Michael Yu – Founder, Chairman and CEO, Innovent Biologics, China



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Dr Michael Yu, founder, Chairman and CEO of Innovent Biologics, one of China's most successful and innovative biopharma start-up, shares his long-term vision to build a company that can last a hundred years and more, Innovent's mission to commercialize and develop affordable, high-quality biologics for ordinary people globally, and the principles behind Innovent's tremendous success in the past seven years, with 13 products in clinical development already and four products expected to reach commercial stage in 2021.

Michael, it has been a great year for Innovent Biologics, most notably with your Hong Kong IPO in October. As founder, Chairman and CEO, you must have a grand vision for your company. Where is Innovent now on its journey?

I am very pleased to say that we have been chosen as 'IPO of the Year' by the leading finance magazine in Asia, International Financing Review (IFR) Asia! But in terms of Innovent's journey, we are still in our infancy.

Innovent started in August 2011 with the mission to discover and commercialize high-quality biologics that are affordable for ordinary people. What motivated this mission? In China, the development of the biologics industry is far behind more developed countries like the US or Europe. For example, Innovent is specifically focused on monoclonal antibodies. In the US, over 90 percent

of patients that qualify for such therapies have access to them. In China, only 6 percent of such patients do. Furthermore, the affordability and availability of such therapies are very limited. This is what inspired the establishment of Innovent.

As in any company, when you are starting a new business, you need to also develop a business plan. Our vision was to become the premier biopharma company in China with the potential to be respected by the global industry!

Therefore, in the past seven years, our efforts have been focused on two aspects: firstly, developing our product pipeline; and secondly, developing our biologics manufacturing capabilities. The latter is particularly important because even today, no Chinese-manufactured biologic product is available in developed markets. This state of affairs is even more striking because China is known to be the manufacturer of the world – you see ‘made in China’ on all kinds of products! Yet China cannot manufacture biologic products for global markets. The reason is that even today, there are no biologics manufacturing facilities in China in compliance with global standards. Therefore, a strategic priority of the business was to develop our own manufacturing facilities that meet global standards. Already, our facility here has passed audits conducted by a global multinational pharma company. We hope that this will eventually mean our products can be sold not only in China but also for global markets. That is our dream.

As I said, we are still in our infancy. We have a long way to go but we are really happy about our progress so far. When we started in 2011, nobody expected that China will join the ICH and start aligning its standards to global standards. This means that we have a significant head-start because we have followed global standards from our very inception.

It is very interesting that after seven years of development, with 20 products in your pipeline and a successful IPO, you still characterize Innovent as being at the beginning of its journey, where for many biotechs in the US or Europe, the journey would have been completed! What does this longer-term perspective mean for your investors and partners?

I spent many years in Silicon Valley and my family is still there. In the US and particularly in Silicon Valley, many start-ups – especially biotech start-ups – are built for sale. Their investors, therefore, have a relatively short-term view in terms of the kind of returns they expect. These start-ups often do not even need to have a product on the market. As they can access NASDAQ. If they have a good idea and Phase I data, they immediately go to the capital markets! Therefore, their investors

do not need to wait until product launch – which may be ten years later – to see returns.

On the contrary, I would like to build a company that can last a hundred years. We really want to be a global powerhouse of innovative medicines. That requires a couple of decades of work. I have no intention of selling Innovent. That is the difference.

Our investors are very aligned with this vision. Seven years ago, when I started Innovent, many investors we approached thought we were very unrealistic. I had just returned from the US at that time and many investors thought I did not know the China market well. At the same time, there were many opportunities back then to make quick money, especially in real estate because the housing market was booming back then. Looking back, if I had taken the money I have invested in Innovent and put it in real estate, my returns would have been tenfold! Therefore, most of our investors were and still remain international institutions like Fidelity, Lilly Asia Ventures, Temasek Holdings and so on. These are the investors that see what the opportunities could be five to ten years later. It is clear that they were right: the housing market has cooled down and biotech is now booming!

