




BioBusiness Asia 2009

Company Name	Simpson Biotech Co., Ltd.		
Presenter	Chia-Chin Sheu	Title	President
Address	1-1 Wen Min 2 nd Street, Kuei Shan, Taoyuan, 33383 Taiwan		
Website	http://www.simpsonbiotech.com		
No. of employee	34	Year of foundation	1998
Company Categories	<input type="checkbox"/> Novel Therapeutics <input type="checkbox"/> Genomics Pharmaceuticals <input type="checkbox"/> R&D Service <input type="checkbox"/> Medical Devices Other <u>Contract Manufacturing</u>		
Paid-in Capital	10 millions US Dollars		
Company Stage	<input type="checkbox"/> Seed <input type="checkbox"/> Start up Expansion <input type="checkbox"/> Mezzanine		
Company Overview	Simpson Biotech Co., Ltd. (SBC) is a bio-fermentation company established in 1998. SBC currently focuses on (i) protein expression & purification techniques used for the production of biosimilars and industrial enzymes, (ii) fermentation and applications of mycelia from several medicinal fungi and early stage drug discovery from these mycelia products.		
Company History			
Main Products/ Service & Niche of Products/ Service	<p><u>Major Products/Services:</u></p> <ol style="list-style-type: none"> 1. HERPEPS™: (High Efficiency Recombinant Protein Expression and Purification System) and recombinant proteins OEM/ODM fermentation services/Contract manufacturing including biosimilar production license 2. Early stage drug discovery from medicinal fungi and their pre-clinical studies thereof <ul style="list-style-type: none"> ● Hepasim®: The major active compounds isolated from fermented fungus, <i>Antrodia camphorata</i> Mycelia (ACM with potent anti-virus (HCV/HBV), hepatoprotective, anti-fibrosis, anti-inflammation and anti-tumor activities ● Camphoratan™ A: The 2nd active compound (polysaccharide) isolated and identified from ACM with strong anti-fulminant hepatic injury activities 3. Industrial enzymes: phytase, xylanase (animal feed), lipase (biodiesel, food additives) <i>etc.</i> 		

Market Potentials	<p>1. Advantages of HERPEPS™:</p> <ul style="list-style-type: none"> ● Extremely low production cost: starch as affinity resin, i.e. <\$1.5/g for Phytase (feed enzyme) ● Obtain clean-cut (tag-free) biosimilars/enzymes ● High recovery rate: >70% (>90% in Lab. Scale) ● Very high fermentation titers: > 10g/L (<i>pichia</i>) ● Successfully expressed in many hosts (<i>P. pastoris</i>, <i>S. cerevisiae</i>, <i>E. coli</i>, Baculovirus ...) ● Poor-expressed proteins can now use larger batch while still under budget. ● Disposable protein purify/de-tag sub-system – Reduce contamination & save money ● Simple one-step purification process for tag-in industrial enzymes <p>Applications:</p> <ul style="list-style-type: none"> ● Biosimilars (INF-alfa, etc.) ● Protein A ● Enzymes (Phytase, Lipase, Xylanase <i>etc.</i>) <p>2. Hepasim®- Anti-virus & Anti-fibrosis Compounds from Fungus!</p> <ul style="list-style-type: none"> ● Hepasim® A~I: Anti-HCV (Hepatitis C Virus) replication: Promising IC50 = 0.9 µg/mL (~3.3 micromolar ; PCT Patent Pending) ● Hepasim® B: Anti-HBV, (J. Chin Med (2005) 16(1): 57-61) ● Hepasim® Y: Anti-Liver fibrosis/cirrhosis (TGF-β induced; in vivo) at fewµg/kg level !! (PCT Patent Pending) ● Hepasim® C: Reduced Hepatic Inflammation (cytokine, CCl4 & COX-2 induced; in vivo) activities (US Pat. 7109232) ● Hepasim® A~E: Anti-Tumor activities (liver, lung, melanoma, in vivo; prostate, intestine, bone, blood, lymph, breast cancer in vitro); IC50= 2~40 ppm (/w different cell lines; US Pat. 7109232) ● Some molecular targets (i.e. HCV, Inflammatory, Anti-Tumor) identified
Company Core Competence or Competitive Advantage	<p>1. HERPEPS™: Ultimate Low-Cost Protein Expression/Purification Platform: for Biosimilars, Protein A & Industrial Enzymes (<\$1.5/g)! The key technologies:</p> <ul style="list-style-type: none"> ● Proprietary Starch-Binding Protein (SBP) as the affinity-tag ● Proprietary endoprotease de-tag system ● Proprietary SEC-4 secretion factor to increase secretions in <i>Pichia</i> host ● Optimized media & fermentation processes <p>2. Hepasim®:</p> <ul style="list-style-type: none"> ● Anti-fibrosis/cirrhosis compounds at nM level ! ● Anti HCV (NS3/4A protease inhibitor) at IC50 ~3.3 micromolar <p>3 ACM as Botanical Drug:</p> <ul style="list-style-type: none"> ● Extremely high (15%) percentage of active compound (Hepasim®) inside CMC becomes more easy ● Not only Antivirus (HBV/HCV) but also Anti-Fibrosis (at a very promising nanomolar level) and anti-tumor ! ● 2 Clinical trials ongoing (use ACM as dietary supplement) : ● Ruby®Mushroom (commercial name) has been sold as a dietary supplement in Taiwan for more than 8 years, and now in many countries including US, Japan etc. - implies that the toxicity of Hepasim® should be relatively low ● Metabolic and pharmacokinetic studies of Hepasim® helps explain the reason why the toxicity should be relatively low.

<p>Partnering Objectives</p>	<p>We are looking for partnership ...</p> <ul style="list-style-type: none">  The Ultimately Cost Effective Protein Expression/Purification Platform(HERPEPS): <ul style="list-style-type: none"> ◆ Non-exclusive/Region/Field-of-use license ◆ OEM/ODM fermentation ◆ Small-scale pilot fermentation ◆ Large-scale fermentation technology turnkey  Botanical Drug Development (Ruby Mushroom[®] Mycelia): <ul style="list-style-type: none"> ◆ <u>Experienced management teams</u> for botanical drug development ◆ <u>Pharmaceutical companies</u> with experiences in new botanical drug development ◆ <u>Venture capital</u> for resource integration  Hepasim[®] (Anti-HCV/HBV, Anti-Inflammation, Anti-Fibrosis & Anti-Tumor): Licensing out  Camphoratan[™] A (Anti-Inflammation, Immune Regulation): Licensing out
------------------------------	---