm company | CRO+CMO | Phase IIb for age-related macular degeneration | API | US/China |
| 6 | Taigen Biotech | CRO | Phase II clinical trial for myocardial infarction | API | China/Taiwan |
| 7 | US-based new drug company | CRO | Phase II clinical trial for prevention of HIV infection | API | US |
| 8 | Alsan Pharmaceuticals | CRO+CMO | Phase II clinical trial for cancer | API | China/Global |
| 9 | Top 5 global pharma | CMO | Phase II clinical trial for diabetes | Intermediate | US |
| 10 | Top 5 global pharma | CRO+CMO | Phase I clinical trial | API | NA |
| 11 | US NASDAQ listed pharma | CRO | Phase III clinical trial for opioid-induced constipation | Crude API | US |

# Key Progress for China Market

| | |
|---|---|
| **ScinoPharm Taiwan** | Submitted drug import license applications for 12 APIs (anti-cancer, cardiovascular, Alzheimer's disease, benign prostatic hyperplasia, hepatitis B, etc. ) |
| **ScinoPharm Changshu** | • Obtained drug production permits for 11 APIs for anti-cancer, anti-viral, glaucoma, etc. )<br>• Submitted 5 drug license applications for USFDA, 1 for EDQM and 2 for CFDA |
| **Strategic Alliance** | 5 formulation development and 1 new drug projects smoothly undergoing. Expected to be commercially available in 2019-2022 |



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# Financial & Operating Results

# Quarterly P&L - Consolidated

| In NT$ million, except for EPS | 1Q 2016 (Reviewed) | 1Q 2015 (Reviewed) | YoY |
|---|---|---|---|
| Net Sales | 1,022 | 979 | *4%* |
| Gross Profit | 431 | 344 | *25%* |
| *Gross margin* | *42%* | *35%* | |
| Operating Expenses | (236) | (203) | *16%* |
| Operating Income | 195 | 141 | *39%* |
| *Operating margin* | *19%* | *15%* | |
| Other Rev.(Exp.) | (4) | (7) | *-35%* |
| Net Income before Tax | 191 | 134 | *42%* |
| Net Income after Tax | 172 | 113 | *52%* |
| *Net margin after tax* | *17%* | *12%* | |
| EPS (after tax) | 0.24 | 0.15 | *60%* |



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# Balance Sheet- Consolidated

| In NT$ million | 2016/3/31 (Reviewed) | | 2015/3/31 (Reviewed) | |
|---|---|---|---|---|
| Cash and Cash Equivalents | 2,560 | *21%* | 2,008 | *17%* |
| Accounts Receivable | 645 | *5%* | 653 | *6%* |
| Inventories | 2,167 | *17%* | 2,402 | *21%* |
| Long-Term Investments | 364 | *3%* | 244 | *2%* |
| Property, plant & equipment | 5,361 | *43%* | 5,109 | *44%* |
| Other assets | 1,394 | *11%* | 1,155 | *10%* |
| Total Assets | 12,491 | *100%* | 11,571 | *100%* |
| Current Liabilities | 2,374 | *19%* | 2,004 | *17%* |
| L-T Liabilities and Others | 90 | *1%* | 91 | *1%* |
| Stockholders' Equities | 10,027 | *80%* | 9,476 | *82%* |



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# Cash Flows- Consolidated

| In NT$ million | 1Q 2016 (Reviewed) | 1Q 2015 (Reviewed) |
|---|---|---|
| Cash and cash equivalents at beginning of period | 2,336 | 1,928 |
| Cash flows from operating activities | 663 | 241 |
| CAPEX | (263) | (269) |
| Short-term borrowings | (16) | 86 |
| Others | (160) | 22 |
| Cash and cash equivalents at end of period | 2,560 | 2,008 |



