Carsten Lu – CEO, Adlai Nortye, China



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Carsten Lu of Chinese biotech Adlai Nortye outlines his strategy for navigating a crowded immuno-oncology field in China, his partnership strategy, and the firm's early move to establish a footprint in the USA.

Carsten, could you start by introducing Adlai Nortye to our international audience?

Established in 2016, Adlai Nortye is an immuno-oncology biotech company with the mission to transform cancer into chronic diseases that can be treated and cured. We see ourselves as a company with Chinese roots but global reach. Our vision is to become a global biopharmaceutical company and develop a strong and highly differentiated product pipeline. Our mission is to improve patient lives by developing differentiated, innovative medicines that help people live better and longer. Through close collaborations with global partners, Adlai Nortye has successfully positioned itself in the field of immuno-oncology with several programs ongoing from early pre-clinical to Phase III.

I am from Zhejiang province and I studied biology at undergraduate level before pursuing an EMBA. I started my career with a Chinese generics company before deciding to establish a diagnostic start-up company with my classmate. Subsequently, I sold my share of that company to establish a generics company focused on manufacturing peptide drugs, which was called Sinopep.

Adlai Nortye is therefore my third start-up within the biotech and healthcare industries. The name itself is rather unique and reflects the origins of the company. I coined the word ‘Nortye’ because it sounds similar to the Chinese name of my second company, Sinopep (“□□ ”), which was a combination of ‘honest’ (□) and ‘well-being’ (□). ‘Adlai’ is a word meaning ‘God’s righteousness’ in Hebrew, and this was a name chosen by my pastor.

In the past three years alone, Adlai Nortye has achieved a significant number of milestones. What has contributed to your success and productivity?

Indeed, the past three years have been quite productive. I can name a number of major milestones, starting from November 2017, when we licensed in Pelareorep, a safe and well-tolerated intravenously delivered immuno-oncolytic virus, from Oncolytics Biotech.

In January 2018, we entered into a global licence agreement with Eisai for an EP4 antagonist. In May 2018, we raised USD 53 million in our Series B fundraising round. In July, we entered into a global license agreement with Novartis for Buparlisib. In August, we opened our new USA headquarters in North Brunswick, New Jersey. At the end of 2018, we reached an agreement with the US FDA to initiate phase III clinical trials for AN2025 (Buparlisib).

In January 2019, we announced a landmark clinical collaboration with MSD (Merck & Co. in the US and Canada) to evaluate the combination of Adlai Nortye’s AN0025 (EP4 Antagonist) and Merck’s anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with solid tumors. In March 2019, we received NMPA approval for Phase III clinical trials for AN1004 (Pelareorep).

The main contributing factors have been the powerful values at the core of Adlai Nortye, and a highly productive team. This is what has allowed us to set so many key milestones in the past three years. In the past three years, we might be one of the fastest growing biotech companies in China. The Chinese biotech industry itself is already moving at supersonic speeds to catch up to international norms but I think Adlai Nortye is running even faster.

With immuno-oncology being such a crowded field, especially in China, how do you ensure that Adlai Nortye’s portfolio is well-differentiated and competitive?

If you look at the typical biotech companies in the US or Europe, they often tend to be single-asset companies, or they have a couple of assets, at most. In China, many companies have the

opportunity to establish more of a platform company with a much richer pipeline of assets. Comparatively, this lowers the risks involved with drug discovery and development.

For Adlai Nortye, this is a very important strategy for us, especially because we focus on immuno-oncology, which is the future of oncology. The future of immuno-oncology is definitely in combination therapy. Only a company with a rich pipeline can be competitive when it comes to combination therapy. This is why we have focused on the breadth of our pipeline.

Our portfolio is also extremely innovative. This also differentiates us from many other Chinese biotechs, which mainly tend to focus on ‘me too’s. Such ‘me too’s could be competitive in China or even in the Asia-Pacific region but it is difficult for them to compete internationally.

We will also focus on maximizing the combined potential of our internally-developed assets and our licensed-in assets.

