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Introduction of Pharmaceutical Business

Outline

1. Pharmaceutical Industry Overview

- New Drugs
- Generics

2. Regulations and Registration

3. API Business

Pharmaceutical Industry

- **Heavy investment, long lead time, high risk for product development**
- **Highly regulated, and major liability**
- **Steady growth & resistant to economic recession**
- **Important contribution to the wellbeing of mankind**

Pharmaceutical Market

key market dynamics

- **Global sales of pharmaceuticals expected to rise from US$956 billion in 2011 to nearly US$1.2 trillion in 2016 with CAGR of 3-6%.**
- **Top 10 pharmaceutical companies account >40% of market share.**
- **Rapid expansion of "Pharmerging" markets**
  - **China, Russia, Turkey, South Korea and Mexico, expected growing in total by 13~16% over next 5 years.**
  - **China especially expected to grow >20% per year, ~21% of overall global growth through 2013.**

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New Drug

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Drug Discovery & Development

- **Discovery**
  - **High throughput screening using existing chemical library**
  - **Optimize lead structures**
  - **In-vitro bioassay**
  - **In-vivo animal studies**
- **Development**
  - **Formulation development**
  - **Pharmacokinetics**
  - **Toxicology – 2 species**
  - **Clinical trials**
    - **Phase I – healthy volunteers/dosing effect for safety & toxicity studies**
    - **Phase II – patient efficacy test, simple test**
    - **Phase III – large patient population for drug interaction & safety**

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Generics

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Patent and Data Exclusivity

- **Branded drug – drugs sold under trade name, usually under IP protection**
- **Patents associated with a new drug – substance, method of use, process, formulation, polymorph, particle size, etc.**
- **Patent term extension/SPC**
- **Data exclusivity – US, EU, Japan etc.**
- **Generic drugs (generics) – drugs sold when constraining patent(s) expired**

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Generic Drugs

- **Drug approval – The Hatch-Waxman Act**
  NDA (New Drug Application) vs ANDA (Abbreviated)
- **Generics – containing the same API as the ref drug. By definition, generics are identical or bioequivalent to the brand drug with respect to pharmacokinetic/pharmacodynamic properties**
- **Generic applicant – ANDA- BA/BE studies**
- **API manufacturer – DMF filing**

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Regulations and Registration

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Pharmaceutical Business

- **Steady growth & resistant to economic recession**
- **Important contribution to the wellbeing of mankind**
- **Highly regulated industry**

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Competition

Pharmaceutical is a highly regulated industry - High Entry Barriers

- **Complicated Regulatory Requirements**
- **Long lead time for marketing authorization (5-7 yrs, some even began before originator's launch)**
- **Heavy investment in maintenance of marketing authorization (*c*GMP)**

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API Business

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API Production

- **Technology**
  - Organic Synthesis (asymmetric reaction, enzymatic reaction etc.)
  - Fermentation (beta-lactam, macrlides etc.)
  - Biopharmaceutical (proteins, MAbs etc.)
- **Mode**
  - Mostly batchwise
- **Quality**
  - USP, EP, JP, etc.
  - ICH Guidelines
  - FDA API GMP Guideline
  - Control of impurities, crystal forms, water contents, etc.

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API Business Hightlights

- **Regulated Business**
  - Drug marketing & process change must be approved by regulatory authority in each country
  - GMP (Good Manufacturing Practice) required by authority
  - Patent protection (Substance, Process, Polymorph, etc.)
  - EHS requirements (Environmental Health & Safety)
- **B to B Business**
  - Product sales through formulation customers
  - Customers include brand & generic companies
  - For Generics, products cannot be launched till originators' patents expire

