Practice of Crisis Management
– Bankruptcy & Reorganization of TTY Biopharm Co., Ltd. (台灣東洋)

Gary T. Tseng
Deputy Chairman, TTY Biopharm
May 28th, 2010
A Tip of Wisdom

Alice: Would you tell me, please, which way I ought to go from here?

Cat: That depends on a good deal on where you want to get to?

Alice: I don’t much care where.

Cat: Then it doesn’t matter which way you go.

– Lewis Carrol, “Alice’s Adventure in Wonderland.” 1865
Where the Crises Emerge

- Changes of industrial environment
- Enterprise getting aged
  - Used to take for granted
  - Stick to existing advantages
  - Not be able to reposition itself in time
  - Not be able to build up new competence
- Greedy for growth
  - Pursuit of revenue at the expense of gross margin
  - Inconsistency in its manufacturing, marketing, R&D and financing strategies.
  - Looking for short term interests at the expense of long term ones.
- Myth of being big
Mirror, Mirror, on the wall, who is the fairest of them all?

– Grimm (1785-18063): Snow White
Positioning – Optimal Process

Where are we now?
- Internal Analysis
- Company Analysis
- External Analysis
  - Market / Competitor / Environment Analysis

Where do we want to go?
- Objective Setting
  - Quantitative / Qualitative Objectives
  - Position

How will we get there?
- Strategy Formulation
  - Area, Style, Position, Substance
  - Where to compete? How to compete? With what to compete?

Which action do we have to take?
- Competence
- Process
- Organization
- Personal
- Procurement
- Culture

How will we know where we have arrived?
- MUST BE FIT
  - Value - Trade off
  - Are we on the right way?
Evolution of TTY

Strength of TTY

Future Pharmaceutical Trend

Trade-Off

Portfolio management

Technology driven development
(Formulation + Product selection + Strategic and fir governmental regulations)
Evolution of TTY

1. Pure generic Pharmacy
2. Reorganizing & repositioning in 1994
3. Brand Generic Pharmacy
4. Marketing-Oriented Pharmacy (Specialty Pharma)
5. Development-Oriented Marketing Pharmacy (Specialty / Niche Pharma / Global Player)
Repositioning of TTY

Go Niche, or Go Big, or Get Out!

Trade-Off

Go Niche

Innovation

Value Chain Integration
TTY’s Drug Development & Its Position in Value Chain

TTY Department / Function

PDD
MRA
RA
Factory
NPD (New Product Development)
Supporting Function
### Repositioning of TTY

**Manufacture process defines the the Product**

<table>
<thead>
<tr>
<th>項目</th>
<th></th>
<th>IND</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>NDA</th>
<th>Phase IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>時程</td>
<td></td>
<td>5~7年</td>
<td>6個月~1年</td>
<td>1~2年</td>
<td>2~3年</td>
<td>1~2年</td>
<td>Long term</td>
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<tr>
<td>目的</td>
<td></td>
<td>生物安全性及活性試驗</td>
<td>安全性及劑量</td>
<td>有效性及不良反應</td>
<td>確認有效性長期使用之不良反應監測</td>
<td>FDA 審查</td>
<td>安全性</td>
</tr>
<tr>
<td>取樣人數</td>
<td></td>
<td>実驗室及動物試驗</td>
<td>20~100名健康志願者</td>
<td>100~400名志願病患</td>
<td>1000~3000名志願病患</td>
<td>數百~數千人</td>
<td></td>
</tr>
<tr>
<td>成功率</td>
<td>(250/10,000)</td>
<td>&lt;1% (5/10,000)</td>
<td>70%</td>
<td>33%</td>
<td>25%</td>
<td>20% (1/5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.5~3仟萬</td>
<td>3~3.5仟萬</td>
<td>8~9仟萬</td>
<td>2億</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Research**

