Jimmy Wei â?? President, Chime Biologics

We are a global CDMO committed to delivering exceptional value and quality to our clients. Our extensive experience in meeting the stringent quality standards of global regulators underscores our dedication to excellence

29.05.2024

Tags:

China, CDMO, Manufacturing, Biosimilars, Chime Biologics

Jimmy Wei founded Chime Biologics over 12 years ago with the vision of establishing a global biologics company in China, focusing on biosimilar development and CDMO services. The companyâ??s growth since then has been influenced by the success of other biologics companies like WuXi Biologics and Samsung Biologics, regulatory changes in China that eased outsourcing manufacturing, and a strategic shift towards global markets. In 2020 and 2021, Chime Biologics raised approximately USD 315 million, marking a peak in the market and transforming the company into a fully independent global CDMO. Wei outlines how Chime Biologics has significantly expanded its manufacturing capacity since then and how it now offers comprehensive services from cell line development to commercial manufacturing, with more than half of its new business coming from overseas markets.

Can you share the story behind Chime Biologics and how it came to fruition?

I founded Chime Biologics over 12 years ago. It was initially an incubation project backed by Kleiner Perkins and three other funds, with me representing Kleiner Perkins. Our vision was to establish a global biologics company in China, recognizing the burgeoning potential of the biological market here. We focused on two main areas: biosimilar development and CDMO services.

To kick start the venture, we assembled a talented team with extensive experience, both in China and the US, and secured $40 million in funding, a substantial amount for the Chinese venture capital

landscape at that time. To build a world-class biologics company in China, we established manufacturing facilities in Wuhan, my hometown, where I had strong personal connections and the level of science and talent available is rather high. Interestingly, despite being a venture capitalist initially, I was asked to manage the China business as a condition of investment, given my intimate knowledge of the Chinese market and familiarity with Wuhan.

Reflecting back to the early days, how did you address concerns about regulatory frameworks and manufacturing standards in China that were not aligned to global ones when pitching to venture capitalists in 2012?

Itâ??s understandable that there would have been skepticism, especially regarding Chinaâ??s regulatory landscape and manufacturing capabilities back in 2012. However, our vision was based on a clear trend: pledge to make world-class biopharmaceuticals affordable and accessible to all patients globally through technology and manufacturing innovation. We recognized that if Chinaâ??s pharmaceutical industry grew, so too would the demand for biologic drugs. This led us to believe that establishing a biologics company in China was not only viable but essential for long-term success. While others may have doubted, we saw it as a strategic move.

Moreover, we werenâ??t alone in this endeavor. Other companies like WuXi Biologics and Innovent were also founded around the same time, indicating a collective belief in the potential of the biologics industry in China. As pioneers in this space, we were committed to navigating the regulatory challenges and building the necessary infrastructure for biologic development and manufacturing, starting with just a PowerPoint presentation and a bold vision.

Looking at Chime Biologics journey, what do you consider the main inflection points both for the company and the manufacturing of biologics as a service class?

There have been several significant inflection points that shaped the trajectory of Chime Biologics over the past decade. Firstly, the success of companies like WuXi Biologics and Samsung Biologics was truly transformative. Their rapid growth and achievements demonstrated the potential for high-quality, low-cost manufacturing in the biologics sector, setting a precedent for the industry as a whole.

Additionally, regulatory changes in China played a crucial role in our development. For instance, the relaxation of regulations around outsourcing manufacturing allowed us to adapt our strategy and pursue global markets more aggressively. This was particularly important for us, as our initial focus was not on the Chinese market but on a global scale. Finally, the local market dynamics also influenced our evolution. Despite our global focus, having a presence in the local market became increasingly important, leading to the transformation of Chime Biologics a fully independent global CDMO. We raised approximately $315 million US dollars in 2020 and 2021, during what was considered the peak of the market.

Could you elaborate on your current assets and manufacturing capacity ?

Since our transition to a pure global CDMO in 2020, weâ??ve made significant investments to expand our capacity. Initially, our drug substance manufacturing capacity was at 9,000 liters. Today, weâ??ve scaled up to 28,000 liters, tripling our capacity. This expansion was crucial to attract clients

and efficiently meet their needs. Moreover, weâ??ve diversified our capabilities. In addition to drug substance manufacturing, we now offer drug product manufacturing and have established an Innovation Center in Shanghai, focusing on highly efficient cell line development and the state-of-art development of early-stage projects. This evolution has enabled us to become an end-to-end solution provider, offering services from cell line development to commercial manufacturing. Notably, more than half of our new business now comes from overseas markets, reflecting our growing presence and competitiveness on a global scale.

In the biomanufacturing industry, cost and productivity are crucial factors. How does Chime Biologics balance these aspects and are Chinaâ??s low labour costs a real competitive advantage?

In biomanufacturing, cost and productivity are intertwined, and itâ??s not solely about labor cost. While cheaper labor can be found in certain regions, the sophistication of biomanufacturing requires skilled and experienced personnel. In China, weâ??ve found a balance between cost efficiency and productivity, leveraging our advantage of lower labor costs in cities like Wuhan while ensuring high efficiency through accumulated experience. Our workforce, comprised of stable and skilled individuals, has been with us for years, with many team members trained extensively, sometimes for up to 18 months. This accumulation of experience, coupled with cost advantages, has positioned us competitively in the market.

What types of projects is Chime Biologics aiming for currently, and how is its customer base split?