You mentioned this 'built for sale' type of companies in Silicon Valley. In China today we are now seeing the rise of 'built for in-licensing' biotech companies, who are bringing in innovative therapies available globally into the Chinese market in order to make them more affordable and accessible. Why did Innovent not choose to go down that path? What makes innovation so important to the company?

Biotech is not like flipping houses. I have nothing against in-licensing and Innovent has in-licensed some products as well. However, the majority of our efforts and investment are devoted to developing our in-house, internal organic capabilities. We have over 500 people in R&D and we invest heavily in them. As a result, each year our laboratory produces around 5 to 6 INDs, all developed in-house. These are the ingredients for our continued development and growth, and keeps our company going!

No biotech company – in China or globally – will be sustainable if it is based only on in-licensing. Sure, in-licensing can help to start the engine but if you want to have your own car, you need to invest time, effort and resources into building it. For long-term growth and development, biotech companies need to have their own internal drug development capabilities.

I do believe this is also a very important reason that investors like us. As you can see, some other companies listed on HKEX have seen their shares go down but ours has been rising. It is because investors see the value and sustainability of our R&D platform.

The world is starting to believe that China is capable of biopharma innovation. But we are still waiting to see the first truly innovative product from a Chinese company! How long more do you think the world will have to wait?

McKinsey published a report recently putting China in the third tier of innovation in biopharma. The first tier is the US. The second tier is Europe and Japan. While some Chinese people might have felt insulted, I am sorry to say that I do believe that report is a true reflection of reality in China today. The vast majority – over 95 percent – of the Chinese industry is generics – and still today, the quality is low and bioequivalence is not always established. Fortunately, the government has invested a lot of efforts to rectify this.

But for innovation to emerge, there must be an innovation ecosystem. Why does over 50 percent of pharmaceutical innovation come from the US? It is because they have this innovation ecosystem in place, with three very critical elements.

The first is basic science and research, with entities like the National Institutes of Health (NIH) in the US. China may publish many papers and patents now but how much of that is truly original research? Not much. Without original research, innovation does not have much to build on.

The second is regulatory science. I call it regulatory science because it is a science, not just policy. Regulators need to be able to properly judge or assess innovative medicines – and to be able to do that, you have to really understand the science behind the innovation. The US FDA does this at the moment, but many other countries have regulatory agencies that simply follow the US FDA’s decisions. In that case, the pharma industry in that country will also become a follower.

The third is the pricing system. Innovation needs financial support. No investment, no innovation. The government has implemented a series of reforms here such as updating the National Reimbursement Drug List (NRDL). At the end of the day, companies and individuals put their lives into their work. If the resulting innovations cannot generate returns, no one will invest in such activities. Innovative products must be able to enter the healthcare insurance system, which in China is critical for revenue generation. Profit from these revenues can then be re-invested in more innovations.

China is not there yet but the ecosystem is improving. In the last couple of years, we are finally starting to see some innovative products coming out of China and being out-licensed to global companies – not many, but there are some, including Innovent, of course. Our 2015 deal with Eli Lilly is still today the largest out-licensing deal for a biologic product from a domestic Chinese company to Big Pharma.

What is the significance of this deal between Eli Lilly and Innovent?

We benefited immensely from this deal, not just in terms of the financing for our R&D but also through the validation of the quality of our innovation from Big Pharma. Having that financing from Eli Lilly meant that we needed to raise less money from other investors. The deal also increased the capitalization of our company so that already raised the potential returns for our existing investors. Having that validation from a company that Eli Lilly also gave current and potential investors more confidence in us. That, in turn, caused other sources of capital to start flowing. This deal with Eli Lilly was a very critical milestone for Innovent. In the last couple of years, we have not lacked for investment.