Adlai Nortye has struck up great partnerships both biotechs like Oncolytics Biotech and Big Pharma like Novartis, MSD and Eisai. What makes a good partner for Adlai Nortye?

Our core focus is in IO and building a robust and differentiated IO portfolio for combination therapy. Therefore, we are looking for unique and differentiated compounds with mechanisms of action that are synergistic with our current assets. This is our strategy to ensure that we can develop products that meet unmet medical needs and compete globally.

As IO assets are rather broad-spectrum, we are not looking at specific indications but rather products with these synergistic mechanisms of action I mentioned. We are looking for early-stage candidates that we can develop ourselves.

Could you outline your commercial strategy for Adlai Nortye?

We have already devised a global strategy. Certainly, in the US and China, we will build our own commercial teams, as the top two markets globally. For other key global markets like the EU and Japan, we will look for strategic partners.

The US is particularly important to us since it is the country with the highest drug prices globally. More pertinently, in our target indications, we have estimated that the US represents around half of the global market. The costs of establishing a direct commercial presence in the US are actually

not as high as commonly assumed. For our target indications, we have done our market analysis and expect that a team of around 30 medical sales reps should suffice.

What also works in our favour is that we are not playing in very crowded areas like breast or lung cancers. For instance, head and neck squamous cell carcinoma (HNSCC) is a highly unmet medical need with few available treatment options at the moment.

At the end of the day, a commercial strategy depends on how competitive and how needed a product is. The strength of the product is key to commercial success.

Adlai Nortye currently has a presence in the US. What made you decide to establish an office there so early?

Since our vision is to become a global pharma company, we must eventually build and manage a company with international operations. We expect to fix mistakes along the way. Having an office there before our products are have been approved gives us more room for and lowers the cost of trial and error. At the same time, having a presence there supports our ongoing US clinical trials and also our biologics R&D. We hope that starting early will give us more time to optimize our US operations.

For instance, given the differences between China and the US, there will inevitably be cultural and professional differences. The Chinese tech world has popularized this notion of ‘996’ – working 9 am to 9 pm, six days a week. For us, as we have many teleconferences involving both our US and China offices, one side or the other will be taking such calls outside of normal work hours. With time, however, people get used to this. Besides such cultural differences, we also have cultural differences between people that used to work in Big Pharma and people that are used to working in start-ups. Ex-Big Pharma executives often have to adjust to working with more limited resources.

What benefits are there for Adlai Nortye to be based in Hangzhou?

Hangzhou, as the birthplace of Chinese Internet giant Alibaba, is a great place to build a start-up. Its digital infrastructure, internationalization, quality of life, atmosphere of innovation and robust VC ecosystem are all strong selling points. In addition, the Hangzhou government takes a rather *laissez-faire* approach to business. At the same time, compared to Shanghai, Hangzhou has lower costs of living and is a more stable city.

We initially picked Hangzhou pragmatically because one of our first angel investors was based here but since then, we have been approached by many other municipal governments from Shanghai, Shenzhen and Suzhou but following careful consideration, we decided that Hangzhou was still the best location for our HQ.

On a more personal note, with your track record of successful entrepreneurship, what do you see as the winning formula for building a successful company?

I have been an entrepreneur for 16 years now and Adlai Nortye is my third company. I believe many other biotech CEOs will share the same formula: firstly, you must choose a vision or a direction that is promising and full of potential. Secondly, you must build a team that has a strong value proposition and competitive advantage. Thirdly, you have to fundraise enough capital and manage cash flow wisely. Finally, of course, you need a bit of luck!

To begin wrapping up, what are the next milestones we can expect for Adlai Nortye?

We will be having another round of fundraising in the next couple of months, and we are planning for an IPO in 2020.

Looking ahead, in five years' time, we hope to see our products launched on the market. We also hope to have generated very positive and robust data on our clinical assets. Finally, we aim to build Adlai Nortye into a global biotech company with a market capitalization of USD 10 billion.

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