Challenges in Building a Vibrant Biotech/Pharma Industry in Taiwan – an Industry Perspective

www.scinopharm.com

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ScinoPharm’s Mission

• Leading provider of API services for new drug development & brand companies
  – Contract Process R&D and Clinical Supplies
  – Contract Manufacturing

• Dominant player in generic API market

• Supplying small molecules, peptides, biopharmaceutical services
Corporate Structure

Corporate Ownership

- Watson Pharm, 30.65%
- SPT Employees & Others, 17.41%
- Taiwan Sugar, 4.72%
- Development Fund, Taiwan Government, 15.86%
- Mega Bank, 1.23%
- Uni-President Group, 30.15%

Corporate Ownership
Business Strategies

• Maintain balance between generic & brand business, non-competing on same product, to best handle the cyclical nature of the industry

• Offer quality services at substantial discounts over Western suppliers

• Provide comprehensive (life-cycle) and supply chain services to brand pharma from clinical materials to commercial products

• Focus on generic APIs with high technological barriers

• Provide low cost R&D and manufacturing of early steps in China coupled with high quality, IP-protected GMP production in Taiwan
Progress Overview

• A leading oncological API supplier
• Providing services to both generic & brand companies
• Passed multiple FDA inspections
• ~40 Generic APIs, ~ 8 new APIs/Yr, total 24 US DMFs
• >60 NCE API projects, 5 in phase III, 1 launched
• > 150 Customers worldwide, >35 supply agreements
• Expand from small molecules to peptides, nucleic acids & proteins
ScinoPharm in Taiwan

- 330K ft² facilities with 109 M³ reactor volume, 11 lines, 6.6 hectares of land with expansion potential
- US FDA approved & >30 GMP audits by customers
- High potency, injectable grade capabilities
- Custom synthesis business
- Generic API development
- Small molecules, peptides, Biopharmaceuticals
- ~400 people
ScinoPharm in China

- One hour from Shanghai
- Full synthetic & analytical capabilities
- Captive services to ScinoPharm Taiwan
- Generic API process development
- Key intermediates production
- Appropriate GMP
- Small molecules
- ~100 people
ScinoPharm Biotech

• Developed cell lines and lab processes for 6 biogenerics (biosimilars)

• Host systems include *E. Coli*, Yeast and *CHO* cells

• Full Scope Development Capabilities
  – Cloning
  – Expression & Amplification
  – Fermentation & Cell Culture
  – Recovery & Purification
  – Product Characterization
  – Bioassay
  – MAAb Humanization

• Products meeting EP specifications, ready for scale up

• Have access to a GMP facility

• Also involves in NCE contract service

• ~20 people
Technologies

• Small Molecules
  – *High Potency*
  – *High Technological Barriers*
  – *Patent Non-infringing*
• Peptides
• Nucleic Acids
• Biopharmaceuticals
Custom Synthesis Product Pipelines

SPT CRO/CMO Projects Distribution

- Pre-clinical: 14
- Phase I/II: 25
- Phase III: 6
- Commercial, NCE: 1
- Commercial, CMO: 18

Total=64

Drug Stage

Project #
What does Taiwan have to offer?

• Capital
• Strong government support
• Work force with pride and strong sense of loyalty
• Sentiment associated with home coming
What is missing in Taiwan?

• Global perspectives
• Western management skill
• Consistent law and regulation
• Faith in human integrity
• Respect for professionalism
Taiwan Economy

- Dominated by family businesses
- Opportunistic instead of long term
- Major driving force from the government
Challenges facing Taiwan

- Too small a domestic market
- Not regarded as a sovereign country
- Detached from the international reality
- Limited talent pool
- Young people are complacent and not adventurous
- Over management by the government
- Technology licensing mechanism not well established in most universities
- Academicians’ lack of genuine interest in helping industrial development
- Most local companies lack the financial and technical resources to become global leaders
Possible Actions

• Encourage regular scientific exchanges between NCKU and ScinoPharm including frequent “brain-storming” discussions

• ScinoPharm offers academic scholarships

• ScinoPharm offers summer internships

• ScinoPharm offers a course on “Overview of the International Pharmaceutical Industry”

• A portion of the “thesis” work can be performed at ScinoPharm

• ScinoPharm work with NCKU to co-develop a course on “Scientific Management in Industry”
Thank You!!