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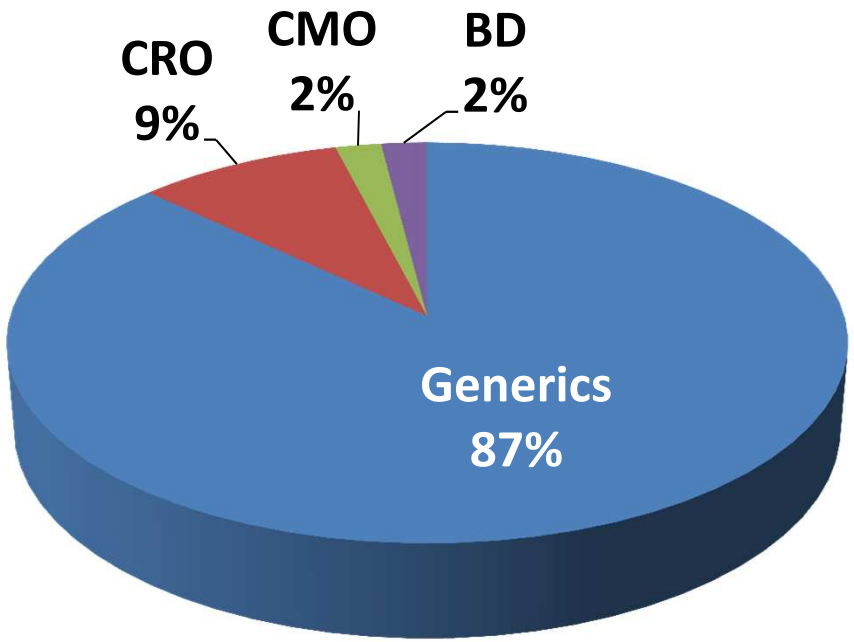
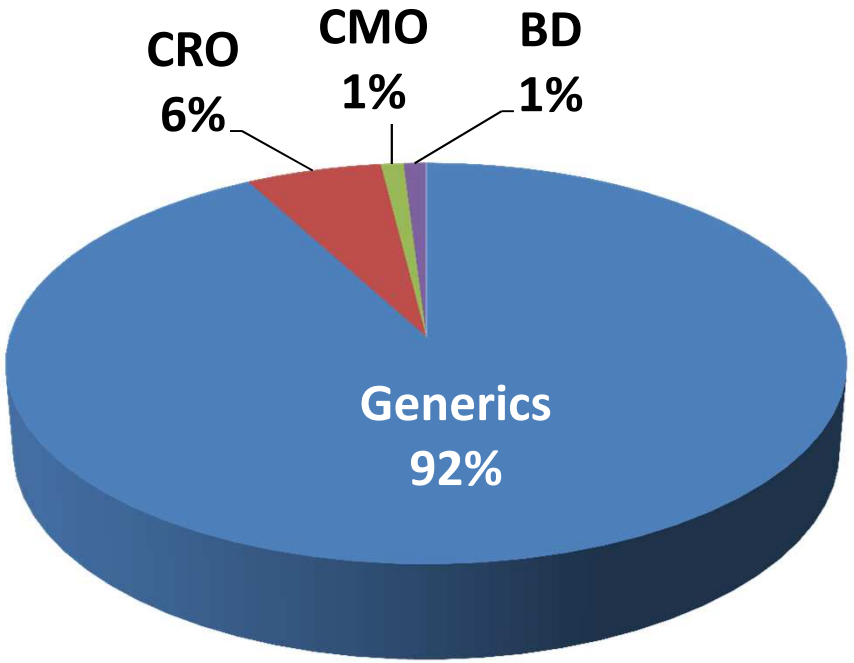
# Sales by Business