中研院  
國衛院  
台灣東洋  
永信生達  
中化  
智擎生技、永昕生技

[TTY Biopharm](#)
TTY Business Model
Factors of differentiation

- Product portfolios (product range advantage)
- Medium market size but unmet need in
  - Logistic: service/ just on time for supply chain
  - Satisfy customers’ prescription need
  - Orphan drugs
- Competitive cost (Fit)
- Technology platform (Fit)
<table>
<thead>
<tr>
<th>定位</th>
<th>Competency Alliance</th>
<th>Consistency</th>
<th>Insist</th>
</tr>
</thead>
</table>
| 作法 | 傳統藥廠 | 1. Where to compete  
2. How to compete  
3. With what to compete | Culture shaping | D Day → 3  
M → 6M → 1Y  
→ 4Y → 7Y |
| | 癌症、心血管、胃腸、抗感染 | 活化資產：土地/AR/ 庫存開創劑型  
通路: DR, GP, HP → HP  
License: 300 → 60  
Logistic: 成會合理化，價格授權合理化，IT與策略一致，送貨，倉儲  
研發適當化及集中化 | 文化與策略的一致性 | Trust →  
Suspect →  
Against →  
IPO →  
Exciting →  
Dilemma ???  
Reposition |
Generic Markets and Business Models

**Sub Markets**
- Low Price Generics
- Medium Cost Pure Generics
- Innovative, Differentiated Generics
- Branded Products

**Business Model/Positioning**
- Low Price Generic Drug Manufacturer
- Production Focused High Quality Generics Manufacturer
- Integrated Manufacturer of Innovative, High Quality Generics
- New Drug Entity

**Factors of Differentiation**
- New Entity
- New Formulation
- New Combination
- Tailor-Made Clinical Trial
- Marketing & Sales
- Alliance
- Specialty RX
- Marketing profiles of localization

* Market Description: market size, market areas, basic market information, etc.
Trends for Bio-pharmaceutical Industry in Taiwan

- Entry Barrier (Profit)
  - Generic
  - New Formulation
  - New Indication
  - Special Formulation (Technology Platform)
  - New Derivatives
  - New Entity
  - New Combination
Definition of Each Section

- **Generic**
  - Cost: NT$200,000~800,000
  - Core competence: Manufacture, promotion
  - Market: local

- **New Formulation**
  - Cost: NT$800,000~3 billion
  - Core competence: Regulation, CT, CMC, Patent
  - Market: local, region

- **Special Formulation**
  - Cost: NT$3 billion~5 billion
  - Core competence: CMC, Steerage Regulation, Technology platform, CT, Patent
  - Market: region (global)

- **New Entity**
  - Cost: NT$15 billion up
  - Market: Global
Definition of Product Category

Core products
- Highly pharmaco-economic
- Highly differentiation
- Long product life cycle

Supporting Products
- Slightly pharmaco-economic
- Slightly differentiation

Through

- License-in (NCE) or
- New Formulation

Creates

- Market channel
- Category profile (know-how)
- Person of potentiality

Through

Own Formulation
Clinical Trial
Marketing Activities Enforcing Brand Images

Creates

- Portfolio with core products
- Category profile
- Critical mass
- Higher margin
Category Management

- Core Products
- Supporting Products
- Opportunity Products

Category Profile Marketing

- Create Critical Mass
- Create Significant Margin
- Prolong Business Life Cycle
## TTY Strategic Goal

| 2015年 | 營業額140E (淨利來源：台灣20%; 其他市場80%) |
| 2010年 | 市值150億; 營業額60億 (台灣佔50%; 其他市場佔50%); 淨利潤10億 |

