Interview: George J. Lee, Ph.D. – Chairman; Tzu-Ming Pan, Ph.D – Vice Chairman and Chief Technology and Science Officer, SunWay Biotech, Taiwan



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George Lee and Tzu-Ming Pan introduce SunWay Biotech's groundbreaking red yeast rice extract, ANKASCIN

® 568-R, which has been recognized as a New Dietary Ingredient by the US FDA. SunWay Biotech is now bringing this unique product onto the global stage and are considering developing a pharmaceutical product based on the same compounds.

Could you introduce SunWay Biotech and the company's current product portfolio to our international readers?

George Lee (G.L.): SunWay Biotech was founded in 2007 with the idea of leveraging the innovative technologies developed by the research teams of Professor Pan, Distinguished Professor at the Department of Biochemical Science and technology of National Taiwan University *[considered one of Taiwan's best universities, e.d.]*. SunWay Biotech's vision is to establish a world-class, R&D-centered organization focused on the development of ground-breaking health foods and ingredients, while becoming a role model in terms of health promotion and the prevention of metabolic diseases and other life-changing conditions widely impacting rapidly-aging societies.

SunWay Biotech currently holds two major products in its portfolio: our flagship Red Yeast Rice extract ANKASCIN® 568-R which was granted New Dietary Ingredient (NDI) status by the US FDA in

January 2015, and our company's probiotic Vigiis® 101-LAB.

Professor Pan, in 2012 you became a fellow of the US Institute of Food Technologists (IFT) for your research on red yeast rice, a unique professional distinction rewarding your outstanding contributions to the food science and technology field. What is so unique about SunWay Biotech's ANKASCIN® 568-R that it was granted an NDI by the US FDA?

Tzu-Ming Pan (T-M.P.): All red yeast rice products currently available on the global market contain monacolin K, a type of statin whose long-term consumption may cause cumulative side effects such as liver damage, rhabdomyolysis, and acute kidney diseases.

ANKASCIN® 568-R proudly stands out as the only red yeast extract on the market that is free of all statins, as the result of more than ten years of research conducted by my teams at National Taiwan University. Throughout the development of this unique extract, we notably released more than 120 scientific publications including in vitro and in vivo experiments and conducted two randomized double-blind placebo-controlled clinical trials in Taiwan, in order to clearly demonstrate the unrivalled efficacy and safety of this extract's two new active compounds, monascin (MS) and ankaflavin (AK).

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Combined together, MS and AK display even better therapeutic outcomes than current products containing statins, while these benefits cover a wide array of health areas ranging from metabolic syndromes to the prevention and delay of Alzheimer's disease, as metabolic syndrome has recently been studied as a contributing factor to the condition. On rats with Alzheimer's diseases, we notably noticed that ANKASCIN® 568-R prevented and improved accumulation of Aβ40 and apolipoprotein E in the hippocampus, while contributing to improve cognition and memory of the subjects, as monascin and ankaflavin can pass through the blood-brain barrier and reduce oxidative stress in the brain.

Of course, ANKASCIN® 568-R has also proven to be extremely effective in the prevention of lipid plaques forming before atherosclerosis, as well as contributing to the successful treatment of hyperglycemia, hyperlipidemia and hypertension. One of the two aforementioned clinical trials for example indicated that, after eight weeks of administration, levels of serum cholesterol (TC) and low-density lipoprotein cholesterol (LDL-C) were statistically significantly reduced by 11.1 percent and 20.4 percent, respectively. Our other clinical trial showed that, after 12 weeks of administration, fasting blood glucose (FBG) levels were statistically significantly reduced by 9.3

percent.

Besides receiving the aforementioned NDI certification by the US FDA, we also filed more than 28 patents to protect this game-changing, GMO-free red yeast extract, while we now want to bring it onto all international markets.

What will be your commercial strategy to fully leverage the great competitive advantages of this product?

G.L.: Since ANKASCIN® 568-R was introduced into the US market by our Canadian partner in 2016, the product has been selling extremely well. As a matter of fact, we provided this brand client with a first batch of around 40 kilograms of ANKASCIN® 568-R. Such a quantity of extract roughly allows the production of more than 10,000 bottles of finished products, which were sold off in only a couple of months. As a result, our partner just ordered another batch of raw materials, which we are currently producing in our Taipei-based facility.

