

Samantha Du - Chairman & CEO, Zai Lab, China



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Samantha Du, Chairman and CEO of Zai Lab, the flagship China biotech company, shares her inspirational story of being one of the pioneers to forge a path for Chinese biopharma innovation; the recent product launch of Optune® in Hong Kong in December 2018, Zai Lab's second product on the market; and her aspirations for the future of Zai Lab.

Samantha, congratulations firstly on the commercial launch of Optune® in the Hong Kong market in December 2018, which is the second product Zai Lab has on the market. What is the significance of this launch for the overall development of the country?

This certainly marks a great milestone for Zai Lab's development. With the launch of Optune® coupled with Zejula®, we now have two commercial products on the Hong Kong market. For Optune®, we like it because there is no substitute or comparable treatment available. Of course, we are looking forward to launching this product in the mainland Chinese market as well. We have already filed a Chinese NDA for Zejula® - more than a year ahead of expectations.

We made the decision to launch our products in Hong Kong with a pure-play commercial platform, and this is the strategy we will take with our future launches in the mainland Chinese market even though we are still a small company. In China, we believe the top 100 hospitals account for approximately 80 percent of innovative oncology products so our sales and marketing efforts can be very focused and science-based.

The commercial platform we are developing is also driven by medical information and education. We work very closely with KOLs from our clinical trials to commercial launches. We believe it is very important for doctors to be educated by qualified medical representatives about the products rather than simply relying on a commercial distribution network and including it on hospital procurement lists. This is critical – and actually benefits the whole ecosystem. Chinese patients rely on their doctors and respect their opinions and knowledge, so it is very important the biopharma companies like us provide correct and informative medical education on our products. Incidentally, this would help Big Pharma (MNCs) as well because they have historically not focused on penetrating into the lower-tier cities and community hospital centres. If local companies like us with the reach invest in such efforts, it raises medical awareness in the entire ecosystem.

Looking ahead, we already have seven products in late-stage development and hope to file one or two more NDAs by end of this year, so we are very excited about the future of Zai Lab and the industry.

How have the recent changes within the Chinese biopharma industry affected Zai Lab?

China's biotech industry is still in its infancy. The Chinese government has made it very clear that China wants to transform its pharma industry to one focused on innovation. This has set the tone for the entire industry and is the reason we are seeing many new regulatory policies like the '4+7' volume-based policy for generic pharma, with the intention of increasing the quality of the generic products within the Chinese market.

China has also been reforming its national reimbursement system. Previously, the National Reimbursement Drug List (NRDL) was only updated every eight to nine years but beginning from 2017, it seems to have become a fairly frequent event – and the government is placing more emphasis on listing innovative products rather than high-priced generics. Of course, companies can also look at listing their products on provincial and municipal reimbursement lists before the NRDL. Successfully listing a product on the reimbursement list of a relatively affluent province like Zhejiang province can also be very beneficial to companies to enhance access to innovative drugs.

Another positive step is the government's decision to open up the private healthcare insurance space. Previously, international companies had to form a 50-50 joint-venture with a local partner but now foreign companies are being encouraged to enter into the Chinese market. The national reimbursement market in China is very important but the out of pocket expenditure is also substantial. For a highly innovative breakthrough oncology drug, the private pay revenue

opportunity in China has shown to be significant even in its first full year of launch, which demonstrates the purchasing power and unmet medical need in China.

Today the focus is on innovation but with hundreds of millions of Chinese patients still only having access to very basic healthcare, what makes it so important for China - and Chinese companies like Zai Lab - to focus on innovation and competing in terms of innovation on the global stage, when you could simply focus on commercializing existing innovative therapies?

As a country rises to the position of second-largest global pharma market, I believe it becomes responsible to not only benefit from other countries' innovations but also to bring innovations to the world! When Japan became the second-largest pharma market in the world, we started to see the Japanese pharma multinationals emerge. China needs those kinds of companies too and today we are fully capable of moving in this direction. We have the talent, the financial engine and the patient population to run accelerated clinical programs.