### Portfolio Development
- 非重點產品研發外包
- 建立國際 R&D 合作開發伙伴 (Co-develop/ Market Harmonize)
- Developing Special formula/ Bio-Drug/ 有IP保護之”Me too NCE”
- 配合IP佈局及突破策略，執行CMC及劑型修正
- 2008年啟動 1st Biodrug Concept Proved
- 2009年啟動 1st NCE/NBE Concept Proved in China
- 2010年完成 API Plant 在大陸建立 (High Potency)
- 2012年完成 Bio-Drug Clinical Trials in Taiwan & China
- 2012年完成 2個 Bio-drugs 在台灣或大陸取證
- 2013~取得 Bio-drug 產品全球授權

### Portfolio Marketing
- 深耕 (Data/ Network/ Sales) 策略性客戶，同時建立商業覆蓋伙伴
- 發展或購併業務團隊 (in Home Market)；非策略性客戶委外經銷
- 專注經營 Oncology, Critical ID, CNS, CV/GI，在國際交互授權
- 2008~2009年在 Fragment Market 合計拿到20張藥證
- 2010年達到全球擁有超過20國家的代理商，進入中東地區（含北非）10個國家、東協10個國家及歐盟10個國家
- 2010年3 Products Launched in EU or JP

### OD/HR
- 2009年在大陸建立 Oncology NPD team團隊
- 並於2012年完成整合 Oncology Portfolio 完成整體組織團隊建構
- 2012年在大陸上市 CNS Specialty產品，成為大陸前五大 CNS Specialty Pharma公司
- 2015年在亞洲、歐洲完成 5 IPO & 15 Overseas Branch Offices

### Manufacturing
- 非重點產品生產外包
- 建立國際規格之 CMC/CTD Format/GCP/FDA Grade GMP
- 2009年中壢癌症廠 FDA or JP 送件申請
- 2009年第一個產品通過Japan審查
- 2009年啟動並於2011年TOT China 針劑廠建立

### TTY Policy/Milestone

| Portfolio Development | 2007年年中 所有抗癌藥品擁有國際規格之CMC/CTD format, ICH data 於符合FDA規格製造廠生產 |
| OD/HR | 5年內(by 2012) 2個Bio-Drug 在台灣或大陸取證 |

### Manufacturing
- 2009年中壢癌症廠 FDA or JP 送件申請
TTY’s Evolution in the Past 15 Years

Multi-National Pharmaceutical Companies
Pfizer, Sanofi-Avantis GSK......

<table>
<thead>
<tr>
<th>Pure Generic</th>
<th>Premium</th>
<th>Brand Generic</th>
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</thead>
</table>

(2003-2006) Specialty (Niche) Pharma
(Local Player)

(2006-2012)
Specialty (Niche)
Pharma International Players

2012-2018 NCE/NBE Globalization
Execution

- Plans are nothing; planning is everything.
  Dwight David Eisenhower (1890-1969)

Speed

- Today, there are just two types of companies: the quick and the dead.
  Andy Grove, Chairman and former CEO of Intel (1999)
About TTY (TTY Biopharm Co., Ltd.)
From Bankruptcy to IPO

- Founded in 1960
- Traded on the Taiwan GTSM (2001, symbol: 4105)
- Shares outstanding: 128.3 Million Shares
- TTY Biopharm sales as of 2009: NTD 2.2 billion
- Number of employees: 401 (TTY Biopharm)
- Headquarters: Taipei, Taiwan

