Yu Xuefeng â?? CEO & Chairman, CanSinoBIO

Our approach combines strategic business considerations with a commitment to social responsibility

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CanSinoBIO was established to create high-quality, affordable vaccines for developing countries, addressing global health disparities. Having already developed an inhalable COVID-19 vaccine, the Chinese firm is now working on new TB and polio vaccines using advanced technologies. CEO and Chairman Yu Xuefeng outlines CanSinoâ??s approach to IP protection and sharing, partnerships â?? including a deal with AstraZeneca â?? and its upcoming entry into new therapeutic areas including immuno-oncology and gene therapy.

Vaccines became front-page news during the COVID-19 pandemic having previously often been left out of the global conversation. How, as head of a vaccine-focused company, did you navigate the increased scrutiny of this period?

First of all, I would like to correct the notion that people didnâ??t care about vaccines before COVID-19. Individuals might not have been as vocal or aware, but vaccines have always been incredibly important. From the moment we are born, most of us receive vaccinations that protect us from various diseases. Vaccination is arguably one of the most valuable medical inventions to date. It has significantly reduced the burden of infectious diseases and extended our lifespan tremendously.

Thereâ??s a powerful statistic from the US: for every dollar invested in vaccines, thereâ??s a $40 return in terms of health and economic benefits. Vaccines eliminate diseases, and when these diseases are no longer in circulation, people tend to forget their past devastation. Diseases like smallpox and polio, for instance, once caused widespread suffering and death. In our generation,

seeing people paralyzed by polio was not uncommon but it is now almost nonexistent thanks to vaccines.

This impact is recognized by medical professionals, governments, and even the public, although perhaps less consciously. Vaccines donâ??t just protect the individual; they protect communities by reducing the spread of infectious diseases. When I first joined the vaccine industry, I quickly understood how protected we are because of these medical marvels. This realization made my work feel profoundly meaningful. Developing better vaccines became a passion, as I knew it could benefit everyone, not just a few.

For me, navigating the COVID-19 period was both a professional challenge and a personal mission. It reinforced my belief in the power of vaccines and the importance of our work in this field. The debates about vaccine platforms and efficacy underscored the need for continued innovation and education about vaccinesâ?? critical role in public health.

When you started CanSinoBIO, did you ever anticipate being in the spotlight as you are now?

No, not at all. I donâ??t think anyone did. When I first entered the vaccine industry at Pasteur MÃ©rieux Connaught (which later became Aventis Pasteur, and is now Sanofi Pasteur, part of Sanofiâ??s vaccine division) I was proud to join one of the worldâ??s largest vaccine companies, with a history of significant achievements. Over my 12 years there, I contributed to many clinical trials and other activities.

However, it wasnâ??t until I moved back to China that I realized the stark differences in vaccine availability and quality between regions. In the West, we often take high-quality vaccines for granted, but many parts of the world are far behind. This realization drove me to think about what I could do to bridge this gap.

Initially, I didnâ??t foresee the extent of the impact we could have, but I was motivated by the desire to improve vaccine access for people in China and other developing countries. My experiences in Africa, particularly during the Ebola outbreak, highlighted the dire need for better medical resources. Visiting Sierra Leone and seeing the lack of basic medical care was a shocking reminder of the disparities in our world.

China is somewhat in the middle groundâ??better off than some but still facing significant challenges. In developed countries, peopleâ??s lifespans are much longer because they donâ??t suffer from infectious diseases as much. In contrast, in developing regions, many people die young from preventable diseases. This disparity was amplified during the COVID-19 pandemic when vaccine shortages hit developing countries hard.

Even in middle-income countries, where infrastructure is relatively good, access to vaccines can be limited. This global inequity in vaccine distribution is something we are working hard to address. My journey has shown me that improving vaccine access is not just about technology but about ensuring that everyone, regardless of where they live, can benefit from life-saving medical advancements.

What are your thoughts on how intellectual property (IP) for COVID vaccines was handled globally? Some policymakers in the Global South were upset and claimed that the Doha Declaration Agreement was not respectedâ?¦

From day one of starting our business, we have always maintained that respecting IP is crucial because we have our own IP to protect as well. If we donâ??t respect othersâ?? IP, we cannot expect others to respect ours. This principle has guided our actions consistently.

A perfect example is mRNA technology, which was a significant point of contention during the pandemic. While access to such technologies is covered by the 2001 Doha Declaration on the TRIPS Agreement and Public Health [which stressed the need for the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to be part of wider action to address public health problems afflicting developing economies and least-developed countries, confirming the right of WTO members to take measures to protect public health. It led to a legal amendment of the Agreement that provided a new pathway for access to affordable medicines â?? Ed.], we took a different approach. We licensed lipid nanoparticle (LNP) technology from our partner for our COVID-19 vaccine development. This was not a shortcut; we paid substantial sums to secure this license, demonstrating our commitment to respecting IP rights. We firmly believe that adhering to IP laws is essential for fostering innovation and ensuring mutual respect in the industry.

