Linxian Li – Founder and CEO, Innorna

Our transition from public health to precision-targeted therapeutics reflects both the maturity of our platform and the ambition behind it.

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Few biotech companies emerge with both scientific depth and a clear sense of direction. Innorna, founded by Dr Linxian Li after years spent refining RNA delivery systems in academic settings, is one of them. What began as a technical platform matured through a pandemic-era proof of concept and now moves steadily into more complex territory; liver genetic diseases, in vivo CAR-T therapies, and globally aligned clinical development.

How did your academic and professional journey lead to the creation of Innorna, and what were the company's initial scientific priorities?

The foundation of Innorna is rooted in years of academic research at the intersection of RNA science and advanced delivery technologies. I completed my PhD at Heidelberg University in Germany, where I began developing lipid nanoparticles (LNPs) for RNA delivery. I then moved to the Massachusetts Institute of Technology (MIT) for postdoctoral work with Professors Robert Langer and Daniel Anderson– pioneers in the field and co-founders of companies such as Moderna, CRISPR Therapeutics, and Orna Therapeutics. At MIT, I focused on using LNPs to deliver messenger RNA (mRNA), gaining critical experience in the translational potential of this platform. Following my time at MIT, I joined the Ming Wai Lau Centre for Reparative Medicine – established by Karolinska Institute – as an assistant professor in Hong Kong's Science and Technology Park (HKSTP). In 2019, I co-authored a paper with Langer and Anderson on mRNA-based cancer vaccines, which provided the scientific impetus to establish Innorna.

While our initial ambition was to apply LNP technology to the more complex challenges of cell and gene therapy, the onset of the COVID-19 pandemic shifted our focus temporarily toward vaccines. This led to the development of our COVID-19 mRNA vaccine as a proof of concept, followed by programmes targeting respiratory syncytial virus (RSV) and herpes zoster. All three candidates have received Investigational New Drug (IND) approval from the US FDA. Our COVID-19 vaccine has completed Phase I and is cleared to enter Phase II in the US, while the RSV and herpes zoster vaccines are currently in Phase I. Both have also received IND approval in China last year.

What makes mRNA an enabler of a next-generation therapeutic platform, and how is Innorna harnessing its potential across different areas of medicine?

mRNA offers a fundamentally elegant approach to therapy, enabling the body to synthesise therapeutic proteins through precise, transient instructions without permanent genetic modification or viral components. The technology’s appeal extends well beyond its success in COVID-19 vaccines as it also provides a foundation for broad applications in gene and cell therapy. By encoding proteins of interest, mRNA allows for controlled expression of therapeutic targets, from systemic protein replacement to immune modulation via receptors such as T-cell receptors (TCRs) and chimeric antigen receptors (CARs). This opens the door to a new therapeutic paradigm in which disease is addressed not only at the protein level but at the genetic messenger level itself.

Yet despite its promise, the effectiveness of mRNA depends heavily on delivery. LNPs remain the most established system, particularly for local administration, where lymphatic targeting enables robust immune activation. In systemic use, however, LNPs primarily accumulate in the liver, making hepatic indications a natural entry point.

At Innorna, we are advancing four liver-focused programmes while expanding delivery capabilities to other tissues – such as muscle, the central nervous system, cardiac tissue, and immune cells – through targeted optimisation. Among our most forward-looking initiatives is an in vivo CAR-T therapy, which circumvents traditional ex vivo cell engineering by delivering mRNA directly to circulating T cells, enabling them to transiently express CAR molecules and initiate tumour-specific responses without the need for lentiviral transduction or complex manufacturing steps.

With a team of 160, we are currently managing ten active programmes. In addition to our COVID-19 vaccine, two programmes are already in Phase I clinical trials, and three more are scheduled to enter Phase I this year. Our strategic approach prioritises high-impact, scientifically feasible indications, enabling us to advance a broad yet focused pipeline while pushing the boundaries of

mRNA therapeutics.

Why has Innorna chosen to follow a US regulatory pathway rather than relying on early-stage mechanisms available in China?

