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ASIA EDITION

Ã¢â?¬Å?China and Asia are already the global leaders of Antibody-drug conjugatesÃ¢â?¬Â•

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Chime Biologics, based in Asia, has positioned itself as a global leader in the Contract Development and Manufacturing Organisation (CDMO) sector. Known for its innovation, the company introduced the world's first modular biopharmaceutical plant, KUBio, to support the entire biologics development process, from cell line creation to commercial manufacturing. Leveraging advanced technology from its Shanghai Innovation Center and a proven track record in IND-enabling through BLA filing at its Wuhan facility, Chime Biologics offers a comprehensive, one-stop solution for CMC (chemistry, manufacturing, and controls) services worldwide. In an interaction with BioSpectrum, Dr Jimmy Wei, President of Chime Biologics, shared insights into the company's rapid growth, trends in the CDMO industry, the rising prominence of Antibody-drug conjugates (ADCs) and Asia's growing role in global biomanufacturing.

Chime Biologics has a vision to make biologics more accessible and affordable. How does this vision drive your day-to-day operations and long-term strategies?

We are committed to being a global CDMO with industry-leading capabilities and efficiency, focusing on operational excellence and cost reduction. This vision drives our one-centre strategy, which centralises all operations at our single operational centre unlike multiple facilities favoured by some competitors. With this strategy, we ensure streamlined processes and minimal duplication, significantly reducing the costs of manufacturing while maintaining high quality. For example, as we expand our manufacturing capacity from 10,000L to 30,000L by 2025—a threefold increase—we are only increasing our workforce by 50 per cent.

What are the key factors behind your rapid growth and success in the CDMO sector?

Our facility complies with US Food and Drug Administration (FDA), European Medicines Agency (EMA), and National Medical Products Administration (NMPA) standards, positioning us as one of the most capable CDMOs globally. Compliance in these key markets enables us to serve a diverse, international clientele, reflected in our fully booked 10,000L capacity for the next 12 months.

What truly differentiates Chime Biologics is our team. Our senior leadership comprises professionals with extensive global experience, having worked across the U.S., Canada, and Singapore. English serves as our primary language of communication, ensuring more seamless collaboration. Beyond the leadership, our mid-level directors bring an average of almost ten years of hands-on industry expertise, giving us a competitive edge in navigating complex regulatory landscapes and delivering tailored solutions.

This depth of experience is a key differentiator, particularly in Asia, where many competitors are relatively young. Our team's collective expertise, coupled with our state-of-the-art facilities, enables us to consistently deliver high-quality, efficient solutions to our clients worldwide, underscoring our commitment to excellence and innovation.

What trends are shaping your business, and how is Chime Biologics adapting to them?

Small and medium-sized pharmaceutical companies face a very challenging environment to access capital and markets. Our clients too are facing tremendous pressure to optimise their costs and find the most affordable CDMO solution. This trend is especially pronounced in Europe and parts of Asia and is likely to persist in 2025 and the coming years.

To enable our clients to advance their pipeline to the next level, we've developed a highly flexible business model tailored to their diverse needs with upfront milestone-based payments linking the success of these clients to our CDMO service, which sets us apart from the traditional fee-for-service model. By aligning our success with the clients, we provide a more collaborative approach that helps them achieve an optimal balance between quality, cost, and efficiency.

ADCs are becoming increasingly important in healthcare. How is Chime Biologics positioning itself to address global demand? How can China and Asia position themselves as global leaders in this area?

China and Asia are already the global leaders of ADCs. China is one of the few countries globally with all the infrastructure for ADC development which is very complex. It requires the enriched experience of large molecules, small molecules, and conjugation technology.

Japan has strong R&D capabilities in biopharmaceuticals. Nevertheless, in recent years, Japan has been less agile in adopting certain emerging technologies compared to China. Since ADC development is relatively more expensive but much slower in other countries. China has emerged as a key player in the last few years. I think probably 80-90 per cent of ADC investments globally have some ties to China.

We also decided to enter the ADC space but with a differentiated and integrated offering. Firstly, we are building a very strong, dedicated ADC team with a lot of experience. Secondly, we established partnerships in this space. For example, we entered into a strategic partnership with Waterstone Pharmaceuticals to supply linker-payload to cover small molecules. We also established partnerships with ADC conjugation and ADC drug product manufacturers.

Although we have many partners, we still control and manage the quality, and are responsible for the quality of the overall drug development. Through our open platform, we differentiate ourselves from other ADC CDMOs by offering clients diverse technologies, including antibodies, linkers technologies, and payloads. Clients could choose what works best based on the clinical and regulatory needs, while our team of in-house and external experts will advise.

This is of great value since ADC conjugation is the key issue when it comes to development with a global scarcity of talent with frontline development and CMC experience. Manufacturing is less of a bottleneck since ADCs require smaller batch 200L for manufacturing when compared to antibody manufacturing which may require 2,000L facilities.

How does Chime Biologics plan to navigate regulatory hurdles, especially with evolving global compliance standards like FDA and EMA expectations?

FDA, EMA, and NMPA guidelines and standards are always evolving. We have to keep an eye on all these new trends to ensure compliance with these standards. We established a dedicated team in-house to watch what's going on with these regulatory developments and invite the former FDA auditors, EMA auditors to regularly come to our site. This is one area where we invest the most.

What will be the biggest issue in the biotech industry in 2025 and why?

Geopolitical development is the number one issue. The second issue, in my opinion, is access to financing. A constant challenge for regulators and the industry worldwide is to ensure that every drug produced is safe, stable, and reproducible. A science and technology-based approach will never go out of style as we work with biotech companies to help innovative therapies reach the market more swiftly.

Ayesha Siddiqui