Furthermore, no country starts the journey with a 100 percent affluent population and already, China has made great strides in terms of raising the economic and living standards of its citizens. I can share my personal story: 40 years ago, my family was considered well-off in China but we were still unable to have meat often. I would say a large proportion of Chinese people today are already in a much better situation than that! They certainly deserve access to basic healthcare and this is why the government has undertaken a significant amount of healthcare reforms including expanding universal health insurance and the Centralized Drug Procurement in "4+7 Cities". These will increase the incentive for companies to invest in high-quality, affordable generics.

But Chinese people also deserve access to the most innovative products - and companies like Zai Lab do offer patient assistance programs and other charitable initiatives to support those patients that are less financially well-off. It is not either-or. Furthermore, as the whole country's health consciousness develops, the trickle-down effect would be immense. If more people learn about the latest innovations, for instance, through working in or with companies like Zai Lab, that knowledge and awareness will eventually spread through society.

While Zai Lab also has its own internal R&D programs, its most advanced drug candidates at the moment are all in-licensed products. What is the company's portfolio

development and expansion strategy in the future?

It is important for Zai Lab to have both internal discovery capabilities as well as external partnerships. The fundamentals remain to deliver first-in-class and/or best-in-class drugs to patients.

At the JP Morgan Healthcare Conference in January this year, we finally disclosed our discovery pipeline and strategy, and we expect to file at least one new IND annually with global rights each year from 2020. Zai Lab had been established from the very beginning with the mission of doing internal innovation. The moment we were ready to raise funds, we established a 40,000 square ft lab in Shanghai to begin our own R&D. We also recently opened a small lab in Palo Alto in San Francisco. Both focus on oncology and autoimmune diseases.

It is also important to understand new scientific development. We'll rely on more of our understanding of disease biology, success rate targeted patient population with the understanding of the MOA and mutation. We are taking a target and pathway patient-subgroup, precision medicine approach.

This will also help the whole healthcare ecosystem by reducing the costs of drug development. At the 2019 J.P.Morgan Healthcare Conference, someone from the reimbursement system at the US FDA was talking about the need to reduce the cost of pharma R&D and for me, one way to do so is through judicious project selection and development. These days, what is exciting is that there are so many new scientific developments emerging, especially with regard to the use of AI for drug discovery and development and for analyzing clinical data. We should take advantage of all these new innovations and not rely on old models.

For better or worse, the global industry looks to Zai Lab's growth as an indicator of the development of the Chinese biotech industry. Do you feel any pressure to be a de facto spokesperson for the industry?

I have been in this position for near 20 years. I have always been guided by the conviction to speak the truth. I believe you must always be honest and straight forward. When I first started in the industry, I was asked by so many people if I was going to enter the generics space. I said no, not at all! I want to do something innovative. There used to be no way to even import biological reagents into China, but now China has really progressed a lot, not only from market, science talent pool, financing, but also government regulatory reforms. I was not alone. It hasn't always been easy over

the many years but I am very proud to see the industry develop and cannot wait to see what may lie ahead.

As a biotech industry veteran in both the US and China and probably one of the most recognizable pioneers within the Chinese biotech start-up landscape today, what kind of culture are you cultivating within Zai Lab in order to support the company's future growth?

I believe successful biotech companies must create this sense of ownership amongst all its employees. In our last Annual Meeting, Zai Lab employees came up with a slogan: 'all in, all win'. This is what drives us forward. When I started the company, the motto was 'one company, one dream'. That came from me. But today it is about 'all in, all win'. We built this business to last so it is very important for us to have a strong, ethical corporate culture. To prioritize this, we have a very active Culture Committee in the company. People need to feel comfortable working in Zai Lab. I am very proud that our staff turnover rate is phenomenally low and well below the industry average! This is very rare within the biotech scene given the importance of human capital. Part of this is due to a deliberate decision by me to ensure that we maintain a strong sense of ownership through stock options across all levels of employees. Today, employees still maintain a large ownership position in the company. This is also very rare in a biotech company, particularly in China.

As a leader, we always need room to learn, adapt and grow. As you said, we have somehow become a reference for the Chinese biotech industry. Last year, there was a lot of talk about the 'Zai Model', 'Zai Better', 'Zai 2.0' and so on. But Zai Lab itself is already a Zai 5.0! We are always innovating. I do not like to be a manager but I see my role as more of a leader.

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