



#### ScinoPharm Management Presentation

**TWSE 1789** 

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# Overview of ScinoPharm - An Active Pharmaceutical Ingredient Company

ScinoPharm has become the first Biotech/Pharma company to enter the "Top 100 valuable companies by market cap in TWSE", now ranking at #86

# **Company Overview**

- Maintain dominant position in Specialty APIs for generic market. Established strong presence in US/EU generic market, some channeled through Indian generic companies. Aggressively developing Japanese and Chinese markets
- Developed more than 50 generic APIs with 17 launched. Filed 41 DMFs in US (613 DMFs WW), leader in supplying oncology injectable APIs with 19 US DMFs
- 70+ NCE CRAMs projects, with 5 in phase III with NDA filing in 2-3 years & 3 already launched. <u>The</u> <u>only company in Asia supplying API for multiple</u> <u>NCEs for commercial</u>



#### ScinoPharm Changshu complies with latest Chinese GMP





# ScinoPharm Changshu Phase I QC Lab



High Standard Clean Room

Microbe Incubator

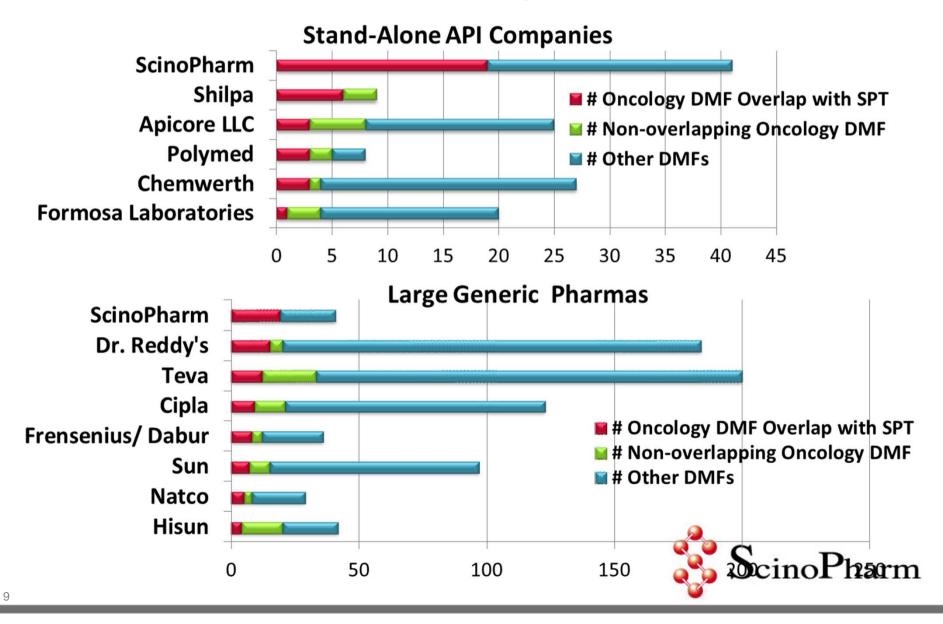


# Recent developments in SPT & SPC

- SPT's Bay 4, 5 will start pilot production and IQ/OQ by the end of Q3 and will start full production by the year-end of 2012
- SPC's phase I production facilities have obtained pilot production permits from local authorities
- SPC's phase I small and mid production lines have completed IQ/OQ and started production. Additional two large lines will complete IQ/OQ by end of August and start production in September



#### ScinoPharm - Oncological API Leader



# Financial & Operation Results

#### **P&L - Consolidated**

NT\$MM, except EPS	1H, 2012 (audited)	1H, 2011 (audited)	YoY
Net Sales	1,884	1,760	7%
Gross Profit	961	883	<b>9%</b>
Gross margin	51%	<b>50%</b>	
Operating Expense	(478)	(390)	22%
Operating Income	483	493	-2%
Operating margin	26%	28%	
Other Rev.(Exp.)	7	(19)	40%
Net Income after Tax	423	399	6%
Net margin before tax Net margin after tax	26% 22%	27% 23%	
EPS (after tax)	0.65	0.64	2%