What was the initial idea behind CanSinoBIO and how has the companyâ??s focus evolved?

Our initial focus, agreed upon by all our partners, was to create high-quality, innovative vaccines at an affordable cost for the developing world. This was not just for China; we aimed to address global needs wherever they existed. Even today, our long-term vision remains the same.

We wanted to ensure our vaccines were effective, affordable, and of high quality, particularly for the developing world. Initially, we saw that many vaccines in China did not meet global standards. We believed we could leverage our knowledge and skills to upgrade these vaccines to the next generation. This included import replacement, where we used our expertise to produce vaccines that China lacked at the time. This approach was both a business strategy to ensure sustainability and a commitment to innovation to meet medical needs.

For instance, we are working on a tuberculosis (TB) vaccine. Globally, we havenâ??t seen a new TB vaccine in almost 100 years, despite the increasing disease burden and the spread of multidrug-resistant strains. This represents our third tier of focus: innovative solutions to significant medical challenges.

Another example is our effort in polio eradication. The current oral polio vaccine (OPV) is a live vaccine that can mutate and perpetuate the virus in the environment, making eradication difficult. We have developed a polio vaccine using virus-like particles (VLPs) This technology, which we have spent nearly 10 years developing, allows us to produce polio vaccines without the associated biosafety risks. We recently completed our phase I clinical trial, and the results are promising. This development, supported by the Bill & Melinda Gates Foundation and WHO, has the potential to revolutionize polio vaccination globally.

So, while our focus has evolved to address new challenges, our core mission of providing high-quality, affordable vaccines to the developing world remains unchanged.

How do you manage the challenges of running multiple platform technologies, and what strategies do you employ to ensure each oneâ??s success?

Managing multiple platform technologies is indeed challenging, but our extensive experience in the vaccine field allows us to understand where each technology best fits. We have five platform technologies, and each is tailored to different types of vaccines.

For instance, our COVID-19 and TB vaccines use our adenovirus-based viral vector technology platform. This platform was also used for our Ebola vaccine, showcasing its versatility. We can quickly develop new vaccines by changing the genes within this viral vector, a process that has proven very successful. Our COVID-19 vaccine, for example, has been distributed in over 10 countries and administered to tens of millions of people. In Mexico, where a significant population has used our vaccine, we have received the most positive feedback among several vaccines available.

While we havenâ??t pursued FDA approval in the US due to their ample vaccine supply and the high costs involved, we have WHO emergency use listing (EUL) and individual countriesâ?? approvals. This strategy allows us to focus on regions that need our vaccines the most without duplicating efforts in markets already well-supplied.

In addition to the viral vector platform, we have a protein structure design and VLP assembly technology platform and our innovative virus-like particle (VLP) polio vaccine, which we have developed over nearly a decade.

We also focus on pneumococcal vaccines, moving beyond the serotype wars. While many companies keep adding more serotypes, we have developed a pneumococcal common antigen vaccine that covers all 90+ serotypes from the start. Our phase I data is promising, showing that antibodies induced by this vaccine can kill the bacteria. This innovative approach has caught the attention of large pharmaceutical companies, seeing it as a potential next-generation, globally accessible vaccine.

Moreover, our synthetic biotechnology platform supports our meningococcal and pneumococcal conjugate vaccines. We have already brought Aisaâ??s first quadrivalent meningococcal conjugate vaccine to market, which has seen good uptake over the past two years. We are also expecting to launch a 13-valent pneumococcal polysaccharide conjugate vaccine next year.

Did you also explore mRNA technology? If so, what has been your approach and experience with it?

We have been working on mRNA technology for about six to seven years, long before the COVID-19 pandemic brought it to the forefront. We recognized the potential advantages of mRNA technology, particularly for emergency responses and pandemics, due to its quick development timeline and clear mechanism of action.

Our approach with mRNA technology has been to make it more suitable for vaccine use, rather than simply copying existing methods. For instance, one of the major challenges with mRNA vaccines is their storage and stability requirements. Most current mRNA vaccines need to be stored at very low temperatures, around minus 20 degrees Celsius, which is not feasible for many emerging markets that lack the necessary infrastructure. Additionally, the typical distribution and usage cycle for vaccines can lead to significant waste if they have a short shelf life.

To address these issues, we have been working on developing an mRNA vaccine that is stable at standard refrigeration temperatures (2 to 8 degrees Celsius), which would make it much more practical for widespread use, especially in regions with limited cold chain capabilities. We are also

exploring formulations that reduce reactogenicity, as the current generation of mRNA vaccines can cause side effects like fever and local reactions, which are not well-received by many people.

