John Gong â?? Chairman & CEO, 3D Medicines

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3D Medicines has charted a deliberate path from domestic clinical execution to global oncology innovation. Since its IPO, the company has sharpened its focus on differentiated assets like Envafolimab, while expanding into radioligand and mRNA-based platforms with broad therapeutic potential. Chairman and CEO Dr John Gong outlines how strategic discipline, early internationalisation, and a flexible partnership model underpin 3Dâ??s long-term growth vision: â??We donâ??t just want to out-license, we want to build something enduring, together.â?•

What have been the key developments for 3D Medicines since its IPO, particularly in advancing its global oncology ambitions?

We launched 3D Medicines at a uniquely opportune time. I returned to China in 2008, just as the biotech and pharmaceutical industries were entering a period of rapid expansion. The ecosystem was evolving quickly, with companies like WuXi leading the contract development space and innovators such as BeiGene starting to take shape, and it felt like the right moment to contribute something with lasting impact. Given Chinaâ??s staggering cancer burden, with over four million diagnoses annually and mortality rates among the highest globally, we chose to focus on oncology, a space both challenging and deeply meaningful.

The therapeutic landscape has shifted significantly over the past decade. While targeted therapies began gaining traction in China just over ten years ago, immunotherapy has since emerged as a

more powerful and patient-friendly alternative. Recognising its potential early, we built our development strategy around it. Our lead programme, Envafolimab (KN035), a PD-L1 inhibitor originally developed by Alphamab Oncology, exemplifies this approach. They completed the preclinical work, and we took over clinical development, intending to pursue a global path.

At the time, regulatory timelines in China were still lengthy, so we filed the initial IND with the US FDA, where we received rapid approval and began dosing our first patients. We later expanded trials to China and Japan. That cross-border strategy allowed us to move swiftly, achieving approval in China within four years, an unusually short timeframe then. I still recall the exact day it was approved: Thanksgiving. It was a defining milestone that came just one year ahead of our IPO and affirmed our early decision to position 3D Medicines as a globally focused oncology innovator.

How did strategic decision-making shape 3D Medicinesâ?? development path, and what role did timing and financing play in the companyâ??s global ambitions?

When it comes to advancing a new drug, strategy often outweighs both manpower and funding. While regulatory requirements vary across markets, the fundamental standards of efficacy, safety, and quality are consistent, and with the increasing alignment through the International Council for Harmonisation (ICH), a coherent global development plan becomes not only possible but essential. Early on, we adopted a cross-border approach â?? using US clinical data to support filings in China, and Chinese data to underpin further international expansion â?? which allowed us to compress timelines significantly.

That said, our ability to pursue full global development was constrained by financial realities. As a small biotech, we prioritised commercialising Envafolimab in China, where costs were more manageable. We executed that plan efficiently, but bringing the drug to the US required at least USD 15 million for a single pivotal trial, capital we didnâ??t yet have. If we had listed in 2021, at the height of biotech market activity, we could likely have secured three to four times what we ultimately raised. Instead, our IPO came in 2022, just as the market turned. We listed under Hong Kongâ??s Chapter 18A for pre-revenue biotechs and raised approximately USD 70-80 million; not insignificant, but well below the previous yearâ??s benchmark of USD 300 million.

Ironically, by the time we listed, we had already generated more than HKD 500 million (USD ~64 million) in revenue, primarily from Envafolimab sales in China, nearly qualifying us for a Main Board listing. Since then, we have streamlined our focus, moving away from diagnostics to concentrate fully on novel drug development, where we see the greatest opportunity for long-term impact.

How has 3D Medicines structured the commercial rollout of its oncology assets across China and international markets?

In China, we adopted a hybrid model that allows us to retain ownership while benefiting from commercial scale. We partnered with Simcere, a well-established pharmaceutical company, which now acts as our Contract Sales Organisation (CSO) for Envafolimab. Simcere oversees promotional and marketing efforts, but as the Marketing Authorisation Holder (MAH), we maintain regulatory control and book all revenue. This structure gives us both strategic oversight and operational efficiency without requiring the immediate buildout of our own salesforce.

Internationally, our long-standing co-development agreement with Alphamab Oncology remains in place. Under this partnership, we lead global clinical development, registration, and commercial

planning, while Alphamab is responsible for manufacturing and supply. In key emerging markets â?? including India, Latin America, the Middle East, and parts of Eastern Europe â?? we licensed commercial rights to Glenmark, a partner with solid regional capabilities. However, we deliberately retained rights in high-priority territories such as the United States, Europe, and Japan, as well as in select Southeast Asian markets like Singapore, Thailand, and Malaysia. This globally balanced structure reflects a deliberate effort to expand access while preserving long-term value in strategic markets.

What makes Envafolimab a differentiated asset in the PD-1/PD-L1 space, and how is 3D Medicines positioning it in less saturated global markets?

While discussions around PD-1/PD-L1 therapies often focus on overcrowding in China, there remains a substantial unmet need in emerging markets, where access to innovative yet affordable oncology treatments is still limited. Envafolimab stands apart as a structurally distinct single-domain antibody with a smaller molecular size, higher binding affinity, and comparable efficacy at lower doses. Its most notable advantage is its mode of administration: a true subcutaneous injection, not dependent on infusion pumps, offering patients, particularly the elderly, a more convenient and accessible alternative.

