Michelle Lin – CEO and Hsu Chang – Senior Advisor, EpiSonica, Taiwan

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Michelle Lin, CEO, and Hsu Chang, Senior Advisor of EpiSonica, highlight the innovative new solutions that the company has created for women's health and medical imagining. The advanced technology will make impressive waves in ultrasound tumor ablation and breast cancer screening – meeting high unmet medical needs. They go on to share their strategy as a key startup shaping the way for Taiwan's emerging medical device sector.

Dr. Lin, can you please begin by introducing yourself and your background with EpiSonica?

Lin: I am the Founder and General Partner of Transpacific Venture Partners (TPV) and last year I took on the role of CEO of EpiSonica. Before entering the private sector, I spent much of my career in the government, including serving as Director of Biotech Office at the Executive Yuan (The Cabinet). Prior to that, I was a director of the business & promotion division in the Development Center of Biotechnology (DCB).

Before starting my venture fund, I initiated and organized the Stanford-Taiwan Biomedical Fellowship Program (STB) to cultivate eager young medical technology innovators from Taiwan with the innovative and entrepreneurial Med Tech culture in Silicon Valley, thus creating an innovative Med Tech platform in Taiwan. STB has since successfully incubated eighteen start-up medical

device companies in Taiwan. I am proud to contribute to Taiwan government's mission in shaping the medical device industry into an essential economic transformation, by bridging a strong ICT industry with an excellent clinical research community.

How mature is Taiwan's medical device sector and what is the contribution of EpiSonica?

Lin: Building the industry absolutely takes time. Currently, there are 500 medical device startups in Taiwan, but most are still at an early stage. There is generally a lack of expertise when it comes to product development and business development. EpiSonica is very lucky to have a strong team. Both of our products, ***i*ABUS** and **ArcBlate**, have rooted on very strong core technology competence. We are offering breakthrough innovative solutions to highly unmet medical needs in women's health.

EpiSonica currently has two innovative products for women's health – *i*ABUS and ArcBlate. What is the unique technology behind these solutions and the unmet medical needs that these devices are fulfilling?

Chang: We are proud of our MRI Guided High-Intensity Focused Ultrasound Tumor Ablation System (MRgHIFU). This technology was originally developed at the National Health Research Institutes (NHRI) of Taiwan and licensed to EpiSonica for commercialization in 2013. Even after fifteen plus years of active development in a world-wide therapeutic ultrasound community, MRgHIFU is still considered to be a significant technology breakthrough. Ultrasonic energy is applied from outside the body and focused onto a very localized small region quickly raising the tissue temperature to around 70□ C, effectively causing the heated tissue to undergo necrosis, all the while under real-time Magnetic Resonance Imaging (MRI) guidance with the device operating inside the MRI.

One of our innovations was to design the **ArcBlate** to take full advantage of the MRI capability in providing not only cross-sectional tissue imaging with superior soft tissue contrast but also fast temperature mapping, by allowing the arc to mount easily onto any MRI couch and eliminating mutual interference. The other was to enable the HIFU transducer which is mounted on the arc to carry four different degrees of freedom in controlling the position of the focal point onto the treatment target. This allows the procedure to be accurately monitored in real time for more precise control of not only the position of the thermal lesion, but the ultrasonic thermal dosage as

well. The **ArcBlate** can be used to treat any abdominal organ, but we have primarily emphasized the uterine fibroids ablation because it is the most practical and proven application for HIFU up to now.

Our automated breast ultrasound system (***i*ABUS**) was designed as a high-end ultrasound breast examination platform. Patients lie in prone position on top of the gantry which carries the ultrasound imaging probe to rotate 360 degrees automatically within 90 seconds, capturing up to 900 images in one rotation. The system will then reconstruct the radially acquired images into a 3D representation. In order to meet large mass screening demand, intelligent and precision positioning device as well as computer or AI assisted detection and diagnostics tools are to be developed as we accumulate large image database.

As breast cancer rates continue to increase, early detection becomes critical. Up to now, the current standard in screening has been X-ray mammograms. However, recent studies in the US have revealed that for women with dense breasts, the false positive rate can be as high as 50% resulting in unnecessary biopsy procedures. Currently, 37 states require some level of breast density notification after a mammogram in USA and providers must suggest the patients with additional breast screening options. Ultrasound becomes a primary modality to supplement mammogram especially in Asia where 80% of women have dense breasts, and this is a severely unmet medical need.

What is your assessment of the competitive landscape in this field and what is EpiSonica's differentiation?

