Jeng Her – Founder and CEO, AP Biosciences

I encourage our team to adopt a forward-looking mindset: to take calculated risks, challenge conventions, and view obstacles as opportunities for learning and progress

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After more than two decades in Silicon Valley, Dr Jeng Her returned to Taiwan with a bold ambition: to help transform its emerging biotech sector into a globally recognised force in antibody innovation. As Founder and CEO of AP Biosciences, he has positioned the company at the forefront of bispecific antibody development while championing greater international collaboration, regulatory alignment, and investor confidence in early-stage science. Now preparing for the next phase of growth, Dr Her reflects on his journey, the evolution of Taiwan's biotech ecosystem, and the promise of a new generation of scientific leaders.

When did you establish AP Biosciences, and what was your original motivation?

I founded AP Biosciences in 2013, the year I returned to Taiwan after more than two decades abroad. Before that, I had been involved with another antibody company, KaloBios Pharmaceuticals, which went public on NASDAQ that same year. Coming home, I saw Taiwan as a promising environment for biologics innovation. The country offered an impressive scientific talent pool, something evidenced by the presence of multinationals, as well as growing government recognition of the sector's potential, a supportive capital market, and an ecosystem that could provide almost everything needed, from vector construction and upstream production to CDMO services and legal expertise. What was missing in 2013 was strong business development capacity. With my background, the natural path was to build on what I knew best: antibody drug development.

What motivated your return to Taiwan after a successful career in Silicon Valley, and how has your perspective on innovation evolved since then?

Biotechnology in Taiwan truly began to take shape in the early 2000s, when the government started promoting the sector as a strategic complement to the semiconductor industry. Over the years, many local entrepreneurs launched ventures in diagnostics, reagents, or service provision, but few pursued innovative drug development. Those early pioneers, often professionals returning from the United States or Europe, laid the groundwork for the ecosystem we see today.

With that context, I established AP Biosciences with USD 3.5 million in initial angel funding, initially providing R&D services to generate early revenue while laying the foundation for a proprietary antibody platform. From the outset, my vision was to create a scalable technology base capable of generating multiple candidates across different indications, advancing the most promising which aligned with our therapeutic focus internally while out-licensing others to sustain growth. That balance between scientific innovation and pragmatic business strategy remains at the heart of how we operate today.

How do you view Taiwan’s potential as a base for discovery and preclinical development, and what must change for its biotech sector to compete globally?

I was born in Taiwan and studied physics at National Taiwan University before completing a PhD in microbiology and immunology at the University of Virginia, where I first began working on antibody therapeutics. Between 2010 and 2012, I considered relocating to mainland China and travelled frequently to Nanjing to assess the environment. Ultimately, I realised that Taiwan offered a clearer sense of direction, an ecosystem small enough to navigate effectively yet sophisticated enough to support meaningful innovation. Here, I could more easily envision what I and, later, AP Biosciences could achieve within a defined timeframe.

Taiwan offers several advantages as a base for early-stage innovation: its strategic position in Asia, a transparent and biotech-friendly capital market, and a government that continues to champion new drug development. The local talent pool, while gradually shrinking, remains strong. Importantly, despite market volatility, no Taiwanese biotech focused on new drug development has closed down, a sign of the sector’s underlying resilience and prudent management.

That said, Taiwan still faces structural constraints that must be addressed for its biotech ambitions to reach global scale. The clinical trial framework for new drugs, particularly for Phase I studies, remains misaligned with the standards of the FDA. Regulators often lack hands-on experience with emerging modalities such as biologics, resulting in cautious decision-making and elongated approval timelines. Industry stakeholders have long called for reform, and while progress has been made, further alignment with international practices is needed to accelerate innovation.

Neighbouring markets offer useful lessons. South Korea has built a collaborative environment in which regulators and companies work closely to overcome bottlenecks, while China has introduced a rolling submission system for Investigational New Drug (IND) applications, enabling data to be submitted progressively and shortening review times. These examples illustrate the kind of regulatory agility that could help Taiwan translate its scientific potential into global impact.

What is the rationale and differentiation behind your bispecific antibody approach, and how has this concept advanced into the clinic?

By that time, the development of monospecific antibodies, targeting a single antigen, was already well established. The question was how to improve upon them. Our answer was bispecific antibodies: molecules capable of binding two antigens, but designed to deliver biological effects that a simple drug combination could not. The first FDA-approved bispecific, blinatumomab (Blincyto), validated the concept of CD3-directed T-cell engagers, yet it also revealed the challenge of cytokine release syndrome, a major safety concern across this class.

