Lau Lit Fui – CSO & President, Zhaoke Ophthalmology

In China, the ophthalmology market is expected to grow from USD 1.8 billion in 2015 to USD 20.2 billion by 2030 ... a 17.5 percent increase year on year

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Established in 2017 as a spin-off from Lee's Pharmaceutical, Zhaoke Ophthalmology is aiming to be a global player in the ophthalmology field, building on its strong footprint in China and Asia to eventually establish operations in the US and Europe. President and Chief Scientific Officer Lau Lit Fui outlines how the now HKEX-listed company's capital-raising efforts have evolved, the key areas in its comprehensive portfolio of innovative and generic treatments covering major front- and back-of-eye diseases, and what Zhaoke's future growth trajectory might look like.

What was the career trajectory that led you to take up this position as CSO and president of Zhaoke Ophthalmology?

I am the president and CSO of Zhaoke Ophthalmology and I have been with the company for four years now. I was born in Hong Kong and completed my undergraduate degree and master's at the Chinese University of Hong Kong (CUHK), before moving to the US to do my PhD and my postdoctoral fellowship at Johns Hopkins University.

Following these studies, I worked at Pfizer at the global R&D site in Connecticut within my speciality area of neuro-regenerative medicine in Alzheimer's, Parkinson's, and stroke. After nearly 20 years in the US, I was offered a leading role with GSK at their new R&D centre for neurodegenerative medicine in Shanghai and could not pass on the opportunity. Consequently, after this position I worked at the Lee's Pharm group from 2012 until 2019, and then finally took up this role at Zhaoke Ophthalmology, a spinoff of Lee's Pharm, making it a simple transition.

It is always a big jump to move from an MNC to a local company which tends to lack some of the resources to push the boundaries of R&D. With that in mind, what was the reason behind the decision to join the Lee's Pharm Group back in 2012?

My experience at Pfizer and GSK was mainly in early discovery and some preclinical development, so joining Lee's Pharm opened the doors to learning a lot more across the entire value chain and gave me many opportunities. I went from working in a specific and defined role in pure R&D to working on tasks such as sales and marketing, clinical trials, fundraising, BD, M&A and IPO. All in all, within that role at Lee's Pharm I was able to dip my toes into the water of the full scope of business operations and gain an extremely rich hands-on experience.

What is the primary focus of Lee's Pharm Group?

Lee's Pharm was founded in 1994 by Dr Benjamin Lee after he completed his postdoctoral studies in the US and chose to come back to Hong Kong and start his own company. It is an R&D-focused company with a footprint primarily in greater China (mainland China, Hong Kong, Macau and Taiwan) and has a wide range of therapeutic areas, including cardiovascular disease, neuroscience, dermatology, gynaecology, and rare diseases.

The company has many products already on the market, mostly in mainland China, and it is revenue generating, both from products resulting from its own research and through licensing agreements with companies from Japan, the US and Europe. Lee's Pharm is always on the lookout for suitable partners with which to work.

How did Zhaoke Ophthalmology come about as a spinoff from Lee's Pharm?

Zhaoke Ophthalmology is now a completely independent company and is aiming to be a global player in its therapeutic area. A little over 10 years ago Lee's Pharm had a single ophthalmology product, making the enterprise familiar with this therapeutic area and its unmet medical need within it, especially in China. We knew that to be successful we needed a larger portfolio, so we began doing our own ophthalmological R&D and licensing products from abroad.

Now we are beginning to set up an international footprint, which starts with out-licensing our myopia product NVK002 to a distributor in South Korea. The next step is to move towards Southeast Asia, to countries such as Malaysia, Thailand, Philippines, Singapore, Vietnam, and Indonesia to name a few. Our long-term aspirations are to move into the US and Europe, and we have patents in those locations already so are on the move to expand. We also had a pre-IND consultation with the FDA as an initial step in a process to globalize our in-house developed innovative dry eye drug Cyclosporine A Ophthalmic Gel.

A big part of growing a company is raising capital – how has the process so far been for Zhaoke Ophthalmology?

In 2017 Zhaoke Ophthalmology was officially founded and two rounds of funding have been successfully undertaken since then. In 2019 we raised USD 50 million from VCs and reputable investors and in 2020 we raised 145 million for Series B funding, with Hillhouse COFL and TPG Asia being the lead investors. And finally, we were listed on the Main Board of the Hong Kong Stock Exchange in April 2021, raising an additional over USD 200 million.

We strongly believe to have a very compelling story for investors. Firstly, in China, the ophthalmology market is expected to grow from USD 1.8 billion in 2015 to USD 20.2 billion by 2030, according to China Insights Consultancy. That is a 17.5 percent increase year on year, so the market size and potential are there for growth.

Secondly, in China there is a significantly low diagnosis rate for eye diseases, compared to US. This means that if we are able to bring innovative products to market, it will raise awareness in the patient and medical communities and spread the word about the treatment of the disease. It will be a positive cycle and open up the market for us as more people will be tested and diagnosed. This is all being fuelled by the prevalent habits of today, such as the intensive use of mobile

phones and computers, which increases the risks for myopia and dry eyes.

Thirdly, there is no single dominant player in the Chinese ophthalmology market, with the biggest share being around 13 percent (2019 data), so it is all very much fragmented and a level playing field. We believe that with what we can offer, we will become a leader in the field.