EPS are calculated based on weighted average number of outstanding shares



### **Balance Sheet- Consolidated**

Cash and Cash Equivalents2,97230%2,00926%Accounts Receivable7327%6849%Inventories2,02221%1,40419%Long-Term Investments1502%2063%Fixed Assets3,47535%2,94238%Other Assets4725%3795%Total Assets9,823100%7,624100%L-T Liabilities and Others290%260%Stockholders' Equities8,36685%7,01792%	NT\$MM	2012/06/30 (audited)		2011/06/30 (audited)	
Inventories       2,022       21%       1,404       19%         Long-Term Investments       150       2%       206       3%         Fixed Assets       3,475       35%       2,942       38%         Other Assets       472       5%       379       5%         Total Assets       9,823       100%       7,624       100%         L-T Liabilities and Others       29       0%       26       0%	Cash and Cash Equivalents	2,972	30%	2,009	26%
Long-Term Investments         150         2%         206         3%           Fixed Assets         3,475         35%         2,942         38%           Other Assets         472         5%         379         5%           Total Assets         9,823         100%         7,624         100%           Lorrent Liabilities         1,428         15%         581         8%	Accounts Receivable	732	7%	684	9%
Fixed Assets       3,475       35%       2,942       38%         Other Assets       472       5%       379       5%         Total Assets       9,823       100%       7,624       100%         Current Liabilities       1,428       15%       581       8%         L-T Liabilities and Others       29       0%       26       0%	Inventories	2,022	21%	1,404	19%
Other Assets4725%3795%Total Assets9,823100%7,624100%Current Liabilities1,42815%5818%L-T Liabilities and Others290%260%	Long-Term Investments	150	2%	206	3%
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	Current Liabilities	1,428	15%	581	8%
Stockholders' Equities 8,366 85% 7,017 92%	L-T Liabilities and Others	29	0%	26	0%
	Stockholders' Equities	8,366	85%	7,017	92%

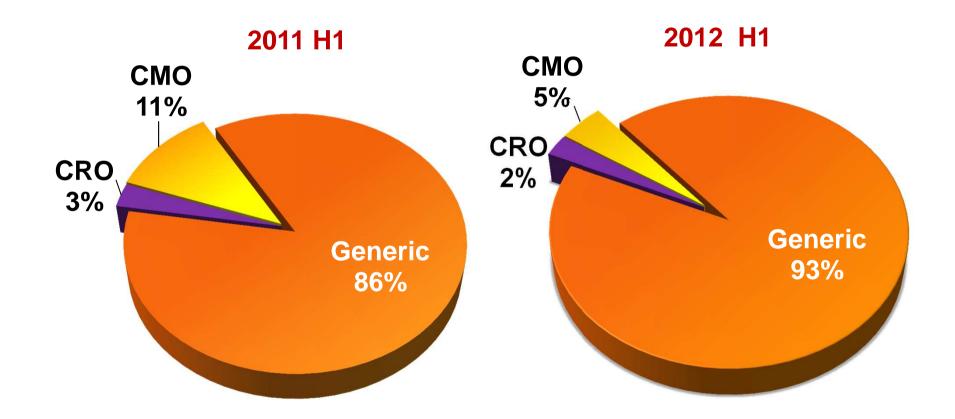


### **Cash Flows- Consolidated**

NT\$MM	1H, 2012 (audited)	1H, 2011 (audited)
Cash and cash equivalents at beginning of period	3,294	1,908
Cash flows from operating activities	96	407
CAPEX	(383)	(277)
Other Investing activities	35	29
Cash flows from financing activities	-	-
Cash and cash equivalents at end of period	2,972	2,009



### Sales by Business





### **Sales by Indications**

2012 H1 2011 H1 Others 12% Others Oncology 11% Oncolog **CNS** 64% y75% 13% **CNS** 25%



# **Obesity Drug Market**

## What is Obesity?

- Body Mass Index (BMI) a simple index of weight-for-height that is used to classify overweight and obesity in adults (by WHO)
- How to calculate your BMI?
  - BMI (Kg/m<sup>2</sup>) =  $\frac{\text{Weight}(\text{kg})}{\text{Height}(\text{m})^2}$
  - WHO Definition Overweight, BMI ≥ 25; Obesity, BMI ≥ 30
  - TFDA Definition Overweight, BMI 24~27; Obesity, BMI > 27



References- WHO Fact Sheets 2012; TFDA Consumer Info

### **BMI Calculation**

Weight (kg) Height (cm)	40	50	60	70	80	90	100
150	18	22	27	31	36	40	44
155	17	21	25	29	33	37	42
160	16	20	23	27	31	35	39
165	15	18	22	26	29	33	37
170	14	17	21	24	28	31	35
175	13	16	20	23	26	29	33
180	12	15	19	22	25	28	31

TFDA Definition – Overweight, BMI 24~27; Obesity, BMI > 27



# Obesity

- According to TFDA, 1.8 million people in Taiwan are obese and 3.5 million people are overweight. In 2010, 35.7% (>78m) of US adults are obese; this is expected to reach 42% in 2030
- Obesity increases premature death by 40% and is associated with increased risk for –
  - Coronary heart disease, diabetes, hypertension, stroke
  - Cancer
  - Depression, sleep apnea
  - Osteoarthritis
- Obesity market size
  - Estimated 2010 WW revenue- \$2.4 billion (CAGR 2002-2010 = 3%) 2010 US Revenue - \$1.1 billion
  - Estimated growth CAGR 5%, reaching \$3.4 billion in 2017