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Business Introduction

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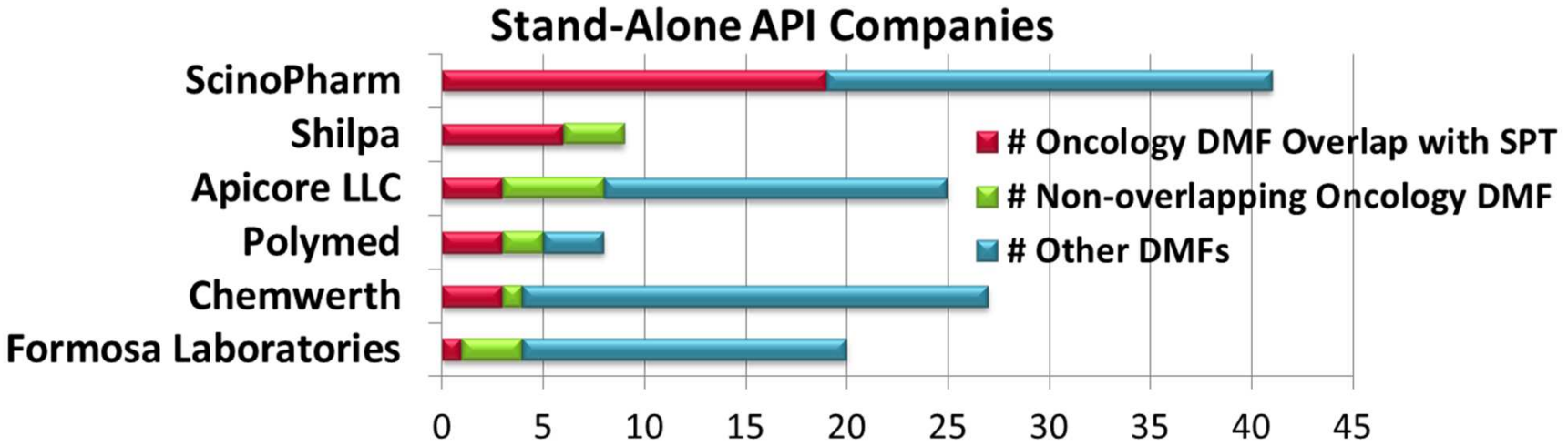
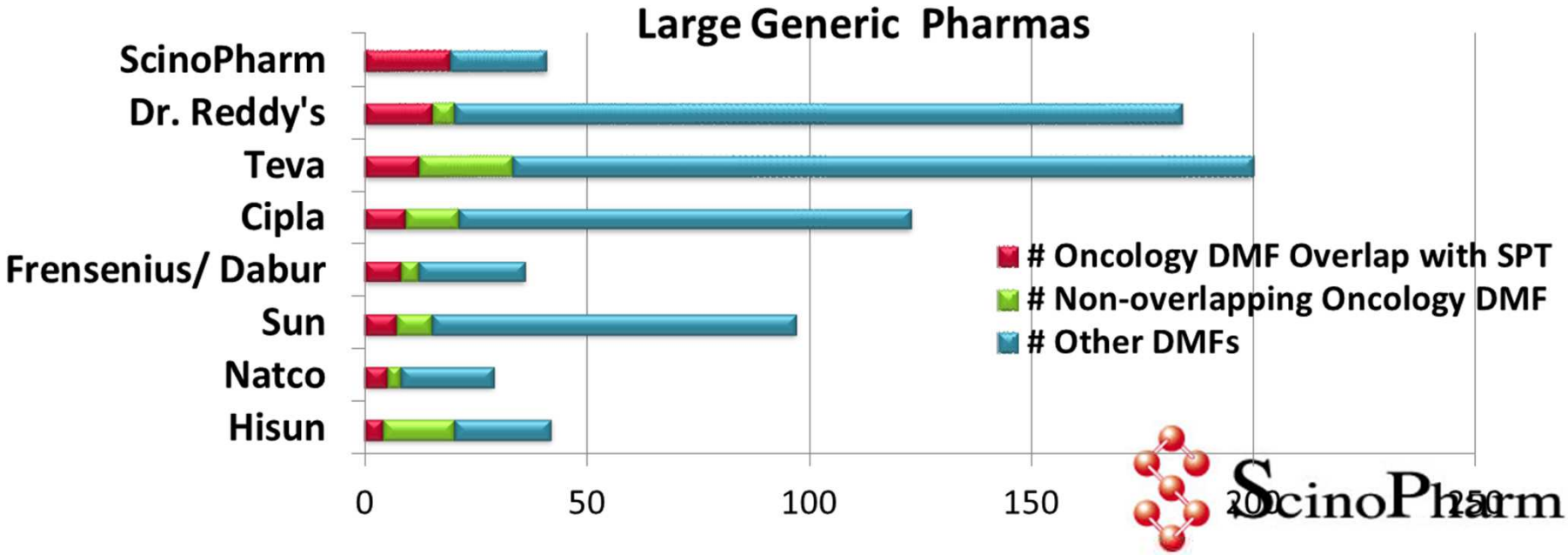
ScinoPharm - Oncological API Leader