Our focus is primarily on late-stage commercial manufacturing projects. Leveraging our extensive experience in this area, weâ??ve attracted customers both domestically and internationally. Our initial success came from serving late-stage domestic customers, such as Lepu Biopharma, a Hong Kong-listed company. This laid a strong foundation for our growth. Subsequently, we expanded our business development efforts overseas, particularly in Europe and the US, targeting small to medium-sized biotech companies. This strategic approach allows us to capitalize on our strengths in late-stage manufacturing while tapping into new markets and customer segments.

How are Chime Biologicsâ?? efforts perceived in Europe and the US, given the competitive landscape and regulatory considerations?

Initially, breaking into the European and US markets posed significant challenges as a relatively new player. However, through persistent engagement, including attending conferences and organizing meetings, weâ??ve garnered positive feedback. Our delivery, quality, and pricing have set us apart, with potential customers expressing confidence in our capabilities. This feedback has emboldened us to expand our European operations significantly, including exploring acquisition opportunities and establishing a European subsidiary. Moreover, our 100% foreign ownership structure, aligns well with our international expansion strategy. Weâ??re currently in the process of setting up a subsidiary in Switzerland, leveraging the countryâ??s favorable business environment and proactive government support, which includes outreach efforts via Chinese language platforms.

Now that youâ??re expanding into very early-stage development, questions about foreign ownership and IP protection must arise. How do you address these concerns?

We understand the importance of safeguarding our clientsâ?? intellectual property and data integrity. To address these concerns, we have implemented rigorous measures and obtained an ISO/IEC 27001:2022 certificate for information security management . Our in-house protocols and procedures are designed to protect IP throughout the development and manufacturing process. We find that when clients visit our facilities and witness our commitment to data security firsthand, they feel reassured and comfortable entrusting us with their projects.

Our leadership team comprises individuals with diverse backgrounds, including Americans, Singaporean, and a German, all with extensive experience in the industry, particularly in the US market. Our communication is primarily in English, and our standard operating procedures are bilingual. Even our facility KUBio, the worldâ??s first modular biopharmaceutical factory, built in Germany and shipped to Wuhan, surpasses European standards. Regarding certifications, we are continually striving to meet and exceed regulatory requirements. This year alone, we have undergone six EU Qualified Person audits, reflecting the high level of interest and confidence from European clients.

As a tangible example, could you share insights into your recent collaboration with Domain Therapeutics (France and US) ? It seems significant, given their cautious selection process for a CDMO partnerâ?¦

Our partnership with Domain Therapeutics marks a pivotal milestone for both parties. For them, it represents their inaugural venture into biologic product development, making it a project of paramount importance. Understandably, they approached the selection of a CDMO with meticulous care, viewing it as vital to the success of their endeavor. We underwent rigorous scrutiny, including on-site due diligence conducted by an experienced French CMC consultant. Their confidence in our capabilities, affirmed by a thorough assessment, underscores our ability to compete not just locally but on a global scale. This collaboration exemplifies our commitment to delivering superior quality, efficiency, and value to biotech partners worldwide.

You seem very interested in forging collaborations in Europe at a moment where European based innovative companies are worried about the continentâ??s own prospects and support for biotech and innovation. Is this approach somewhat counter intuitive?

It does raise questions about Europeâ??s trajectory. The numbers donâ??t paint an optimistic picture, especially with the US dominating the field with its competitive edge. However, Europe still has a multitude of small biotech firms, albeit constrained by budgetary considerations. This presents an opportunity for us, as their focus on value rather than sheer scale plays to our advantage.

Thatâ??s why we view Europe as a crucial market. These companies prioritize value over politics, which aligns well with our approach. Itâ??s quite unique, I must say. Amidst a sea of companies fixated on America, weâ??ve patiently built a strategy for Europe.

What are your main objectives moving forward?

Our main objectives moving forward encompass several key milestones. Firstly, we are focused on obtaining regulatory approval from the FDA or EMA, which would enable us to manufacture products for the lucrative US and European markets. This is a crucial step towards establishing ourselves as a global leader in the biologics industry. In addition to this, we are committed to continuing our growth trajectory by expanding our portfolio to include 15 to 20 commercial products within the next 5 to 10 years. This ambitious goal reflects our dedication to innovation and our confidence in our capabilities as a leading CDMO.

Furthermore, we are actively preparing for an initial public offering (IPO) in Hong Kong, which is slated for next year. This strategic move will not only provide us with additional capital to fuel our expansion plans but also enhance our visibility and credibility in the financial markets. We have already conducted thorough market research and are confident in our readiness to embark on this exciting next phase of our journey. Overall, these objectives align with our overarching vision of becoming a global leader in biologics manufacturing and advancing healthcare innovation on a global scale.

What message would you like to convey to our global audience?

Our message to the PharmaboardroomÂ´s audience is clear, we are a global CDMO committed to delivering exceptional value and quality to our clients. Our extensive experience in meeting the stringent quality standards of global regulators, as evidenced by our numerous successful EU QP Audits, underscores our dedication to excellence. Also is important to consider in the short to mid term, Europe is a key market for us, and we are fully invested in providing innovative solutions and fostering long-term partnerships within the region. As we continue to grow and evolve, we welcome the opportunity to collaborate with European and American partners to drive advancements in biologics manufacturing and healthcare innovation on a global scale.

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