# Anti-Obesity Market Has High Unmet Needs

- Withdrawal of Sanofi-Aventis' Acomplia (rimonabant) in 2008
  - Rimonabant is associated with increased risk of psychiatric side effects
  - Withdrawal of Abbott's Meridia (sibutramine) in 2010
  - Sibutramine is associated with increased risk of serious cardiovascular events- stroke & heart attack
- In 2010, Xenical (orlistat) and few generics were left in the obesity market
  - Embarrassing side effects- oily spotting, flatus, fecal urgency, fatty stools
  - Inadequate safety profiles of generic orlistat- liver malfunction
  - Inadequate efficacy profiles— only delivers short-term results
  - 2011 worldwide sales \$562.9M; 82,976.2 kg
- In 2012, FDA approved two anti-obesity drugs within a month: Qsymia<sup>TM</sup> (by Vivus) and Belviq<sup>®</sup> (by Arena)



References- GlobalData 2010; NewPort

### Qsymia<sup>TM</sup> vs. Belviq®

	Qsymia <sup>TM</sup> (topiramate + phentermine)	Belviq® (lorcaserin HCl)
Approval	July 2012	June 2012
Commercialization	2012Q4	2013Q1~Q2
Efficacy	Placebo adjusted weight loss= 7.5- 9.4%	Placebo adjusted weight loss= 3.1- 3.6%
Safety	Fetal developmental abnormalities	Animal carcinogenicity (tumor formation in rats); valvulopathy (heart valve damage)
Dosage	Once daily capsule of 3.75mg phentermine and 23mg topiramate extended release	Twice daily tablet of 10mg
Remarks	Combination treatment– advantage of having the ability to address obesity linked health risks (diabetes, hypertension, dyslipidemia)	Single agent
		Required to complete six post-marketing studies, including a long-term cardiovascular outcomes trial (CVOT)
		DEA recommended that Belviq be listed as a controlled substance

References-NewPort; Drugs@FDA; GlobalData 2012; Pharmalot 2012; Bloomberg 2012



# ScinoPharm Will Be the Supplier of Topiramate for Vivus' Qsymia<sup>TM</sup>

- Vivus' oral anti-obesity drug, Qsymia<sup>TM</sup>, was approved by the FDA on July 17<sup>th</sup>
- Qsymia<sup>TM</sup> is forecasted to achieve a market value of US\$1 1.2bn within the next 5 years
- ScinoPharm is the only supplier of topiramate for Vivus' Qsymia<sup>TM</sup>, a combination obesity drug of topiramate and phentermine



# Anti-Obesity Pipeline Late in Line for Competition

- Orexigen's oral combination pill, Contrave (bupropion + naltrexone), faces a prolonged regulatory hurdle
  - Pre-approval cardio-vascular outcomes trial (CVOT) is required expected approval is in 2014
  - Placebo adjusted weight loss= 3.2- 5.2%

API	Brand Name	Originator	Phase	Route
bupropion + naltrexone	Contrave®	Orexigen	III (complete)	Oral
velneperit	(8-2367)	Shionogi	II	Oral
tesofensine	(NS2330)	NeuroSearch	II	Oral
zonisamide + bupropion	Empatic®	Orexigen/ Takeda	II	Oral
tesamorelin	Egrifta®	Theratechnologies	II	Oral

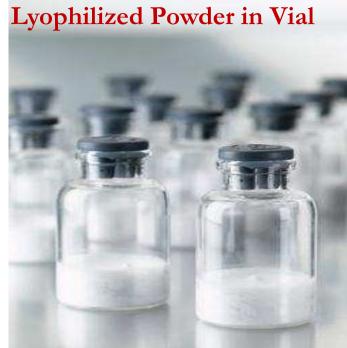


References- Nature reviews (2011);

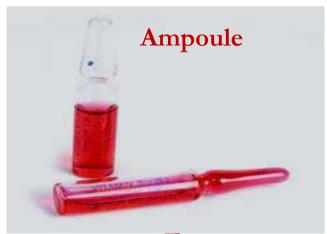
# **Injectable Plant Project**

#### Liquid Solution in Vial











# 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)



## **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



#### Shortage of Injectable CMO capacities

Location	Company	Oncological Liquid Vial	Oncological Lyoph. Vial	Non-Onco Prefilled Syringe
Australia	Hospira	V***	<b>V</b> ***	<b>v</b> ***
Canada	Uman Pharma	V***	V***	V***
Germany	BioPharma Solutions	v	v	v
USA	Ben Venue	Business suspended	Business suspended	Business suspended
USA	OsoBio	v	v	x
USA	Pii	V***	V***	V***
India**	Cipla	V***	V***	V***
India**	Emcure	V*	x	<b>V</b> *
India**	Gland	v	v	V***
India**	Intas	V***	V***	V***
India**	Strides Arcolab	V****	V****	<b>V</b> ****

\* Limited capacities

- \*\* Serious concerns on Indian's quality
- \*\*\* CMO also engages in final sales
- \*\*\*\* Exclusive with Pfizer



# **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.



# **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.



#### **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.



# **Business Outlook**

### **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 Beuter Source: * Newport & IMS Data					inoPharn

**\*\*** Thomson Reuter

### 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





#### Brand Quality with Asian Advantages

www.scinopharm.com