Major Investments

- PharmaEngine, Inc. (Taiwan, 28.63%, NTD 234 million) (智擎生技)
- China
  - WorldCo (100%), Beijing (北京榮港公司)
  - XDHP (55%), Shanghai (上海旭東海普公司)
  - Jiang Su Biopharm Tech Co., Ltd. (100%) (江蘇東揚生技公司)
  - TOT Biopharm (China) 東曜藥業 (50%)
    - Sundia Biopharm Tech. 東迪醫藥科技 (60%)
    - 浙江東曜針劑廠 (100%) TOT Biopharm (China) Specialty Injection
  - 東源生技醫藥科技(上海)股份有限公司 (100%) TOT Shanghai R&D Center
- Philippines (87%) 菲律賓子公司
- Thailand (40%) 泰國子公司
- Vietnam (70%) 越南子公司
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
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<tbody>
<tr>
<td>1960</td>
<td>Founded</td>
</tr>
<tr>
<td>1987</td>
<td>Chung-Li Factory passed its GMP inspection</td>
</tr>
<tr>
<td>1993</td>
<td>Started its business in Shanghai (China) through JV with Hai-Pu Pharmaceutical Co., Ltd.</td>
</tr>
<tr>
<td>1996</td>
<td>Started its reengineering and repositioning</td>
</tr>
<tr>
<td>2000</td>
<td>New anti-cancer drugs – Lipo-Dox &amp; UFUR launched</td>
</tr>
<tr>
<td>2000</td>
<td>New plant specializing in anti-cancer drugs built</td>
</tr>
<tr>
<td>2001</td>
<td>Traded on the Taiwan GTSM (September 2001; Symbol: 4105)</td>
</tr>
<tr>
<td>2002</td>
<td>New anti-cancer drugs – Thado, Asadin &amp; Oxalip launched</td>
</tr>
<tr>
<td>2004</td>
<td>Started its subsidiary business WorldCo International Ltd. in Beijing (China)</td>
</tr>
<tr>
<td>2004</td>
<td>Chung-Li factory passed its cGMP inspection</td>
</tr>
<tr>
<td>2005</td>
<td>New core-product Mopride launched in Taiwan</td>
</tr>
<tr>
<td>2007</td>
<td>New oncology (injection) factory established (Chung-Li, Taiwan)</td>
</tr>
<tr>
<td>2008</td>
<td>Oncology factory passed its PIC/S GMP inspection</td>
</tr>
<tr>
<td>2009</td>
<td>Become a co-development partner of to-BBB, the Dutch brain cancer drug company for the manufacturing of brain-targeted doxorubicin liposomes.</td>
</tr>
<tr>
<td>2009</td>
<td>First generic Docetaxel (Tyxan) Injection approved in EU (collaborated with Alfred E. Tifenbacher GmbH)</td>
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</tbody>
</table>
Dedicated Plant with PIC/S GMP

- The only dedicated plant in Taiwan, which complies with international PIC/S GMP certification and meets EMEA/USFDA standard
- High standard Validation of
  - Equipment qualification / Laboratory instruments qualification / HVAC system / Water system / Compressed air system / Nitrogen system / Cleaning / Analytical method / Process / Computer / Logistic
- Individual flow management
  - Air flow / Man flow / Material flow / Product flow / Waste flow
  - To prevent cross contamination and environmental pollution of oncology products

- HVAC system
- Work Safety
- Environmental Protection
- Precise Manufacturing Process
Translational Lab Facilities (Candidate selection)

CEC/CEP detection center

SPF animal colony

Molecular Biology Laboratory

Pathology
- Mice, Rat and human pathology test
- IHC/FISH staining
- Imaging analysis
- Application: Tumor bio-marker detection

Molecular Biology
- CEC/CEP detection anti-cancer drug efficacy test
- Anti-cancer drug mechanism finding
- Cytotoxicity
- Resistance cancer cell lines set up

Animal Study Platform

Clinical
- Tumor bio-marker screening
- Angiogenesis surrogate marker test

Functional Imaging
Globalization - Expand from Home Base
TTY 長期股權投資產業價值鏈

長期股權投資產業價值鏈

發現新分子藥物

標的新分子

臨床前

研究

申請新藥

研究

Phase I

clinical trials

Phases Phase II / III

Regulatory Work

Approval

上市

後研究

上市

銷售與

市場接受度

Marketing

Discovery/ Research

Pre Clinical Development

Clinical Trials Phase I

Clinical Trials Phase II / III

Regulatory Work

Production

Distribution

Sales & Marketing

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Gligio
Thanks for Your Attention!