Ben Zhao – CEO, Haichang Biotechnology

Our platform technology creates unprecedented opportunities to address previously intractable therapeutic challenges

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Dr Ben Zhao, Chief Executive Officer and co-founder of Haichang Biotechnology (HCBio, Haichang), represents a new paradigm in pharmaceutical innovation, bridging regulatory expertise with entrepreneurial vision. Having transitioned from a distinguished career at the FDA to establishing one of the most promising lipid nanoparticle delivery platforms in the industry, he embodies the strategic fusion of regulatory insight and commercial acumen. HCB has positioned itself at the forefront of targeted drug delivery technology, with two clinical-stage programmes addressing critical unmet medical needs in oncology and immunotherapy.

Could you elaborate on the company's genesis? Did you begin with a technology platform or were you already pursuing specific therapeutic applications?

Our foundation was built upon delivery technology. Our co-Founder, Dr Robert J. Lee served as a professor at Ohio State University College of Pharmacy. We commenced our collaboration focused on drug delivery systems, specifically liposomal technologies, where Dr Lee had developed considerable expertise in industrial-scale manufacturing processes. My background encompasses extensive CMC experience from my tenure at the FDA, complemented by pharmaceutical engineering training. This combination created a formidable partnership for addressing the pharmaceutical market's needs.

Our inaugural product was a long-circulating, PEGylated liposomal doxorubicin—actually the world's first generic version of this formulation. We achieved regulatory approval in 2008, establishing ourselves as pioneers in this therapeutic class.

How did your regulatory experience at the FDA influence the transition to entrepreneurship?

The regulatory perspective provided invaluable insights, though entrepreneurship presented entirely different challenges. In regulatory roles, one primarily identifies deficiencies without necessarily providing pathways to resolution—that responsibility lies with industry. I frequently encountered industry criticism at professional conferences, with stakeholders arguing that regulatory expectations were unrealistic because appropriate analytical methods or manufacturing processes simply did not exist.

This dynamic catalysed our entrepreneurial vision. Rather than perpetuating the cycle of regulatory critique without constructive solutions, we decided to demonstrate the feasibility of producing high-quality therapeutics that genuinely serve patient needs. The transition from regulatory oversight to ground-level innovation required establishing our own laboratory and proving that sophisticated development and manufacturing processes could deliver transformative products.

The journey proved to be extensive and required a full decade to develop our first product. However, this timeline enabled us to understand the fundamental barriers within R&D and industrial applications, particularly in our specialised area of liposomal and lipid nanoparticle delivery systems.

What differentiates your approach in the lipid nanoparticle space, and why do you believe this technology offers superior therapeutic potential?

This represents an exceptional question that we address continuously: what constitutes the translational potential of each product? Over the past decade, we have maintained primary focus on oncology therapeutics, beginning with hepatocellular carcinoma (HCC, Liver Cancer) and breast cancer, areas characterised by substantial unmet medical needs.

HCC presents particular significance in Asian markets, ranking as the third to fifth leading cause of cancer mortality, primarily driven by hepatitis B infection prevalence. Current standard-of-care

treatments, demonstrate limited efficacy with disappointingly low five-year survival rates compared to other oncological indications.

Our proprietary lipid nanoparticle (LNP) technology, called QTsome, addresses two fundamental therapeutic challenges. First, it enhances pharmacokinetic profiles for traditional chemotherapeutic agents, reducing toxicity whilst improving targeting specificity. Conventional chemotherapy lacks selectivity, affecting both malignant and healthy cells, resulting in significant adverse effects. Our particle systems minimise peak concentrations whilst maintaining therapeutic efficacy.

Second, and perhaps more significantly, our technology enables delivery of larger molecular entities such as siRNA or mRNA that cannot traverse cell membranes independently. Through receptor-mediated endocytosis, our lipid nanoparticles facilitate intracellular delivery, unlocking numerous validated but previously “undruggable” targets, particularly in oncology.

Could you elaborate on your proprietary QTSome™ technology and its competitive advantages?

The QTSome™ platform addresses fundamental limitations inherent in conventional four-component lipid nanoparticle systems. Our innovation incorporates a fifth component, a quaternary amine carrying a permanent positive charge, enabling precise zeta potential optimisation.

Consider our primary target, AKT1, which has been pursued extensively by major pharmaceutical companies through small-molecule approaches. The challenge lies in achieving selectivity among AKT isoforms, as AKT2 and AKT3 inhibition can produce significant adverse effects. Current small-molecule inhibitors, including those developed by our competitors, lack this critical selectivity.

Our antisense oligonucleotide (ASO)-based approach enables highly specific targeting of individual isoforms due to limited sequence homology between variants. This selectivity, combined with our enhanced delivery system, creates substantial therapeutic advantages.

Regarding our QTSome™ technology specifically, conventional lipid nanoparticles require complex optimisation to achieve efficient endosomal escape, but this complexity makes precise zeta potential tuning exceptionally difficult, resulting in suboptimal compositions. Our fifth component enables precise tuning and optimisation, achieving superior tissue selectivity whilst improving particle stability.

How do you position your therapeutics within existing treatment paradigms? Are these intended as monotherapy or combination approaches?

Our lead therapeutic candidate is currently being explored in combination with an existing HCC treatment, with our Phase II clinical strategy focused on evaluating synergistic drug combinations.

The use of antisense oligonucleotides (ASOs) for cancer treatment is not new, but earlier approaches involved highly burdensome regimens. For example, typically consisting of continuous intravenous infusions over 14-day cycles, making them difficult to implement clinically. We've significantly improved on this by reducing dosing frequency to just once a week via IV infusion, with the potential to decrease it further in the future. This represents a major advance in patient convenience and clinical practicality.