How is the commercial market organised in China for ophthalmology?

There are three segments. The first is public ophthalmology speciality hospitals, which are the key sites where people with eye issues seek assistance. The second is private ophthalmology hospitals. The biggest Chinese chain, Aier Eye Hospital Group, which is one of our shareholders, has close to 700 hospitals and centres in China. There are also other major players we are in touch with. The third are vision clinics/optometrists.

You raised a good amount of capital in Series A and B funding. How has Zhaoke deployed these funds since?

We raised nearly USD 200 million in two series of fundraising and more than 200 million when we went public on April 29, 2021, and to some extent, we had good timing as the market was more open then than it is today.

Most of the money has been diverted towards clinical trials and commercialization of our core products, with the trials becoming progressively more costly the further along they go. We now have a comprehensive drug portfolio of innovative and generic treatments covering major eye diseases across both the front- and the back of the eye. Currently, we have a commercialized drug targeting glaucoma, Bimatoprost Timolol, and we are focusing on major near-term development programs that are either in the NDA (New Drug Application) stage (i.e. Cyclosporine A Ophthalmic Gel for dry eye disease), pivotal phase III clinical trial (e.g. NVK002 for myopia, TAB014 for aged-related macular degeneration), or preparation of pivotal phase III clinical trial (e.g. Brimochol for presbyopia, ZKY001 for corneal epithelial defects) covering the major ophthalmic diseases. We are also the only ophthalmology company in China with advanced programs (Phase III or later) in all three of the largest front-of-the-eye diseases: dry eye disease, myopia, and presbyopia.

We also diverted funds to preclinical programs such as toxicity, pharmacology, and chemistry, manufacturing and control (CMC) studies and manufacturing ophthalmic products. Furthermore, we

are sponsoring academic research so as to ensure a continuous and healthy supply of our pipeline in addition to our in-licensing efforts.

Entering new markets can be costly and time-consuming. What is the regulatory pathway that is most suitable for the company to expand?

China is our home turf and the market we are most familiar with, so naturally all our assets are submitted through the National Medical Products Administration (NMPA) for registration and approval in China. Besides mainland China we will also enter greater China markets, such as those of Hong Kong, Macau and Taiwan, and are building a footprint in South Korea through our partners there.

Additionally, we are looking to register our products with promising commercialized potential in Southeast Asia and have commercial rights there. It is a very fragmented market in terms of registration, so we must go one by one in the countries to get our products registered and eventually to consumers.

How do you go about growing your commercial footprint in these markets?

Within China, we have our own sales force that has years of experience in ophthalmology. We also explore opportunities to commercialize ophthalmic products with strategic partners. Outside of China, such as in South Korea, we rely on our partners to undertake commercial operations. For Southeast Asia, we have set up a subsidiary that will leverage local specialists on different aspects of our business.

What do you view as the main challenges ahead for Zhaoke?

In general, the main challenges are centred around monetary resources, especially as the financial markets around the world at this moment are not currently in an ideal situation. Therefore, we must be careful with our expenditure, and we must divide our resources in a conservative manner to ensure that we are a company that can operate well into the long term. We are in good cash condition, with approximately RMB1.7 billion cash balance as of mid-2023. We hope that once our products are approved and launched that we will be producing sufficient profits, and not just using the cash from the previous sources of funding. For this, we are speeding up commercialization in

China and around the world.

Would you like to extend outside Asia?

It is part of what we want to do in the future – especially to the mature pharmaceutical markets like the US and Europe- but going into Southeast Asia could be a good initial step as it is closer and could be more open to working with us straight off the bat. We must diversify the risk and not put all our eggs in one basket, so moving into various markets is a good way to do this.

You have positioned Zhaoke's operations in the Greater Bay Area with your manufacturing facilities in Nansha (Guangdong province). What was the reasoning behind this?

Since starting operations, we have been able to take advantage of the incentives put in place by the Chinese government to grow operations in the region. This is through areas such as research funding support in clinical trials and talent support by allowing Hong Kong nationals to work in the area and still take on the lower tax rates they are used to.

Moreover, we are very close to Hong Kong, less than 1 hour by high-speed rail, and the Hong Kong Trade Development Council is facilitating our growth by setting up meetings to meet the correct people in Southeast Asia. Furthermore, the Greater Bay Area is much cheaper for land than Hong Kong, so we have constructed a production facility here. This site ensures we are even more independent and allows us to reach the market with our products at a more competitive price.

All in all, once our core products gain commercial success and make a profit, then as a company we will truly accelerate our growth as we invest back into the business.

Are there any recommendations you would make to the local government to improve the ecosystem here?

The government already has done a lot, but I would say that we need to attract even more healthcare companies to the Greater Bay Area to create critical mass which will in turn drive forward the ecosystem. This will bring more talent in specific areas, and we must not just focus on young innovative companies, but all parts of the value chain including CMOs, CROS, and MNCs.

What is your final message to PharmaBoardroom’s international audience?

Our company is at the beginning of its journey, but we have already been listed on the Hong Kong Stock Exchange. We have a young and robust team and are growing our portfolio with innovative products to meet the unmet medical needs of the market. We are in the process of building our footprint in China, Southeast Asia, and Western markets, and are looking to partner with ophthalmology companies across the world that are open to collaboration.

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