## 2015 Q1




## 2016 Q1



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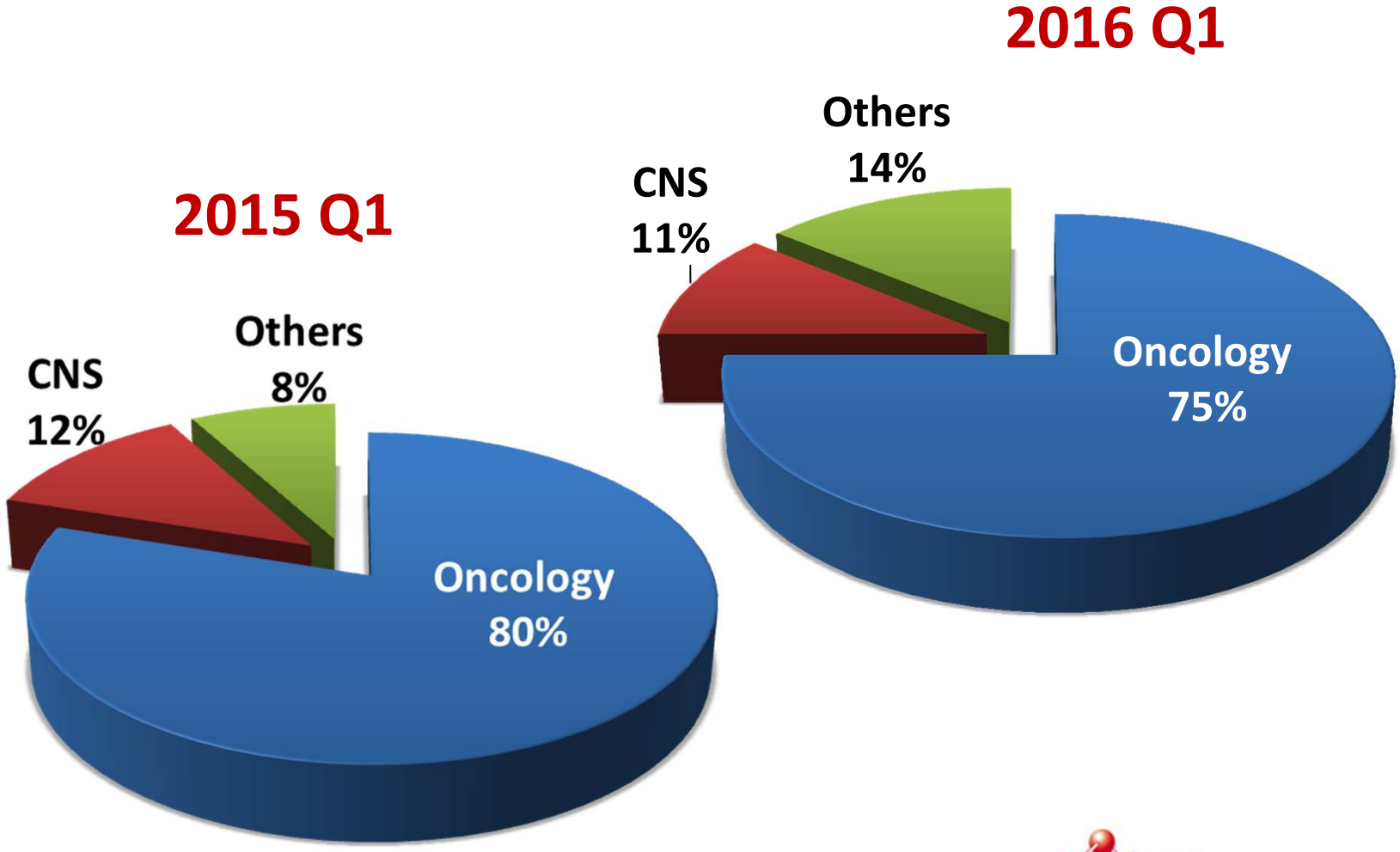
# Sales by Indications



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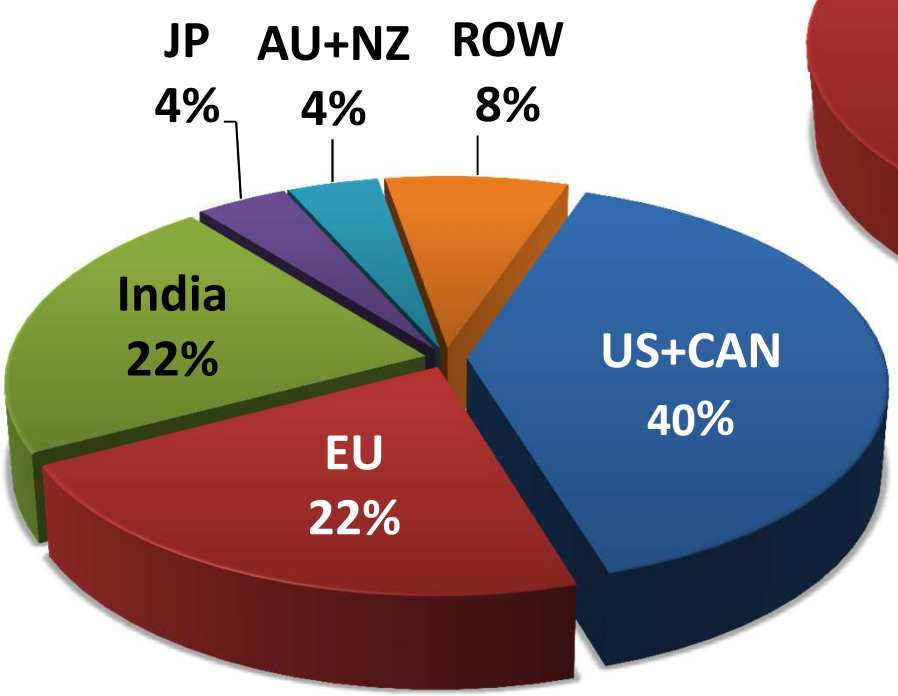
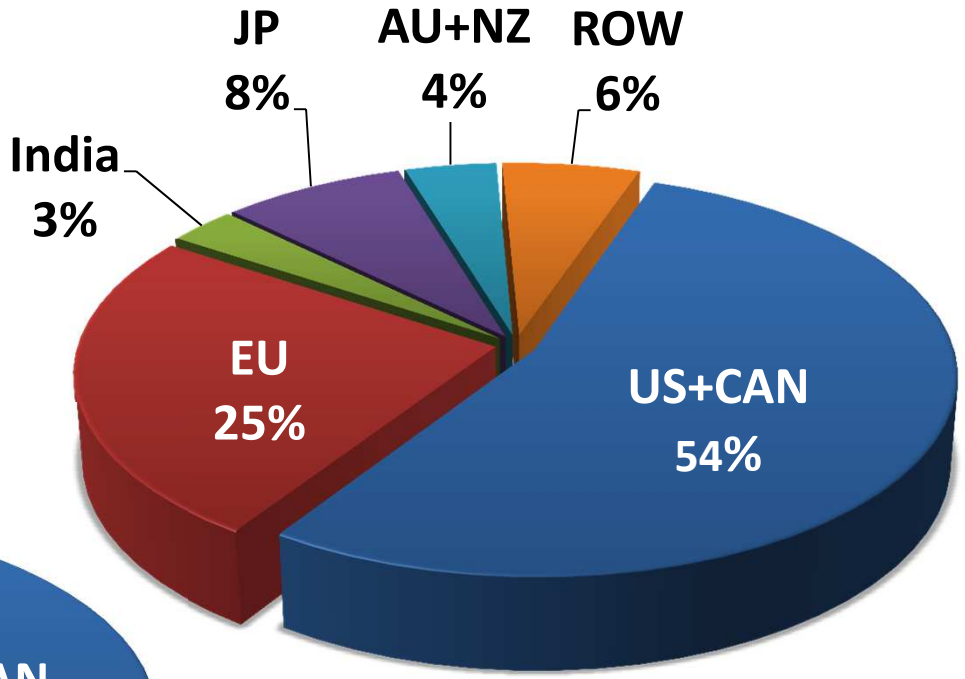
# Sales by Region