Top 5 Generic APIs Account for 66% of 2011 sales

API	Indications	2011 projected MKT Share*	# of US DMF/EDMF & other Filings
Docetaxel Anhydrous	Anti-Cancer	38% (WW)	53
Irinotecan HCI	Anti-Cancer	44% (WW)	47
Galantamine HBr	Alzheimer's disease	49% (WW)	36
Paclitaxel	Anti-Cancer	21% (WW)	47
Gemcitabine Hydrochloride	Anti-Cancer	30% (EU)	51

* Source: Newport Global Sales Data

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2012 Product Launch Plan

API	Region	Indications	Brand Marketer	Regional Sales	WW Sales
Argatroban	US	Antithrombotic, Anticoagulant	GSK	$US 139MM*	$US 205MM*
Galantamine HBr	EU	Alzheimer's disease	Janssen	$US 314MM*	$US 527MM*
Modafinil	US	Antinarcolepsy	Cephalon	$US 1,078MM*	$US 1,182MM*
Riluzole	EU	ALS	Sanofi Aventis	$US 100MM*	$US 224MM*
Anastrozole	JP	Breast Cancer	Astra Zeneca	$US 270MM*	$US 1,109MM*
Levonorgestrel	JP	Oral Contraceptive	Bayer AG	$US 85MM*	$US 2,326MM*
Topiramate	US + EU	Obesity	Vivus	$US 1,000MM**	NDA

Source: * Newport & IMS Data
** Thomson Reuter

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Outlook

- **Sustain Leadership Position in Oncological Injectable APIs**

  Continue developing small molecule oncological injectable APIs and expand into other areas with high technology barriers including Peptides

- **Expand Presences in China**

  Expansion of API business to timely capture the Chinese market facing increasingly stringent GMP requirement

- **Japanese Market Penetration**

  Establishing strategic partnerships with major pharma companies in Japan and expect to market total 6 products in 2012

- **Vertical Integration**

  With synergy of our API business, expand into high-entry-barrier formulation business to maximize ROI

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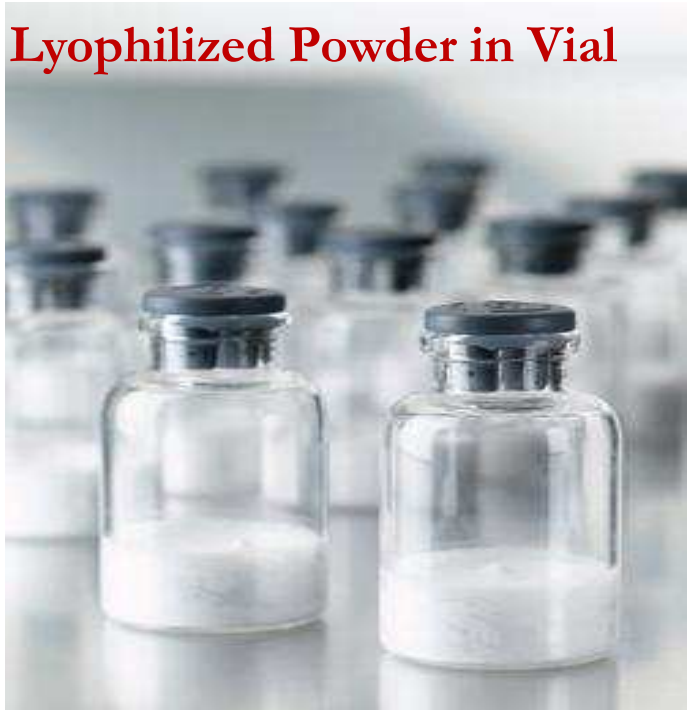
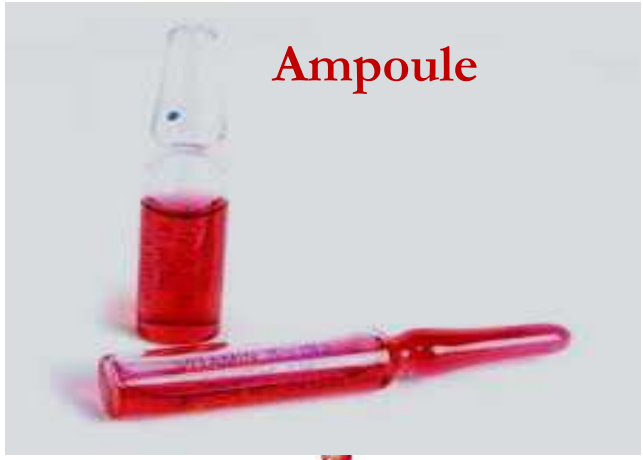
Liquid Solution in Vial

