Positioning the Taiwan Biologics Industry on the Global Map

Thank you for your kind introduction. It is my honor to be here today to share my thoughts on the Taiwan biologics industry with such esteemed colleagues.

Let me start by saying this: the good news is that we have a lot to look forward to. There are many challenges, but there is no doubt in my mind that if we put our minds to it, I firmly believe that we will become an important player in the global biologics space.

The people of Taiwan have an unparalleled entrepreneurial spirit that has propelled us to become a leader in industries where statistics should clearly dictate otherwise. We are a tiny island with a population of a little over 23 million – just one half of one percent of Asia's population – and yet we produce 9 out of 10 of the world's laptops.

Taiwan's semiconductors, information and communication products account for more than 70% of the global market share. We are the number two manufacturer of LCDs (liquid crystal displays) in the world. For such a small nation, we have had a pretty big impact.

Are biologics next? I think everyone in this room would agree that it certainly should be. According to a recent IMS report, annual global spending on pharmaceuticals is set to reach US$1.2 trillion by 2016, with pharmerging markets and biologics being the major drivers. Pharmerging markets are expected to account for 30% of the global market by 2016. While biologics contributed to less than 10% of the revenue of the top ten pharmaceutical companies in the world in 2001, today it is over 70%. The top 3 best-selling drugs in the world, and 4 out of the top 5, are biologics.

It is undeniable that the potential of the market is enormous, but the question is: how does Taiwan capture a meaningful share of the global market, and achieve a similar impact as it has in other industries like semiconductors?

Cultivating a successful high tech industry requires basic elements analogous to the 3C industry – namely good technology, good people, and good supporting infrastructure, including access to capital.

Biologics are high tech, high potential, high barrier of entry products and similar to the semiconductor industry, require a high level of research and development. In 1973, the Industrial Technology Research Institute (or ITRI) was born in Hsinchu. It acquired technology from abroad, developed it, and spun it off into commercial enterprises, effectively serving as a product incubator and feeder for the local semiconductor industry.

The same incubator and product pipeline is critical for the success of Taiwan biologics. To show how far we have come in the biologics industry already, let me digress briefly to when I returned to Taiwan to establish UBI-Asia.

Not long ago, my daughter asked me specifically why I established UBI. Ever since my graduation from National Taiwan University, I have been on a pathway paved by immunology as being the secret weapon of medicine, combined with a powerful motivation to develop medical interventions through the application of basic biomedical sciences. To create out of amino acids, the very sands of life, cost effective and highly efficacious treatment for diseases which ravage the human spirit and body. That, coupled with the unparalleled entrepreneurial spirit, [I mentioned earlier,] compelled me to take my research and create a company that would serve to help mankind. I founded United Biomedical, Inc., (UBI) in 1985. Prior to establishing UBI, I received my B.S. degree in Chemistry from National Taiwan University and my Ph.D. degree in Immunology and Biochemistry from The Rockefeller University. I was the head of the Laboratory of Molecular Immunology at the Memorial Sloan-Kettering Cancer Center and an Adjunct Associate Professor at Cornell University Medical School.

Since then, we at UBI have and continue to pioneer the integration of chemistry, immunology and bioinformatics for the innovative design of a new class of biologics employing designer synthetic peptides, from diagnostics to vaccines and immunotherapeutics, and later to monoclonal antibodies. We successfully developed and commercialized the world's first peptide-based blood screening diagnostics, for detection of HIV and HCV infections, products that are still sold globally today. We developed and commercialized the world's first fully synthetic peptide vaccine for foot-and-mouth disease in swine, and now vaccinate roughly a quarter of the world's pig population annually. The UBI technology platform now extends to a synthetic peptide vaccine for Alzheimer's Disease, entering Phase II trials, and a humanized

monoclonal antibody for the treatment of HIV, currently finishing Phase II trials. Both clinical trials are being conducted in Taiwan. We have a robust pipeline of other products in various stages of development for animal and human indications with the goal of achieving global impact.

From UBI to UBI-Asia and now United BioPharma we have used our HIV mAb, UB-421, as a touchstone to build integrated monoclonal antibody product based platform technologies from research to clinical, and a product pipeline with high market value. Our UB-421 has a great potential for the "functional cure" of HIV, a potential blockbuster both for the company and for mankind.