To address this, we explored another pathway: CD137 (4-1BB). While it had shown strong potential to activate T-cells, it was associated with liver toxicity when used as a monospecific antibody. We therefore engineered antibodies that bind CD137 without activating it independently. Only when simultaneously engaged with a tumour antigen in a bispecific format would T-cell activation occur. This conditional, dual-binding design not only widens the therapeutic index but also offers a considerably safer profile than conventional CD3 engagers.

We substantiated this concept through extensive preclinical research; functional assays, toxicology in monkeys, and studies in transgenic mice all pointed to a favourable safety profile. These results gave us the confidence to bring our lead asset, AP203, into Phase I clinical development. We are currently in the sixth of eight to nine planned cohorts, and although efficacy readouts are still ahead, the safety data to date have been encouraging.

Can you introduce AP203 and explain why it has become the catalyst of your current development efforts?

AP203 is our flagship programme, developed entirely in-house through our T-cube bispecific platform and fully owned by AP Biosciences. It is designed to target PD-L1 on tumour cells with a dual mode of action: on the one hand, it blocks the PD-1/PD-L1 interaction to restore T-cell function, and on the other, it actively redirects T-cells to attack PD-L1-expressing cancer cells. In this sense, AP203 can replicate the immune reactivation achieved by established checkpoint inhibitors such as pembrolizumab (Keytruda, MSD), while also adding a direct cytotoxic mechanism that may extend efficacy beyond the reach of existing therapies. Based on this rationale, we are initially exploring indications including non-small cell lung cancer (NSCLC), colorectal cancer (CRC), head and neck squamous cell carcinoma (HNSCC), and oesophageal squamous cell carcinoma (ESCC).

The distinguishing factor lies in design. Many competing PD-L1 × CD137 bispecifics use only a single binding domain for each target, which we believe is insufficient to activate T-cells reliably, and several of these programmes have struggled to progress. In contrast, AP203 incorporates two binding domains for both PD-L1 and CD137, providing more robust engagement and conditional activation only if both binders are engaged. Structurally, it is symmetric and requires only two polypeptides, which ensures correct chain pairing, streamlines purification, and enhances developability. This has translated into strong manufacturability, with yields of around four grams per litre, recovery rates above 60 percent – on par with standard IgG antibodies – and remarkable stability, having remained intact in formulation for almost four years. By working with our partner EirGenix in Taiwan, we are able to combine these advantages with efficient, cost-effective production.

Clinically, AP203 is progressing through a Phase I trial in Taiwan with eight to nine cohorts planned; we are currently in the sixth. The study will allow us to identify which tumour types to prioritise. NSCLC remains our primary focus given its proven responsiveness to PD-1 inhibition, but we are also seeing encouraging early signs in colorectal cancer. Looking ahead, we intend to expand into South Korea, Australia, and the United States with Phase II trials next year, which we expect to be an important step in confirming the potential of this lead programme.

How does AP203 differentiate itself from existing standards of care, and what have early trials revealed about its potential?

AP203 has been designed to move beyond the limitations of current checkpoint inhibitors by initiating a self-reinforcing cycle of tumour destruction and immune activation. Once cancer cells are killed, their antigens are taken up by macrophages and dendritic cells, which stimulate and expand T-cells; these T-cells then return to the tumour and drive additional killing. This process amplifies the therapeutic effect and could translate into broader, more durable outcomes for patients.

Even at this early stage, the clinical data are promising. The projected effective dose is in the range of 400-600 mg as a flat dose, but at the current level of around 1 mg/kg, we are already observing meaningful activity. Safety has been manageable, with only temporary rises in liver enzymes that resolve within a week or two. Most encouragingly, disease control rates have already exceeded 50 percent, and we have seen tumour shrinkage in two patients at the very first evaluation point, six weeks after treatment. One of these cases involved colorectal cancer with a proficient mismatch repair (pMMR) genotype. This is particularly significant because pembrolizumab (Keytruda) is only approved for deficient mismatch repair (dMMR) colorectal cancer, a group that represents barely ten percent of patients. By contrast, pMMR accounts for the remaining 85-90 percent, meaning AP203 could potentially address a far larger population.

Importantly, these benefits are not confined to treatment-naïve patients. One instance of tumour reduction was seen in an NSCLC patient who had already received prior therapy with an immune checkpoint inhibitor. While these results remain preliminary, they are consistent with the antibody’s mechanism of action and provide a strong rationale for its continued development.

How are you shaping the next stage of clinical development, and what factors will determine your Phase II strategy?

In Phase I, we adopted an all-comer approach, but as encouraging signs of efficacy began to emerge in CRC and NSCLC, our investigators in Taiwan recommended concentrating more patients in these groups to confirm the signal. This focus will guide the design of Phase II, where we plan to enrol patients who have progressed after treatment with Keytruda or other PD-1 inhibitors. Should the data remain compelling, this strategy could form the basis for an accelerated approval pathway.