Many companies claim to be innovative and globally competitive. To me personally, there are only two criteria for innovation – and this applies to the global biotech industry. Firstly, have global regulatory agencies approved your products for the market? Secondly, has Big Pharma approached you to do a deal? Those are the only two milestones that matter.

Part of Innovent's success stems from the strength of the team you have assembled! How did you manage to bring all these top industry leaders together to Innovent?

When we held our roadshow in China, investors always asked us what our top concern was. Talent was always my answer. Talent is the most critical limiting factor for any biotech business: the availability of it, recruitment, retention, training, and so on. We probably have the most diversified management team in China with leading industry veterans that are both overseas returnees and foreigners.

One of the most important reasons we were able to attract them to return or come to China is the fact that Innovent had the capabilities and resources to provide them with a better platform for their own career development and growth than their previous role. At the end of the day, people derive satisfaction not only from money but from seeing the impact of their work and assuming

more responsibilities.

Our mission – to commercialize high-quality, affordable biologics for ordinary people – is also fundamentally very attractive for people. Everyone wants to improve on the status quo. I am very inspired by the German philosopher, Friedrich Nietzsche, who asked the key questions: ‘who am I? Where am I from? Where am I going?’ These are fundamental questions for all human beings, regardless of their status in society or where they are in their life journey. Doing something meaningful for society or other people make your life much more enjoyable.

Personally, I come from the countryside of China. In the village where I was born and raised, modern medicine was not available. People were very poor and if they fell ill, they had no idea what treatments were available outside of the village or even what disease they had! Coming from that background, I feel very grateful that I am now able to contribute to the good of society. Innovent’s products have cured some of my family members and neighbours. Some of my family still live in my hometown, though in much better conditions, and it is very heartwarming whenever I return because the people there value my insights and contributions, and will even sometimes line up to ask me to diagnose them even though I am not a doctor! My mom is 95 years old this year and she sees me as a hero because I have been able to bring medicines to my hometown. That is very powerful.

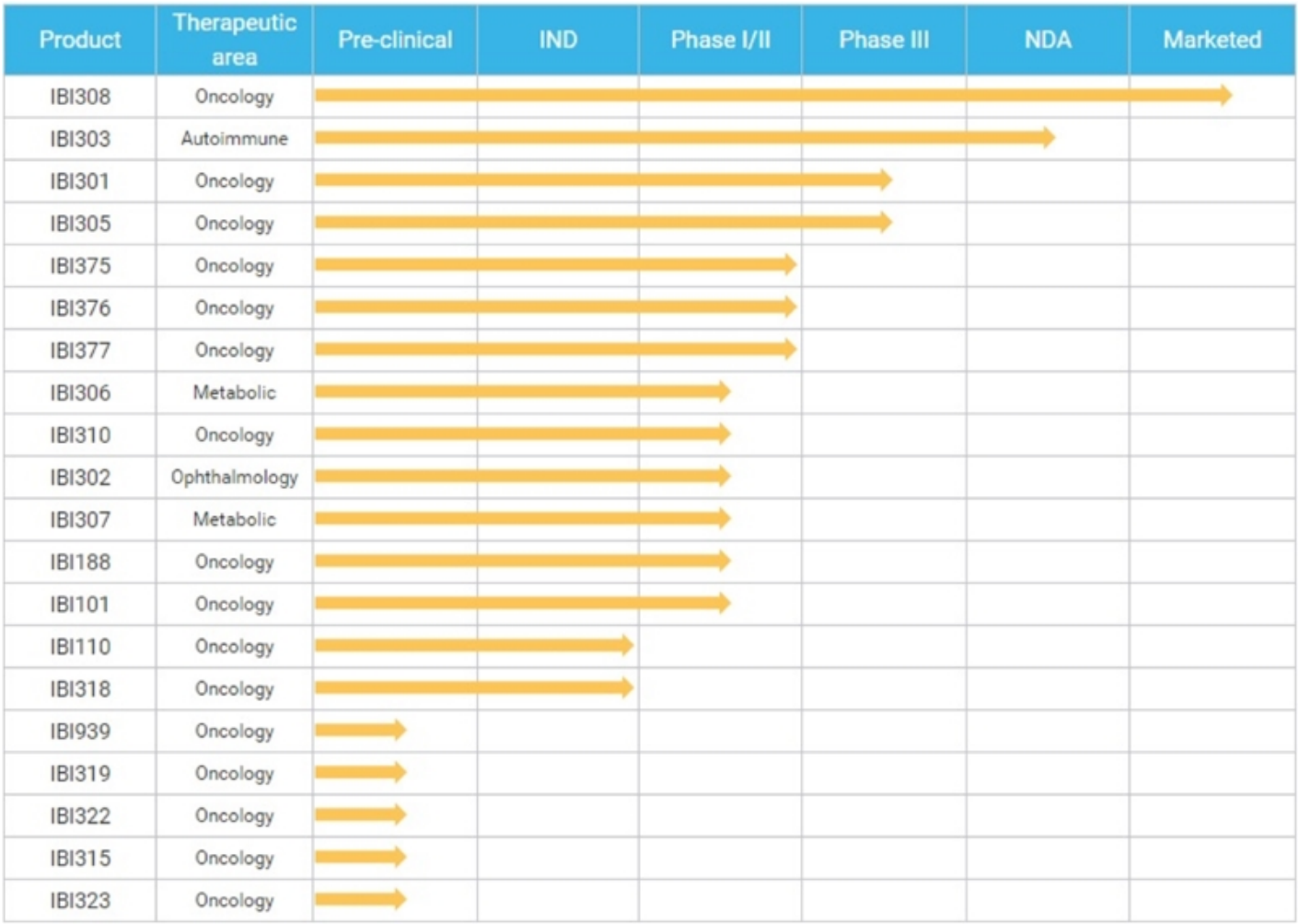
As the company continues to grow rapidly, what is your leadership philosophy for the organization?