I provide this brief outline of UBI as an example of how far we have come in Taiwan with research and technology development. When I came back to Taiwan in 1998 and founded UBI-Asia, there was little domestic technology platform to leverage. I, together with my colleagues at UBI in New York, had to bring in our own technology and serve as our own incubator, engaging in a technology transfer from the U.S. to Taiwan for further development.

Today, however, there is home-grown technology that is not only interesting but also commercially viable. There are research institutions such as the Development Center for Biotechnology, DCB, which is an analogue of ITRI, to the biologics industry. DCB is a non-profit organization, co-sponsored by major government grants and private donations to support research and provide CRO services that develops products to be spun out into commercial firms. It has taken more than a decade, but DCB now delivers quality research resources and programs. UBI has in-licensed and collaborated with DCB on numerous occasions to date, and looks forward to continuing our working relationship closely.

But we as a community should not rely solely on DCB for new projects, especially not in an industry such as biologics, which is so dependent on innovation and research. The process from discovery to creation of a product to proof of efficacy is admittedly a very long and expensive one. Until one identifies useful molecular entities and compositions, and then tests the prototype products by extensive screening, such explorative exercises are like a fishing expedition. A worthy expedition, no doubt, but one that requires a stable resource to nurture.

The National Institute of Health, or NIH, in the United States spends about $30 billion annually to fund research project grants. UBI benefited from this funding tremendously, worth tens of millions through multi-year research grants and contracts for our HIV-and other related product development work, without which we would not be where we are today. Countless other enterprises and drug breakthroughs got their beginning through government support. In order to become a global player, Taiwan needs to step up and encourage our young Principal Investigators in government sponsored research institutes, universities, and qualified industrial players to pursue a coherent effort in product oriented applied R&D, more so in the translational medicine area, and provide them with sufficient funding opportunities to do so.

One related area that cannot be overlooked is the importance of the respect of intellectual property to protect these product developments and innovations. The establishment of patent estates around platform technologies and products is critical to meaningful reciprocal product licensing allowing for global reach. We must also respect international intellectual property statutes for multinational players to feel secure with Taiwan's biologics community and actively include us in the global supply chain of biopharmaceutical products.

As to quality human resources, as I mentioned previously, Taiwan has a uniquely strong domestic pool with an unparalleled entrepreneurial spirit.

Shifting back to the semiconductor analogue, recognizing that a high-tech industry requires a continual input of high-tech engineers, the government encouraged engineering studies and provided professional training through its science-based industrial parks. Moreover, the government provided opportunities for students to study overseas. Many of these students stayed on to gain valuable industry experience during their time abroad, acquiring not only technical knowledge but also industrial technology and operational management skills. When they returned, they often worked in high-level positions within institutions such as ITRI and later spun off into the private sector.

Fortunately for the biologics industry, over this same period, many of these students, including myself, went abroad to study immunology, biochemistry

and other life sciences relevant to the biopharma field. Some become entrepreneurs and started successful bio or pharmaceutical companies in the U.S.

There are numerous success stories, such as Nancy Chang and Tse Wen Chang of Tanox, Jane Hsiao of IVAX, Patrick Kung of T cell Sciences, Frank Kung of Gene Labs, Chi Min Chen of Andrz, Alan Chao of Watson Pharmaceuticals, Larry Hsu of Impax, LanboChen, Chiwhey Wong, to name only a few. These and other great minds have already, and, if not, are poised to return to Taiwan and can offer invaluable insight, serving as mentors for the next generation of Taiwanese scientists and entrepreneurs.

We have over 1 million citizens in Taiwan with advanced Master and Ph.D degrees.

Presently, Taiwan's curriculum in the biotech field focuses on basic science, and lacks courses in industry training. Even still, most graduates meet the basic demands of the biotech industry but do not gravitate to industry, opting instead to move to academic and medical institutes and government agencies. Admittedly, part of this is a function of the industry being relatively nascent.