While the initial excitement around mRNA vaccines was due to their high efficacy against COVID-19, we believe there is room for improvement in terms of stability and side effects. Our goal is to make mRNA vaccines more convenient and acceptable for routine use.

Beyond vaccines, we are also exploring the potential of mRNA technology for therapeutic applications. This broader approach allows us to leverage the unique advantages of mRNA while addressing its current limitations to develop more effective and user-friendly products.

What are some of your other most promising vaccine development platforms?

Additionally, we have a formulation and drug delivery technology platform where we developed the worldâ??s first COVID-19 mucosal vaccination through inhalation. This innovative platform was initially created for a TB vaccine, which we started almost 12 years ago, to provide the best immunization approach for TB by inducing a local mucosal immune response in the respiratory tract and lungs, the first layer of defense against airborne TB bacteria.

Interestingly, this inhalation vaccination technology has also proven effective against COVID-19, a respiratory disease. Our vaccine induces three mechanisms of protection: humoral and cellular immune responses systematically, and a local mucosal immune response. Using only 20% of the injectable dose, it provides an equivalent or better immune response, plus the added benefit of mucosal immunity. It has been more effective, safer, and shows significantly fewer side effects. To date, almost 10 million people have been vaccinated using this approach in China, Morocco, Indonesia, and a few other countries.

How did you manage to finance all these ventures?

Initially, we were funded entirely by venture capital (VC). The VC funding was very active and effective, allowing us to develop multiple platforms and build our manufacturing facilities. This early-stage investment was crucial for our initial growth and technological advancements.

After achieving significant milestones with VC funding, we went public on the Hong Kong and Chinese stock exchanges. The market recognized our value, and the public listing helped us raise substantial capital to support our continous R&D and operations. This funding has been instrumental until we began generating revenue from our product sales, particularly since the start of the COVID-19 pandemic.

From the COVID period onward, we started generating revenue, which now supports our R&D and operations. Despite some revenue fluctuations due to the pandemic, our primary goal has always been to protect public health. Even though the pandemicâ??s unpredictable nature caused some financial write-offs and supply chain challenges, our preparations ensured that people had access to vaccines when they needed them the most.

For example, we made a strategic decision to terminate the phase III of our mRNA COVID-19 vaccine after completing phase II, as we anticipated a limited future demand. This allowed us to cut off expenditures early and avoid unnecessary spending, even though some ongoing activities could not be halted immediately.

Can you explain the rationale behind your partnership with AstraZeneca for vaccine manufacturing?

AstraZenecaâ??s interest in entering the vaccine market grew significantly during the COVID-19 pandemic. Traditionally focused on pharmaceuticals, they saw an opportunity to expand into vaccines, driven by global health needs and strategic business growth. Our collaboration stemmed from mutual interestsâ??we possess substantial manufacturing capacity and expertise in vaccine development. Importantly, our quality systems are aligned with stringent global standards, including FDA and WHO requirements, which are critical for multinational collaborations.

I had the opportunity to discuss this with Pascal Soriot, AstraZenecaâ??s CEO, on multiple occasions. It became clear that our capabilities could complement their efforts effectively. Beyond technical expertise, our ability to maintain high-quality standards was a key factor in AstraZenecaâ??s decision to partner with us. This partnership isnâ??t exclusive; we maintain flexibility to collaborate with other multinational companies. This approach allows us to leverage our diversified product pipelines and expand our footprint in the global vaccine market effectively.

Looking ahead three to five years, how do you see CanSinoBIO evolving? Will you maintain a focus on global population health or explore new frontiers for vaccines?

Over the next three to five years, CanSinoBIO aims to build upon its foundation as a leader in vaccine development while also exploring new avenues in specialized healthcare areas. Our primary commitment remains steadfast in advancing global population health through innovative vaccine solutions. This is where our core expertise lies, and we continue to prioritize this critical aspect of public health.

However, our platform technologies, such as recombinant proteins and mRNA, are highly versatile and applicable beyond vaccines. For instance, we see potential in immuno-oncology, leveraging these technologies to develop novel approaches in cancer treatment. We are actively engaged in collaborations with partners who specialize in gene therapy, such as Ocugen, utilizing our viral vector platform to support promising therapies for genetic disorders currently in phase III trials.

This dual approach allows us to diversify our portfolio while staying true to our mission of improving global health outcomes. By expanding into these new therapeutic areas, we aim to address unmet medical needs and contribute to broader healthcare solutions worldwide. This strategy not only reflects our innovation-driven mindset but also underscores our commitment to expanding our impact beyond traditional vaccine development.

Do you have a final message on behalf of your company?

We see ourselves as doers. We have the experience, the capable people, and a thorough understanding of quality regulatory requirements. Our global network extends far beyond Chinaâ??s borders. We are eager to collaborate with anyone who shares our values to make the world healthier. While we are a China-based public health provider, we are constantly looking for opportunities to expand our impact globally.

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