We recognise the challenge of finding sufficient numbers of such patients in Taiwan alone, which is why we are preparing to extend our Phase II trials to South Korea, Australia, the United States, and potentially Eastern Europe. These regions not only offer larger patient populations but also well-established clinical infrastructures that can support faster and more robust recruitment. China also represents an important opportunity. We are in discussions with a financial advisor who has deep connections to clinical trial networks there, and we already benefit from two significant collaborations: Innovent, which holds the global rights to our IBI302 programme, and Tasly Biopharmaceutical, which has exclusive rights in China for AP505. These partnerships are expected to generate milestone and royalty revenues, further strengthening our financial foundation and enabling us to sustain the long-term development of AP203.

How has AP Biosciences' pipeline developed beyond AP203, and what significance have your early partnerships held in that evolution?

Although AP203 is our flagship today, our commitment to innovation began much earlier. One of our first major programmes was IBI302, which we initiated in 2011 and licensed to Innovent the following year, when the project was still at an early stage and supported mainly by cell-based assay data. Innovent took full ownership of development, advancing it all the way into Phase III trials. At that time, Innovent itself was a young company, and IBI302 was only its second in-licensed asset, so the collaboration proved to be a defining moment for both parties.

IBI302 targets neovascular age-related macular degeneration (nAMD), specifically the wet form of the disease, which causes intraocular bleeding and, without treatment, can lead to blindness. Today, the market is overwhelmingly dominated by Eylea (Regeneron/Bayer) and Vabysmo (Roche), which together account for over 90 percent of global sales. With IBI302, Innovent has an opportunity to establish a competitive third option. The molecule is also being studied in Phase II trials for diabetic macular oedema (DME), another serious condition in which diabetes-induced vascular leakage damages vision.

What makes IBI302 distinctive is its dual mechanism. By inhibiting VEGF receptor signalling, it blocks the abnormal blood-vessel growth characteristic of both AMD and DME, while simultaneously targeting complement activation, an upstream driver of VEGF expression. This combination allows the drug to intervene both before and after VEGF is expressed, potentially offering broader and more sustained efficacy than existing anti-VEGF therapies alone. The decision to pursue this dual-targeting strategy was ours, and it reflects a guiding principle of AP Biosciences: to design

molecules that do more than replicate established modes of action, but instead tackle disease biology in ways that expand therapeutic benefit.

How is AP Biosciences building partnerships to strengthen its global development footprint?

Collaboration has always been central to our growth. One of the main reasons I returned to Taiwan was the conviction that meaningful innovation could be built through strong local partnerships combined with international expertise. In preclinical development, work is broadly divided between CMC and manufacturing and animal studies such as pharmacokinetics and pharmacodynamics. Taiwan has established a capable CDMO base, yet lacks facilities for non-human primate testing, which we therefore conduct through partners in China.

On the clinical side, Taiwan has become well integrated into the global research network. We work with international CROs including Parexel, Novotech, and Avance Clinical, while also deepening collaboration with local hospitals to strengthen trial capacity. Our lead candidate, AP203, a PD-L1 × CD137 bispecific antibody, has received IND clearance and is in Phase I trials across major Taiwanese centres. As we advance to Phase II, we plan to include sites in Australia, South Korea, China, and potentially the United States, while maintaining Taiwan as our strategic base.

Beyond advancing our own programmes, these collaborations reflect a broader mission, to help cultivate Taiwan’s research ecosystem and give local scientists and clinicians greater participation in global drug development.

How would you compare the talent environments in Silicon Valley and Taiwan, and how has this influenced your leadership philosophy?

In the United States, it is far easier to find people who embrace risk and are driven to tackle complex, high-stakes challenges. There is a pervasive sense of possibility, an instinctive belief that innovation is achievable if one dares to pursue it. In Taiwan, by contrast, technical competence is strong, particularly among professionals at the master’s level, but individuals with a global perspective and experience in translating science into scalable innovation remain relatively scarce.

For the past two decades, Taiwan’s biotech sector has relied heavily on professionals returning from overseas. Yet this flow has slowed markedly. When I left Taiwan to pursue my PhD in

microbiology and immunology at the University of Virginia in the early 1990s, many Taiwanese students were heading to the United States for higher education. Today, that number has declined sharply, while more students from mainland China now fill those seats. Consequently, we see fewer people returning to Taiwan with the international exposure, confidence, and entrepreneurial mindset needed to lead innovative ventures.