Innovent has grown so quickly in the past few years, almost doubling in size each year. We have around 1000 employees now and will probably grow to 1500 next year. It is a challenge to have an organization grow so quickly. Every organization has a culture. Hiring and training people to work together on the same page is not easy. Strong leadership is critical because people start to lose their focus and the organization purpose becomes more diffuse. Everyone’s motivations must be aligned for a company to work.

At the top of our to-do list as leaders is to ensure that the people working close to us have the same agenda and share the same core values. Innovent’s core values are ‘integrity’, ‘learning agility’, ‘dedication’ and ‘cooperation’. Those are the KPIs by which we evaluate our employees. When we hire, promote and assess, we do not judge only by their capabilities or numbers but by whether our employees share these core values. Having the same goal is the most important thing.

What can we expect from Innovent Biologics in the next few years?

We have 20 molecules in our pipeline: 13 in clinical development, four in Phase III, one (biosimilar to Humira) has its New Drug Application (NDA) under review and Tyvyt® (sintilimab injection) is now approved for relapsed or refractory classical Hodgkin's lymphoma (r/r cHL).



If you look at the number of products we have in such advanced clinical development, it is really impressive and rare for a seven-year-old biotech company! That is a reflection of our positioning and executional efficiency.

By the end of 2019, we should have three products under NDA review and one product on the market, which would probably make us the only domestic biotech company in China with four commercial-stage products!

Six of our products are also in clinical development in the US.

A final message to our international audience?

For biopharma, this is a once in a lifetime opportunity – for investments, talent, partnership deals. Do not miss out! For any company in our industry, regardless of their size, you should consider China as a potential growth opportunity. For multinational Big Pharma, you can see that China is already their second-most important market globally. For small companies with innovative products, they must consider a development strategy to leverage those innovative products for the Chinese market!

This is a once in a lifetime opportunity: everyone should put China in their agenda for business expansion and growth.

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