Lyophilized Powder in Vial



Prefilled-Syringe

Ampoule



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Difficulties in building and running oncological injectable plant

- With the stricter international CGMP standards in recent years, many injectable plants received warning letters and were required to stop production. Injectable CMOs are in undersupply condition, especially in oncological injectables
- CGMP requires extra cares to be taken to prevent cross contamination on cytotoxic oncological injectables, putting more pressures on the shortage of oncological injectable capacities
- Many injectable plants are outdated, creating contamination issues (including chemical, physical and microbial contaminations)

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Background for ScinoPharm to build an Injectable Plant

- ScinoPharm has been the leader in providing oncological APIs to regulated markets worldwide
- Most customers lack the capabilities of producing oncological injectables and are mostly outsourcing their production to CMOs
- Existing US and EU injectable CMOs are failing to meet the latest GMP standards and are required to stop production. Therefore, there is an undersupply of injectables, especially on oncological injectables
- Many customers asked ScinoPharm to provide injectables and one-stop shopping services

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Business Opportunities of ScinoPharm's Injectable plant

Customers own ANDA

- Customers own ANDA and ask ScinoPharm to be their CMO to make APIs into various injectables (such as liquid vial, lyophilized vial, etc.)
- At present, WW injectable capacities are in tight condition (pls see above page). Many CMO injectable plants or customer's in-house injectable lines have received FDA warning letters. They are forced to stop production.
- ScinoPharm providing injectables can not only satisfy customer's one-stop shopping needs but also secure ScinoPharm's API businesses. Even for those who didn't buy APIs from ScinoPharm can come to us to enjoy the CMO services.
- There are already several top 10 customers expressed their interests in outsourcing their injectable CMO to ScinoPharm.

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Business Opportunities of ScinoPharm's Injectable plant

ScinoPharm owns ANDA

- ScinoPharm can develop formulations using its own oncological APIs or using others' APIs, and apply for the formulation ANDA with FDA. It can then utilize its own injectable plant to make into all kinds of injectables (including liquid vials, lyophilized vials, etc.)
- ScinoPharm will continue its BtoB model and turn its various injectables to generic marketers for final distribution. Therefore, it saves those marketers the burdens of applying for ANDAs and they can easily buy from ScinoPharm and then resell the products.
- The potential customers under this model will not only be confined to those who already purchase APIs from ScinoPharm but could also expand to any distributors or marketers.

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Details of Injectable Plant

- Total CAPEX estimated at about US$ 37.6 million (equivalent to about NT$ 1.1 billion)
- The plant will be built in Tainan, with complete international GMP compliant facilities, including R&D, QA, cleaning, sterilized, production, filling, lyophilized, packaging, and warehouse areas.
- Estimated time for construction will be about 2~3 years.

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Thank You

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