## 2015 Q1




## 2016 Q1



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# Top 5% of Corporate Governance Evaluation

- Ranked in the top 5% among all TWSE listed companies from the 2st Corporate Governance Evaluation, also the only healthcare company to be included
- Being the only healthcare to receive the honor for 2 consecutive years
- A clear indication of ScinoPharm's efforts and achievements in protecting shareholder interests, equal treatment of shareholders, Board of Directors organization and operations, information transparency, and corporate social responsibility



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# Japan Market Observation

# Japanese Generics Landscape

- The government strongly supports for generic drugs, aiming to 80% volume penetration rate by 2018-20
- Significant drug price cut by 15-40% in many generic drugs in 2016. More pressure on API prices
- Takeda & Teva JV could be a trendsetter as Japan pushes for generics
- Severe scrutiny on the discrepancy between actual manufacturing operation & the process description approved by Japanese Health Authority due to the recent big scandal of the blood products in Japan
- More and more generic companies explore business opportunities in Southeast Asia, USA, etc.



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# Market in Favor of ScinoPharm

- CRO/CMO capacities are limited in Japan for high potency substances, and many JP originators used outsourcing partners
- To stabilize API sourcing, Japan pharmas, used to source cheaper generic APIs in India and China, switch to high-quality, EHS/GMP complied vendors, like ScinoPharm
- Via import from Taiwan and Changshu, ScinoPharm intends to timely capture the oncological API with flexibility while providing a single-source service with capability of adding additional down-stream value



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# Booming Market Presence in Japan

- As the first Taiwanese API company qualified by PMDA, ScinoPharm aims to capitalize on its qualified APIs, CRO/CMO and formulation business
- Among 20 customers, 6 of them are top 10 drug firms include tier 1 domestic generic/brand name drug co.'s and JP operation of the global generic pharmas
- A wider presence of oncology products launched. Exemestane and Irinotecan enjoy dominant positions. JP sales continue to grow this year



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# Product Launch Update

# 2016 Product Launch Plan

| API | Region | Indication | 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 HCl | Middle East | Pancreas, Lung, Ovary, Breast Cancers. | Eli Lilly | N/A | US$547.9M |
| Tamsulosin HCl | USA | Benign Prostatic Hyperplasia (BPH) | Boehringer Ingelheim | US$410.0M | US$1,818.4M |

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

✓ Launched



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# Questions

# &

# Answers



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# Brand Quality with Asian Advantages

**www.scinopharm.com**



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