Louis Sze, CEO, Persona Surgical Modelling, Hong Kong

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Louis Sze, CEO of Personal Surgical Modelling, an exciting Hong Kong start-up in the 3D printing medical technology field, shares the companyâ??s achievements over the past few years, his insights on the regulatory and commercialization challenges related to such a groundbreaking new field of healthcare technology, and his main priorities for the next few years.

Louis, could you please briefly introduce us to the current activities of Persona Surgical Modelling?

When we first began as a company, 3D printing was being used mainly for research purposes. Since then, there has been a movement from research to practical application. The question we are now asking is what role 3D printing can play in the healthcare industry. We currently have a greater focus on implementation and regulation of the technology.

When we first started, we were working as a service provider for hospitals using 3D printing to offer precision guidance products for complicated medical procedures. This was a very niche market to be operating in. However, we realized that although the technology was ready, the surgeons were not. Traditionally, surgeons had full control and oversight over how operations were performed.

Now, there is a movement to introduce new technologies like 3D printing, image-guided surgery (IGS), and robotics into the operating room. At the moment, there is no set standard of which methods must be used during which surgeries. Therefore, whether or not these new technologies

are utilized is the surgeonâ??s decision. This created a very competitive landscape to operate in.

The potential impact 3D printing on surgery is therefore very relevant but the demand is generally low. It takes time and skill to produce custom surgical tools for complicated surgeries, so we are looking into other areas where we can diversify. We have begun offering designs in areas such as occupational therapy as well as rehabilitation science and sports science. For instance, we print devices like prosthetics and specialized insoles for foot diseases.

The work capacity for these traditional products is dramatically increased with 3D printing because different steps like molding the foot, polishing, and model editing are done digitally, such as 3D scanning and 3D printing rather than being performed manually. Today, 3D printing is much cheaper than it used to be, so for the same material and labor costs we are achieving greater volumes of product.

Who are Persona Surgical Modellingâ??s main clients? What markets does the company operate in?
In Hong Kong, we work with about 12 hospitals, both public and private (Hong Kong has a total of 40 some hospitals). We work closely with hospitals that often perform complicated surgeries and are in need of custom products. Some hospitals have begun to create their own in-house 3D printing initiatives. Hospitals already create their own imaging using CT, MRI, and radiology technology. With these images, they can begin doing their own simple printing. However, for complicated cases, they still collaborate with 3D printing experts like Persona.

Additionally, we currently work with a few international clients in London and Israel, for example. From going to several trades shows, we realized that some countries that are less developed in this type of technology have very little options available to them for 3D printed surgical products. We are targeting these countries to strategically expand our business network globally.

What 3D printing trends currently exist in the healthcare industry?
Dentistry is a very mature market for 3D printing. Many products such as drill guides, implants, and aligners are mostly 3D printed. The technology reduces risk and helps surgeons work more precisely in the operating room. In this regard, it can be said that other areas of surgery are not as technically standardized as dentistry.

The use of 3D printing is naturally complimentary for orthopedic surgery. We started creating products for this field due to the irregularity of bone cancer and large bone defects. This type of cancer can manifest anywhere in the body â?? the spine, skull, or limbs for instance. There is a need for 3D printing in big bone reconstruction surgery due to the uniqueness of each individual procedure. When removing an affected area of bone you have to first consider how to restore the defect. Before 3D printing, the standard replacement parts dictated how the bone would be cut, which often resulted in the loss of healthy tissue along with the diseased area, or even amputations. With customized 3D printed implants, there is an increased freedom in the surgical capability to minimize tissue loss and restore functions.

What regulatory challenges do 3D printed products face in Hong Kong?
Hong Kong is a unique market considering we do not have the same regulatory systems like the FDA or the CFDA. There is more freedom here but consequently, there is a greater sense of skepticism. Currently, we are relying on foreign examples as a standard of technology. If a product has FDA approval, there is less hesitation about its validity. For this reason, I think Hong Kong is slightly behind other regions in the adoption of 3D printing technology for clinical use.

The difficulty in regulating 3D printing comes from the customization. It is difficult to set a universal standard when each product created is unique. There are some simple guidelines created by the

CFDA which dictate the acceptable volume of a single design being created. Once the volume produced exceeds this limit, there is further investigation into whether the design is feasible or not. In United States, FDA is trying to regulate custom products on the production process of 3D printed products rather than the final product itself.

The protection of intellectual property (IP) being used to create 3D printing designs is a highly discussed topic within the industry. How can this issue be addressed in Hong Kong?
As providers of both product and design servicing, this is an issue we must closely monitor. We can design, print, and distribute products to our clients, or we create a blueprint and the client can print the product themselves. If a product is standard, the digital design can be processed and mass-produced by a third party. For a custom-made product, this is less of an issue, but it continues to be a challenge for artists. When creating a digital blueprint, companies want their IP to be protected. Although Hong Kong is well known for its IP protection policies, the existing laws do not offer adequate protection for 3D printed copies.

I studied the systems of IP protection for 3D printing in other countries and how Hong Kong follow in their footsteps. In Japan for instance, there is a regulatory body that was created specifically to handle 3D printing IP. This regulatory body then created an online exchange platform for the protection 3D print designs. Here, digital artists can store their designs securely while maintaining control of the exchanging and printing of their property. This will protect their design without releasing the blueprints directly to an unknown party.

To begin wrapping up, what are your key objectives for the future of Persona Surgical Modelling?
Our main concern is to ensure we expand our efforts as a company from just performing R&D to commercialization and sales and marketing. A common issue in the start-up community is inability to transit from research to commercialization, which many try to be a totally R&D focus firm. However, running a long-term R&D project can risky, the funding may not be steady and it may help greatly if company can explore some smaller projects, consultation work or specific merchandise to an early taste of running a business and get in touch with the market. This is what we have been doing, for instance, printing figurines for toy companies, offering 3D image scanning services, and also selling the 3D printers themselves. By selling our products and services, we are building client relationships for the future while simultaneously introducing them to 3D printing and making the technology more commonplace.

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