Recently, however, the government, research institutions and industry players have begun to forge a new level of education through collaboration, mentoring and sponsoring talents into essential disciplines designed to meet the demand of the industry and highlight industry as an attractive destination. Complementary to this would be very strong international business development programs for in and out product licensing, Joint venture establishments, or Merger and Acquisition arrangements with critically reviewed and mutually beneficial business partners. These can be enhanced by leadership from successful Taiwanese entrepreneurs, and while easier said than done, would be critical to maximize Taiwan's chances of forming alliances with subsequent global reach.

We at UBI readily and eagerly recruit graduates of local Taiwanese universities. Often, we are their first job in industry. There is a scarcity of executives with extensive industry planning and operation, and mass production experience. As a result, we often send our Taiwanese associates to the U.S. to train and/or bring U.S. supervisors to Taiwan to teach.

I must applaud the government, as it is making strides to provide industry driven training programs to strengthen this area of deficiency. This, coupled with the return of scientists from abroad should lead to a new wave of talented and experienced persons that can lead the growth of the Taiwan biologics industry.

I'd like to address now the next component of a successful eco-system for biologics, namely the supporting infrastructure that is required to cultivate the industry to its fullest potential. Again, the similarities with our historical achievements are uncanny.

Hsinchu Industrial Park was created and populated with, among others, spin-offs from ITRI. This cluster-focused approach results in positive network externalities derived from a close community of smart, like-minded contributors, and is the reason why larger tech corridors around the world, such as Silicon Valley in California, and the I-128 biotech corridor in Massachusetts, exist and thrive. States and cities everywhere have adopted this principle and have created cluster-focused infrastructure to attract specific industries. Just as HsinChu was the birthplace of many of Taiwan's 3C companies, Zhubei and other new industrial parks will help incubate Taiwan's next wave of biologics enterprises.

At UBI-Asia, our operational base is currently headquartered in HsinChu, but we are soon to open an office in the new Biomedical Science Park, Zhubei this quarter. We recently completed an antibody spin-off called United BioPharma at the end of 2013 in partnership with the Formosa group. We are leveraging our antibody platform and proprietary first-in-class products, and combining it with the strength of the Formosa group, Formosa Biomedical Technology, and the network of Chang Gung Memorial Hospitals, the largest healthcare provider in Taiwan, and are choosing to base ourselves in the new dedicated Zhubei Biomedical Science Park.

In biologics, unlike traditional consumer products and even other pharmaceuticals, the product is the process, which means manufacturing expertise and facilities are critical. You need highly sophisticated manufacturing facilities for pilot batches and eventual commercial scale-up, infrastructure that requires significant investment of time and capital.

Fortunately, Taiwan has a strong manufacturing mindset that has been demonstrated for decades in the high tech and traditional industries. We are sophisticated in our design from a GMP manufacturing standpoint, and competitive in our design capabilities, construction feasibility and cost parameters. Furthermore, the willingness and continued support of the banking community to fund the industry with low interest capital will allow necessary investment in manufacturing infrastructure.

At UBI-Asia, we initially acquired two international cGMP pharmaceutical plants, allowing our young biologics minded R&D personnel to learn and work with the particulars of an internationally recognized cGMP facility. We recently became the first U.S. FDA certified facility for sterile injectables in the entire Pacific Rim according to our FDA inspector. We also invested in a pilot antibody plant to facilitate the development of our high end antibody products, a facility without which we would be suspended in limbo. UBI-Asia was fortunate enough to have the resources to gain and leverage such manufacturing experience, and have since paved the way for others to do the same. So, how do we continue to accelerate the path for others?

Here, Taiwan's investment in manufacturing infrastructure serves as another asset for the biologics market. Today, most elements for the new drug development R&D value chain are ready. Core facilities in academia for high end R&D are available to share with the industry, resulting in enormous cost savings for entrepreneurial companies. In addition, the government has invested significantly in supporting research organizations such as DCB, NHRI, ITRI and ATIT which are available to assist in the development process, both by providing invaluable CRO services and offering collaborative insight to new companies. Government also provides funding to industry; for example, UBI Asia has benefited significantly from MOEA's continuous support for moving our UB-421 product forward through R&D and clinical trials. We need to continue to ensure that capital continues to be available to companies who need to scale-up their manufacturing processes and conduct expensive clinical trials, and continue to attract entrepreneurs with incentives, whether they be tax or otherwise, for conducting operations here. All in all, these supporting infrastructure components help promote productivity and reduce costs, giving Taiwan a strong advantage in biologics going forward. Meanwhile, Taiwan's physicians and hospitals are gaining experience and

confidence in conducting clinical trials following GLP and GCP, which help streamline the development of biologic products in Taiwan tremendously.

