Lily Wu – CEO, PapiVax, Taiwan

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Lily Wu, CEO of PapiVax, discusses the biotechs initiative pipeline for the treatment of HPV related diseases and cancers and goes on to elaborate the company's development and future partnership strategies. Wu also discusses the unique structure of PapiVax as a lean, R&D and research-driven biotech which is powered by its talent and key alliances with top US institutions.

Could you please start by explaining how you founded PapiVax?

I used to work in the real estate industry and after 30 years I was quite successful and wanted to live a more meaningful life. At that time my younger brother, Dr Tzyy-Choou Wu, was a Professor at Johns Hopkins and was willing to put his academic research into practice to create a technology that would help people. We started working together six years ago to found PapiVax.

Papivax currently has two therapeutic vaccines for HPV related diseases and cancer – PVX-2 and PVX-6 under clinical development. Can you walk us through the company's pipeline?

PVX-2 is already undergoing phase II clinical trials in Miami where we are enrolling patients. Regarding PVX-6, the asset is currently undergoing phase I trials through a partnership with the University of Alabama who is researching while we provide the drugs. Additionally, we have

another product coming up – PVX-1. This drug is also a clinical-stage product that is in the middle of filing for IND in August, and due to start Phase II trial in 2020. We are considering opening sites both in US and Taiwan. All three of these compounds are therapeutic vaccines targeting infectious diseases and cancers caused by human papillomavirus (HPV).

What unmet medical needs are you aiming to fulfill with these three compounds?

We are using the prime-boost, one-two punch combo to address the issue of DNA vaccines. Even though the compounds are very safe and stable, their initial immunogenicity is not that high. We are trying to remedy this by using another booster like a protein or vaccinia and make the drugs even more effective.

With PVX-2 we target the persistent infection indication to intervene early in the progression of HPV. Even though Gardasil as a preventive HPV-vaccine has proven effective for individuals who have not contracted HPV, there is still a large segment of the population that is not HPV free and are seeking treatment. For those who have contracted HPV, there is an extended period of time before surgery or other intervention is recommended by physicians. PapiVax is aiming to target that window, so patients of all stages of HPV infection have access to treatment if they so desire.

Our newest compound. PVX-1, will be more focused on HPV-induced cancers like cervical and oropharyngeal cancer. Many cervical cancer treatments simply excise the infected area, but surgery is much harder in the oropharyngeal region – the head and neck. This is why we are trying to find a less destructive way to treat this condition. Our therapeutic vaccines do not only cure the infection or cancer but they also have a pan-protective quality thanks to L2 antigen’s ability to stimulate antibody production.

What is the market potential of these products?

For PVX-2 that treats persistent infection and CIN I, the total number of Type 16 & 18 HPV-infection goes to about 3% of the total US population, which amounts to 46 million people. This percentage generally holds up around the globe, so the total patient population is about 225 million.

For PVX-1, the indication is cancer. The total cases of cancer induced by HPV are about 630,000, which include cervical, oropharyngeal, anus, vulva, vagina, penile, and more.

Because the patient population is so big, we are currently seeking future partners in regional licensing to service such a massive population. We are currently setting the price of PVX-2 at USD 1000 per course to stay palatable and comparable to the prophylactic vaccine, and PVX-1 at USD 30,000 per course. PBI's total serviceable market size is about USD 10 billion, and we believe with the right partnership, the entire market size could reach up to USD 100 billion.

The hurdle in vaccine development is high due to the extraordinary levels of safety and efficacy required as the safety of healthy patients cannot be put at risk. How do you tackle the challenges you face in the development of these products?

Indeed because of time, funds, and expertise issues, it is very difficult to get everything done by ourselves. Therefore, having a strong partnership is the key to success for developing such sensitive treatments. Dr. T.C. Wu, the key inventor of our technology, has done extensive animal studies and phase I trials with the compounds to test its efficacy. As a shareholder and member of our Scientific Advisory Board, he is very integrated into PapiVax's organization and has been immensely instrumental in the R&D process. Dr. Pei-Jer Chen is a member of Academia Sinica and also on our Scientific Advisory Board. He is very experienced in both clinical study operations and virology. The last member of this board is Dr. Richard B.S. Roden who is from the UK. In the prime-boost regiment, boost protein and vaccinia are products he has been working with for a long time, so he guided PapiVax through the R&D process. Finally, before licensing the technology to us, Johns Hopkins applied for numerous grants to test our compound which has been a great help. Likewise, the University of Alabama is also conducting phase I trials thanks to our partnership.

The development process is extremely costly and conducting clinical trials requires large pools of funding – a harsh reality faced by many biotechs. As a non-listed company, what is your strategy to raise funds?

Most of our funds are internal, which is very important for a new drug company. In addition to the time and effort spent, our Scientific Advisory Board members invest their own money into the company to show all the investors they have faith and are committed to the project. This is also the case for most of our key experts and consultants. Our angel investors have great faith in our Scientific Advisory Board and product pipeline. They are all Taiwanese VIPs who have achieved financial and business success in their own ventures. Now they want to contribute to society, and they believe PBI is a worthy and promising approach. They also have a great calling to the nation's economy, and like President Tsai, they believe the biotech industry can be the way forward to drive

growth for Taiwan.

Since OBI's infamous clinical trial failure, investors have become even more sceptical of the biotech industry? What is your assessment of Taiwan's capital market?

The excitement for biotech was very high a bubble was bound to burst. After this incident, only solid companies with strong management and technology will ultimately survive. These companies with more solid foundations are pulling through. For a company like PapiVax, product development is more important than marketing stunts. Therefore, we only hire the most essential people and use a CRO company to oversee our clinical trials. We also hire talent with government experience to help us with our regulatory and subsidy aspects. Finally, the most important thing is to keep our eyes on the prize, that is our clinical trial. We have to put all our resources into proving the efficacy of our product, instead of chasing the latest trend and go on R&D tangents. Building investments is not easy but with solid materials and results, investors will come.

What would be your internationalization and partnership strategy moving forward? How do you see the company developing in the near future?

I will mostly focus on two things – our company management and visibility. Before entering into extensive partnerships, we are attending different kinds of exposure outlets like BioAsia and other international avenues to better understand the current landscape. Right now we are mainly partnered with academics and research institutions, but we are also trying to reach out to leading biotech companies that have a strong interest in HPV. I want to get a sense of what they are thinking about the market and whether they see therapeutic vaccines as a valid partnership opportunity. Finally, we are talking to more institutional investors like our shareholder the Taiwan National Fund. We are currently trying to not limit ourselves and broaden our horizons, but we are putting off any concrete partnership decisions til we have more solid data from clinical trials.

What makes you a partner of choice for potential big pharma that you mentioned?

What first makes us attractive is the complement of our pipeline. MNCs are focused on the prophylactic aspect while PapiVax is focused on therapeutics. Our products are also competitive in terms of price as, trying to keep it comparable to the current market so that the patient does not

feel a huge difference. In addition, PapiVax is lean with very little overhead of bureaucracy. It is easier for us to partner with a larger company who already has the infrastructure as they do not have to worry about potential conflicts from our side.

In the end, the most important thing about a partnership is not the cosmetics or infrastructure, but the product and technology. We are a biomedical company; we want to make effective drugs and our pipeline is our strong suit. PapiVax wants to make a difference in the medical community and we are going to see this through in any case.

What would be your final message to our international readers?

PapiVax is committed to bringing a better quality of life with minimal invasion to all HPV- and cancer-infected patients by avoiding surgery and painful chemotherapy. PapiVax and its products will be a force of positive energy so that people can live healthy and free from the fear of diseases!

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