While Mainland China's Investigator-Initiated Trial system allows companies to initiate clinical studies with relative speed and flexibility, our long-term objective is to establish global credibility and market access through a fully regulated development pathway, and the FDA process remains the gold standard for therapeutic approval. Our decision to align all programmes with this framework reflects not only commercial intent but also a commitment to scientific rigour and clinical transparency. Although relatively few FDA-approved therapies currently originate from this region, we do not see that as a structural impediment. It underscores the importance of setting a clear precedent.

Thus far, our regulatory engagements in the US have been smooth, with no indications of delay or procedural friction. The process of identifying clinical sites and engaging principal investigators has also progressed without issue. Despite the presence of well-established mRNA players in the US market, our collaborators have shown genuine interest in our platform and development rationale, highlighting the value of our science-led approach.

How is Innorna defining its strategic roadmap for the coming years in terms of clinical development, financing, and external partnerships?

Innorna's near-term trajectory is shaped by the results of several ongoing clinical trials, with top-line data expected as early as May. These outcomes will serve as key inflection points to guide the advancement of individual programmes and informing strategic decisions at the corporate level. In parallel, the company is actively preparing for a potential public listing, with conversations underway among shareholders to determine the optimal timing and listing venue – either the Hong Kong Stock Exchange or NASDAQ. Backed by a combination of venture capital and private equity investors, Innorna is working to align its corporate structure and timing with long-term growth objectives.

Beyond clinical and financial milestones, the company is strengthening its external partnerships to broaden the reach of its mRNA and LNP platform. Notably, Innorna is collaborating with BeOne Medicines – formerly known as BeiGene – on the application of its delivery technology in oncology

and immunology. It has also entered a collaboration with a leading multinational company in the industry, further validating the global relevance of its platform.

While Innorna retains internal development capabilities, its long-term identity is rooted in its role as a platform-driven biotechnology company rather than a traditional pharmaceutical firm. In the vaccine space, the company is engaged in discussions with Mainland-based partners that may ultimately take on local commercialisation responsibilities. Vaccine development presents unique challenges, ranging from high costs and broad population targeting to stringent safety requirements, and strategic collaboration will be key to unlocking the full value of these assets.

How has Hong Kong's innovation environment contributed to Innorna's growth, and what is your vision for the company's leadership moving forward?

Hong Kong has provided a highly supportive environment for Innorna's early development, particularly through the combined resources of the HKSTP and the Innovation and Technology Commission (ITC). HKSTP has offered both infrastructure and funding support, including targeted incubation programmes designed to guide biotech ventures from inception through to clinical maturity. One of our clinical trials has been partially funded through these mechanisms, and we continue to benefit from their structured approach to nurturing life sciences innovation.

In parallel, the ITC provides matched funding opportunities that enable companies to pursue ambitious research and development goals without being solely dependent on private capital. Compared with the Mainland, where government grants typically come post-trial and are tied to domestically conducted studies, Hong Kong's forward-looking framework offers earlier support for globally oriented companies such as ours.

From a leadership perspective, I have led Innorna since its founding, though it was never my intention to serve as the long-term CEO. From the beginning, I envisioned bringing in an experienced executive from the pharmaceutical industry – someone equipped to scale the company, navigate regulatory complexity, and lead commercial partnerships. However, identifying a candidate who combines operational capability with the motivation to help build a platform-driven biotech from the ground up has been a challenge. We remain open to this transition and continue to seek the right person who can align with our mission and guide Innorna through its next phase of growth.

When is Innorna planning its next fundraising round, and how are you positioning the company amid evolving investor sentiment towards mRNA technologies?

Our next fundraising round is scheduled for the fourth quarter of this year, with a target of raising between USD 30 million and USD 50 million. This follows four previous rounds through which we secured a total of USD 150 million, reflecting the strong early momentum behind mRNA platforms and the confidence investors placed in our scientific foundation. Although recent shifts in public sector support – particularly in the US, where funding for mRNA-based vaccines has been significantly reduced – have prompted questions around the future of the technology, our trajectory is clearly moving beyond vaccines.

The next phase of our development is focused on therapeutic applications with high clinical relevance, including rare genetic liver diseases, and in vivo CAR-T therapies. These areas represent a distinct evolution of the mRNA platform, both in scientific complexity and potential impact. We believe that this transition, from broad public health solutions to precision-targeted therapeutics, will resonate with investors seeking innovation-driven biotech strategies in a more selective funding environment.

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