Importantly, we are among the first to bring antisense agents delivered via LNPs into the clinic. While much of the field remains at the preclinical stage, we've taken the critical step toward clinical translation, demonstrating leadership and innovation in this space.

What is Haichang's current clinical development status, and how are you approaching global regulatory strategy?

We have completed Phase I trials in the United States utilising three clinical centres, with particular focus on California locations due to higher Asian population densities, facilitating patient recruitment.

Our regulatory approach began with US trials before expanding to Chinese and Hong Kong markets following successful bridging studies. We are now advancing to Phase II trials in both Hong Kong and mainland China, whilst initiating discussions for European expansion to create truly multi-regional clinical trial programmes (MRCT).

Interestingly, our Phase I trials demonstrated activity across multiple tumour types beyond our primary HCC focus, including lung and pancreatic cancers. This broad activity profile reflects AKT1 overexpression across numerous cancer types, suggesting substantial market expansion opportunities.

Could you describe Haichang's second clinical programme and its strategic positioning?

Our HC-016 programme, designated Q-Tolimod, represents a toll-like receptor 9 agonist addressing fundamental limitations of checkpoint inhibitors in cancer immunotherapy. Checkpoint inhibitors demonstrate response rates of only approximately 20 percent across solid tumours, primarily due to immunosuppressive tumour microenvironments.

Traditional approaches utilise CpG oligonucleotides for intratumoral administration, but these agents present significant toxicity challenges, generating systemic cytokine responses that limit dosing to suboptimal levels. Our QTSome™ encapsulation technology largely addresses these toxicity concerns by retaining the therapeutic agent at injection sites and regional lymph nodes, preventing systemic circulation and associated adverse effects.

This localised approach generates anti-tumour antigen immunity with systemic efficacy whilst minimising toxicity risks. Our recent data demonstrates that encapsulation also enables systemic administration by inhibiting adverse effects, dramatically expanding potential indications beyond tumours accessible for intratumoral injection.

Additionally, we have identified significant activity against non-muscle invasive bladder cancer (NMIBC)through intravesical instillation, offering advantages over current Bacillus Calmette-Guérin (BCG) therapy, which lacks uniform quality standards across different countries. Our HC-016 maintains precise compositional control with superior CMC (chemistry, manufacturing, and controls) characteristics.

What does your technology platform enable beyond these initial programmes?

Looking ahead, now that we've established a robust foundation for our delivery technology from bench to clinic, we're well-positioned to significantly expand our therapeutic pipeline. While our two lead programmes target specific oncology indications, the true value lies in the platform itself: a modular delivery system that allows us to swap in different active agents to address a wide range of diseases.

Our proven clinical concept opens the door to previously "undruggable" targets, such as those involved in neuroblastoma, where the biology is well understood but therapeutic solutions remain lacking. Beyond oncology, we're exploring indications in metabolic disorders, obesity, and rare single-gene diseases, where early data suggests our approach could have significant impact.

We're also developing in vivo CAR-T strategies, aiming to engineer T-cells directly within the body, thus avoiding the complexity and cost of ex vivo manipulation. The next step for us involves raising

additional capital to accelerate these programmes, further leveraging our delivery platform to expand into non-oncology applications with unmet medical need.

How are you addressing manufacturing requirements for these complex formulations?

Recognising the scarcity of contract development and manufacturing organisations (CDMOs) capable of producing nucleic acid-based lipid nanoparticles, we have established comprehensive internal manufacturing capabilities. Fewer than five CDMOs globally possess the requisite expertise, and each product requires custom development of processes, instrumentation, and analytical methods.

We have constructed a dedicated facility in Hangzhou featuring eight workshops, designed to support Phase III studies through commercial production. This vertical integration strategy serves multiple purposes: ensuring supply chain security, generating additional revenue through partnership manufacturing agreements, and maintaining technological leadership through continuous process innovation.

We are also exploring the establishment of manufacturing capabilities in Hong Kong Science Park, which would provide strategic advantages for serving both Asian and international markets whilst facilitating trans-border material transfers.

How do you envision Haichang’s evolution over the short to mid-term?

We anticipate doubling our workforce from 110 to approximately 350 employees over the next two years, primarily through expansion of clinical development and manufacturing operations. Our recent Series C funding will support advancement of multiple programmes whilst establishing the infrastructure necessary for global commercialisation.

Despite our China headquarters, our executive team possesses extensive international experience. Myself having spent 26 years in the U.S.,, our Chief Medical Officer Dr Men has decades of US experience, and other executives with strong global biopharma backgrounds.. This background positions us excellently for global expansion, particularly into European markets where we see significant commercial opportunities.

We have already achieved regulatory approvals and commercial success with our first-generation products in both European and China markets, generating revenues that support our innovative

programme development. This diversified approach of combining established product revenues with breakthrough innovation provides the financial foundation for sustained growth whilst we advance our next-generation pipeline towards commercialisation.

Looking ahead, what represents the most significant opportunity for Haichang Biotechnology?

Our platform technology creates unprecedented opportunities to address previously intractable therapeutic challenges. By combining regulatory expertise, sophisticated delivery systems, and strategic commercial vision, we are positioned to demonstrate how innovative technologies can unlock the therapeutic potential of targets that have remained beyond the reach of conventional approaches.

The convergence of our proven clinical capabilities, comprehensive manufacturing infrastructure, and expanding global footprint creates a foundation for sustained impact across multiple therapeutic areas. As we continue advancing our clinical programmes and establishing strategic partnerships, Haichang represents not merely a biotechnology company, but a comprehensive platform for transforming how complex therapeutics reach patients who need them most.

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