As I began this talk noting, the good news is that there is certainly a lot to look forward to. The ecosystem is very different from when I started UBI-Asia over fifteen years ago, and very much for the better. The seeds that have been laid have grown and are now attracting other players into the market. The sign of competition is a clear indicator that the industry is maturing, which is why we welcome entry of companies such as JHL biologics into the sector, to forge new competitiveness, the catfish effect, if you will. For those of you not familiar with this term, the "catfish effect" is the effect that a strong competitor has in causing others to better themselves. It is a method used to motivate a team so that each member feels strong competition, thus keeping up the competitiveness of the whole team. At the end of the day, competition fosters growth, which is what we all want.

This does not mean that we are there, yet. Biotech is a very special industry, and in order for the industry as a whole to succeed and for Taiwan to be an important part of the global map, you need one additional element. A strong regulatory body.

As of 2012, only two new Chinese herbal medicines and one new botanical drug domestically developed have been approved. To date, no biologics have been approved.

There are obviously many factors to consider. For instance, it is hard to approve something that has not been developed. The point is that as we as an industry develop more biologic products domestically, we will need a regulatory body capable of providing clear guidance, responding swiftly, and not being afraid to be a pioneer and approve first in man products. Rather than catching up from behind, the Chinese have a saying: "迎頭趕上" or "forge ahead".

We should not wait for the industry to take the lead; otherwise it will be too late. It will not be enough to follow others, to be a passive player and wait for other jurisdictions to approve our products first. The regulators need to be active and proactively engage with industry. Create clear guidance. Let companies know what the guidelines are, what the priorities are, what the

timelines are. We need to ensure that our regulatory body is at the forefront, implementing best practices from others and forge ahead. We need to not only ensure that safe and efficacious products move swiftly through the regulatory process, but that we have post-marketing monitoring efforts to enhance the credibility of the Taiwan market.

We can also accelerate development by using government efforts for Cross-Strait discussions as it relates to regulatory policy. We should strive to reach agreements with the Chinese government, for instance, for early clinical trial data for innovative products to be recognized in China and to conduct only late phase clinical trials for registration in the vast market.

The TFDA has recently made a big step with its recent announcement of biosimilars policy. The new regulations allow for adoption of a placebo control design in pivotal trials for biosimilar approval, a first and in my opinion, pioneering policy that makes sense in the biosimilars space, a $40 billion sales market. At the end of the day, without a strong regulatory body, you will not have products. And without products, you will not have an industry.

Again, the good news is that the most critical and most complicated pieces are here already for a burgeoning biologics industry. It is my intention that we at UBI, UBI Asia and United BioPharma will become a world leading biopharma player with proprietary high impact products and will help put Taiwan in the global arena. But I welcome others to come and together grow the industry. Together, we can originate all kinds of innovative products and be a world player in biologics. Until we break a barrier, until we bring something revolutionary, no one will notice us.

My closing message to Taiwan's stakeholders is as follows:

To our Taiwan government and research institutions: From incubating products and talent, to building industrial clusters to providing industry specific training, thank you for all you have done to date to lay the infrastructure necessary to cultivate a biologics industry. Please keep doing what you are doing and continue to find and develop alliances and inter-agency collaboration programs.

To our esteemed colleagues who are currently abroad: Come back to Taiwan and help to inspire and lead the next generation and ensure a bright future for Taiwan and her many talented people. The weather is mild, the food is better, and you may notice that you likely will have a lot more fun encouraging the future leaders of Taiwan.

To investors and capital sources: Please be patient and bear with us. Biologics development is a longer-term process than most, but the impact is large and meaningful and the reward well worth it. The foundations are laid, and the future is bright.

To the world: Listen closely… as soon you will hear the roar of the Taiwan dragon reborn, and Taiwan will once again be the little island that makes a huge impact.

Thank you all for your time and support today. Ever forward!