Chang: Both products are facing a newly developing market where large unmet needs are just being recognized. For ***i*ABUS**, its unique radial scan geometry matching the natural lobar structure of the breast anatomy, comfort for the patients and the speed of the scan differentiate us from major existing competitors, among which GE and Siemens.

Similar advantage in easy compatibility with most MRI systems with the unique arc design, in conjunction with patient comfort and safety, allow **ArcBlate** to compete favorably with other MRgHIFU vendors, such as Insightec and Profound, for the uterine fibroids application. As for the relatively long existing Ultrasound guided HIFU (USgHIFU) products in China market, MRI guidance clearly competes favorably with precision real-time control in position and thermal dose control.

Why is Taiwan the ideal place to position EpiSonica?

Chang: I have had a rewarding career in MRI, dating back to 1980's in Silicon Valley on one of the first commercial MRI systems in the US approved by FDA. Taiwan's established infrastructure in advanced ICT technology and industry coupled with low-cost manufacturing makes it an ideal place to incubate a medical systems industry. Moreover, Taiwan has a world-class medical research community and well-known top-notch clinical trial infrastructure. These excellent attributes have attracted many like myself in the international medical system industry to return to our homeland in the early 2000's to build Taiwan's own counterpart of GE. That window of opportunity having come and gone, Taiwan is nevertheless an ideal place for EpiSonica, especially when it is positioned as a boutique developer and integrator of innovative application-driven medical systems.

Merging medical devices with emerging technologies such as artificial intelligence is causing big waves in the industry. How is EpiSonica seizing the trend?

Chang: From the beginning of developing ***i*ABUS**, our goal is to position its intended use as assisting diagnosis initially and to eventually evolve toward screening for breast cancer by developing computer aided detection and diagnostic algorithms. With recent emergence of big data and artificially intelligence, we are initiating a two-year project to collect clinical imaging data from our unique systems, work with physicians to identify tumors and associated conditions, and store all of the findings in a cloud imaging database. Taiwan has a very strong AI infrastructure support for medical imaging across different teaching hospitals. We will work with select institutions to develop algorithms to train on identified and labeled data and see how the algorithm is able to predict unlabeled data. Similarly, our expertise on MR navigation of the fibroids ablation will be stored with thermal imaging data to increase the precision in thermal dose determination and control. With the storage capacity and computation speed essentially becoming non-issue, **ArcBlate** will enhance itself ever more intelligent in precision navigation and treatment.

What business strategy have you identified as EpiSonica's products approach their commercial stage?

Lin: We are aiming to receive a 510(K) from the US FDA and a CE mark from the EU by the second quarter of 2020 for ***i*ABUS**. EpiSonica has already established collaborations with a Japanese

manufacturer as ODM partner for the distributions of our products. Our solution is already an essential diagnostic tool, and once we are able to finalize the AI component, ***i*ABUS** can absolutely become the first line screening modality for early breast cancer detection.

EpiSonica's core competence is our R&D and unique IP, so we want to keep a hold on these assets. We are looking for strategic distribution partners to reach the global market. Our own business development team is very experienced in working in the region, especially in China where we share many similarities. However, we will, of course, work with local players to best tap into each market.

How difficult is it to attract investment in a highly competitive Taiwan environment?

Lin: Coming from a venture capital background, I understand that a truly unique technology is for certain to stand out. Since EpiSonica's foundation, I have led two rounds of fundraising which have gone over well. EpiSonica has many competencies – two products, expertise, an innovative solution, and high success potential – so I am confident for the future outlook of the company.

What objectives do you have to further establish EpiSonica as a leading specialty player in women's health?

Lin: In the next five years, EpiSonica will be a medical imaging powerhouse. Since our biggest asset is a platform technology, it can be applied to a wide range of clinical indications. **ArcBlate** is a non-invasive therapeutic tool that can revolutionize the accuracy and precision of how we treat patients. Furthermore, with ***i*ABUS** meeting such a key medical need, EpiSonica can truly be a leading partner to women's health around the world.

Chang: In five years we will have adequate revenues as we keep our options open in various market segments. Our products will continue to improve and we will have the next generation of ***i* ABUS** powered by AI. We may even have a third new product, something we are already brewing!

Ms Lin, reflecting on your career, how do you feel to be in the situation you are today as the CEO of EpiSonica?

Lin: I never planned my career to go in the direction it has. When opportunities arose, I was brave enough to work hard and take advantage. During my time with the government, I was preparing to retire soon, but after working with the young doctors and engineers I was inspired by the new

opportunity of Taiwan’s medical device industry. Joining the EpiSonica team has been another inspiration and I am very happy to be part of a project that is setting the path for the development of Taiwan’s medtech industry.

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