Such ongoing success has been undoubtedly driven by the outstanding quality of our product in the first place, but also by the science-based, evidence-backed approach we have been implementing since our beginnings. It is quite rare to see a health food-focused company conducting two clinical studies to test the efficacy of its product. The outstanding and rigorous results of these two trials – whose guidelines were very similar to FDA requirements – have now become a key asset in our marketing strategy for the US market, where scientific differentiators are becoming critical success factors as the health food sector is rapidly getting highly competitive.

Our product is already extremely popular and reputed in Taiwan where it is available at most personal care stores, such as Watsons *[the largest health care and beauty care chain store in Asia, e.d.]*. We now want to replicate similar successful market penetration in the US market, which is dominated by a handful of nation-wide and/or international health supplements retailors. To expand our reach throughout the US market, we are ready to develop new collaborations, either through classical marketing agreements or the establishment of local joint ventures.

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In the meantime, we are now working on bringing ANKASCIN® 568-R into various international markets, such as the EU, South America, Japan, and China. As for our Taiwanese and US approach, we want to remain focused on the manufacturing of the extract itself, while the manufacturing, marketing, and distribution of the final products will be handled by our local partner. We are already negotiating with potential partners in some of these geographies, but no agreement has

been signed yet.

What are the main specificities of your other product, Vigiis® 101-LAB?

T-M.P.: This unique probiotic is based on *Lactobacillus paracasei* (subsp. *paracasei* NTU 101), an in-house developed ingredient that displays outstanding resistance to gastric acid and bile salt. Keeping up with the science-based approach we have been implementing with the development of ANKASCIN® 568-R, we have already released more than 20 scientific publications demonstrating the unrivalled benefits of Vigiis® 101-LAB when it comes to relieving allergy symptoms, improving diarrhea condition, and preventing constipation. We are very proud of this novel strain, the efficacy and safety of which are absolutely unique.

As chairman of the company, what are your strategic priorities to drive long-term growth?

G.L.: Currently, our main focus is to increase the efficiency of our patented extracting and manufacturing capacity in order to ensure we can generate interesting profits as our products' sales will rapidly pick up.

Nevertheless, in the long term, our R&D focus will be leveraging the therapeutic effects of the two active compounds, Monascin (MS) and Ankaflavin (AK), beyond the health food area. Although statin-based pharmaceutical products display undesirable side effects, they remain widely used for treating metabolic conditions and cardiovascular diseases. As our combination of MS and AK offers similar efficacy without generating any of these aforementioned side-effects, we then plan to use the incomes generated in the health food field to start developing a pharmaceutical product based on this combination of MS and AK. If we can demonstrate the safety of these two compounds, I have no doubt that many pharmaceutical companies would be interested in partnering with us to develop this combination as a pharmaceutical product. Although it truly stands as a mid-term objective for our company, we however do not expect to start the development of this pharmaceutical entity within the next three years.

In the meantime, we also plan to IPO in Taiwan within the next 18 months. In December 2016, we completed the first step of Taiwan's IPO process and obtained public company status, while we have already chosen our underwriter. We can now expect to be registered on Taiwan's emerging stock market within the next twelve months, while we want to be profitable before the end of this year. Overall, the increasing of our sales combined with our ongoing efforts to improve our profitability and the resources we expect to raise with our upcoming IPO should provide us with the financial means we need to accelerate our international strategy. In the US, we do not exclude the

opportunity to set up our own marketing and sales channels in the mid-term if we identify this opportunity could be both feasible and commercially attractive for our company.

Finally, we have also developed a new product in another area, a collagen product which we are currently testing. Although this product is still at a development stage, we have decided to expand our collaboration with our current distributors in Taiwan, which will also handle the commercialization of this product once it reaches the market.

What is the company’s market positioning on the global stage?

G.L.: SunWay Biotech is the world leader for red yeast extract product in particular and in the food health area in general. By being able to market a red yeast product free of monacolin K, our company has truly rekindled the therapeutic potential of the red yeast rice, while red yeast rice has been used in the Chinese Traditional Medicine for almost 3,000 years.

In the meantime, the rapid increasing of our sales in the US further confirms the quality of our product, whose efficacy and safety have been established through multiple scientific publications. The health food market is booming and getting extremely competitive. Nevertheless, the unique specificities of our products have already been recognized by some of the most prestigious distributors internationally, as our products will soon be available in more than 30 countries.

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