In the US, people are taught to think ambitiously, the notion that the sky is the limit. That outlook has deeply shaped my own leadership approach. At AP Biosciences, I encourage our team to adopt that same forward-looking mindset: to take calculated risks, challenge conventions, and view obstacles as opportunities for learning and progress.

How do you envision Taiwan's path towards globalisation, through closer co-operation within Asia or stronger engagement with Western markets?

Having spent 25 years in the United States, I naturally gravitate towards the Western model. The US remains the world's largest pharmaceutical market and offers a uniquely complete ecosystem, where research excellence, financing, regulation, and industrial collaboration coexist within a single well-integrated framework. For any biotech seeking true global reach, it continues to provide the most conducive environment for innovation to mature and scale.

Europe, however, brings a different kind of strength, one rooted in scientific depth and originality. In biotechnology rather than traditional pharmaceuticals, European firms often pursue technologies that look a decade ahead, driven by an academic culture that values exploration over immediate commercialisation. The United Kingdom's Cambridge Antibody Technology is a good example: its pioneering work on phage-display technology three decades ago transformed the field and paved the way for many of today's approved monoclonal antibody therapies.

While Europe excels in research and discovery, the United States remains unrivalled in its ability to translate science into sustainable global success. Both ecosystems have much to offer, yet if I had to choose a single strategic direction for AP Biosciences, it would be to deepen our engagement with the United States, where scientific ambition, industrial capacity, and market opportunity converge most effectively to transform innovation into lasting impact.

In an environment where Chinese companies move with remarkable speed and cost efficiency, what do you regard as AP Biosciences' competitive advantage?

We recognised several years ago that it would be unrealistic to compete with Chinese companies on speed alone. Their ability to advance projects quickly and at low cost is formidable, and it is difficult for anyone in Taiwan, Korea, or elsewhere to match that pace. Our strategy has therefore been to focus on being smarter rather than faster: identifying novel targets with real therapeutic promise, engineering antibodies with distinctive mechanisms of action, and carefully defining the patient populations most likely to benefit. By doing so, we can create a meaningful two- to three-year head start built on innovation and precision.

That said, we are equally aware that such an advantage cannot last indefinitely, as competitors will inevitably catch up. This is why we are placing increasing emphasis on accelerating the clinical development of our programmes. In early discovery, quality and originality remain the guiding principles, but as projects advance, speed becomes critical. In this balance, advancing novel, well-designed programmes while executing trials with greater urgency, lies our true competitive edge.

How would you describe AP Biosciences today, and what will success look like moving forward?

We see AP Biosciences as an innovative antibody developer grounded in strong expertise in protein engineering. At present, our focus is on advancing bispecific antibodies in oncology, but our platform also supports antibody fusions and other modalities, giving us the ability to move into new areas. The oncology landscape is becoming increasingly crowded, and across the industry, we can already see attention shifting towards other areas, including the central nervous system and neurodegenerative disorders. We are conscious of this trend, which is why, alongside our internal programmes, we are actively pursuing partnerships that can give us access to broader scientific capabilities and global resources. We are currently in discussions with two international research institutes, one in the United States and one abroad, that are eager to collaborate with us. The future of bispecific antibodies will extend well beyond oncology, and our ambition is to be at the forefront of this expansion. While our foundation is in Taiwan, our outlook is global, and through strategic partnerships and co-development efforts, we aim to ensure that the innovations we create reach patients worldwide.

For us, success begins with long-term stability. Our immediate goal is to secure three major out-licensing partnerships that can provide a consistent revenue stream through upfront and milestone payments. With collaborations already established with Innovent and Tasly, and a third soon to be

finalised, we are well positioned to maintain financial strength as our own pipeline advances toward commercialisation.

I am also proud of the next generation of leaders at AP Biosciences. Our management team is young, dynamic, and deeply committed to science, and I have been gradually entrusting them with greater responsibility to shape the company’s future. I hope they will continue driving our growth, taking new drugs from concept to market while strengthening our position on the global stage.

Although our current focus is oncology, we see enormous potential for antibody and bispecific antibody therapies beyond cancer, particularly in autoimmune and infectious diseases. The rise of antimicrobial resistance, recognised by the WHO as a critical health threat, underscores the need for new approaches. We believe antibodies could play a vital role, for example by targeting pathogens such as Pseudomonas and blocking infection pathways without fostering resistance. These are areas we intend to explore more deeply once resources expand following our planned IPO next year.

Looking ahead, we are also preparing for the next generation of antibody innovation. While we remain the only company in Taiwan dedicated to bispecific antibodies, we are already exploring bispecific ADCs and even trispecific formats. What matters most is not the complexity of the molecule but its mechanism of action and clinical relevance. True innovation lies in improving therapeutic efficacy and safety, principles that continue to guide everything we do.

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