This uniqueness, however, initially created hesitation among potential partners. Many preferred to wait for more data before engaging. We completed a comprehensive set of Phase I studies in the United States and Japan, covering pharmacokinetics, safety, and tolerability, but financial limitations prevented us from immediately advancing into Phase II. After regulatory approval in China, interest resumed, yet the terms proposed often fell short of reflecting the investment and clinical promise already demonstrated, leading us to pause those discussions.

Despite these early challenges, we continue to believe that Envafolimab has strong global potential, particularly in underserved markets. As PD-1/PD-L1 inhibitors remain central to combination regimens with chemotherapy, radiotherapy, and targeted agents, demand will only grow. In the US, more than half of patients receive immunotherapy following diagnosis, while adoption in China and emerging regions remains significantly lower due to cost constraints and entrenched treatment norms. Still, the direction of travel is clear. With over ten domestic checkpoint inhibitors now approved in China and local innovation advancing rapidly, we see substantial room for differentiated therapies like Envafolimab to reassert their value on the global stage.

How is 3D Medicines advancing its innovation platforms, and how do you prioritise development across radioligand and mRNA programmes?

Following the approval of our first drug, Envafolimab, we turned our attention to building a broader innovation platform capable of sustaining long-term, pipeline-driven growth. This reflects a wider shift in Chinaâ??s biotech landscape â?? from licensing in external technologies to increasingly exporting homegrown innovation â?? and underscores how much the countryâ??s R&D infrastructure has matured.

While antibody-drug conjugates (ADCs) have gained traction among Chinese companies, we believe the next transformative modality lies in radioligand drug conjugates (RDCs), a subset of radioligand therapies (RLTs). Unlike ADCs, which deliver chemical payloads, RDCs deploy targeted radioactive isotopes to induce direct, irreversible DNA damage, a mechanism that may offer superior efficacy in certain tumour types. Although infrastructure challenges remain, particularly in solid tumours, we see

this approach as a strategic priority and a cornerstone of our future platform.

One of the most promising assets in our pipeline is an RDC developed using a mechanism similar to Novartisâ?? Pluvicto, but engineered for significantly longer tumour retention and higher exposure. Preclinical studies have demonstrated strong PSMA-binding affinity, high tumour-targeting specificity, and an extended intratumoural half-life. This pharmacokinetic profile aligns closely with the 6.6-day radioactive decay of lutetium-177, potentially enhancing therapeutic efficacy by maintaining sustained tumour irradiation. The underlying molecule was originally developed nearly a decade ago and has since been reinvented through radiolabelling. Now completing preclinical development and entering Phase I, the programme represents a compelling opportunity for out-licensing or dedicated development structuring.

More broadly, we maintain a portfolio of 13 drug candidates but apply rigorous prioritisation. As we approach capital-intensive stages like Phase III, we focus only on programmes with clear clinical relevance and sustainable differentiation. Our goal is not to accumulate assets but to advance those most likely to make an impact in real-world settings.

In parallel, we are building a proprietary mRNA platform centred on our lipid nanoparticle (LNP) delivery system, which enables selective organ targeting, including the liver and lungs. Our lead candidate in this space is a non-personalised cancer vaccine that leverages shared tumour antigens across more than ten cancer types, offering broad applicability. Currently at the pre-IND stage, we aim to file next year. Consistent with our approach, all assets are developed with international intellectual property protection from the outset, ensuring they are positioned to compete globally from day one.

How is 3D Medicines navigating the financial demands of global expansion, and why are co-development partnerships a strategic priority?

The financial environment in recent years has been difficult, and weâ??ve responded with disciplined capital management. Across our IPO and follow-on rounds, weâ??ve raised more than USD 300 million, and currently maintain around RMB 800 million (USD 110 million) in cash reserves. While this provides a solid foundation, weâ??ve remained conservative in our spending to ensure operational continuity over the long term, covering core expenses while protecting our capacity to invest in innovation.

Rather than focusing solely on raising additional capital, weâ??re prioritising strategic partnerships, particularly co-development structures that offer shared risk and mutual benefit. In one recent example, a global pharmaceutical company approached us to explore the use of our platform in developing an asset of interest. The model would see us jointly advance the programme, with the option for them to license it upon achieving predefined milestones. These arrangements not only bring external validation but also allow both parties to retain flexibility while accelerating development timelines.

This approach reflects a broader shift in how Chinese biotechs are perceived. What was once viewed through a lens of imitation is now increasingly recognised as a source of efficiency and innovation. In fact, weâ??re seeing multinational companies close multiple deals in China in a single year, a clear sign of changing attitudes. From our side, the value proposition is clear: what might take a year to execute in the US can often be completed in a matter of months here. That speed, combined with cost-efficiency and a growing depth of technical expertise, positions us, and others in China, as credible, agile partners in global drug development.

What has informed your approach to partnering with global pharma, and how is 3D Medicines positioned to deliver value in international development?

Global pharmaceutical companies rightly expect consistent quality regardless of location, and we fully share that standard. Whether development takes place in Shanghai, New York, or Paris, the expectations around scientific rigour, data integrity, and regulatory alignment are the same, and must be met. While China has historically been associated with lower operating costs, that perception is shifting. In fact, many US-based companies now view China as expensive. The question is no longer about cost, but about value; the quality of innovation, the speed of execution, and the ability to deliver globally relevant outcomes.

We donâ??t view partnerships as transactions built around large upfront payments. Instead, we favour co-development models where risk and responsibility are shared from the outset. Weâ??ve built a platform capable of supporting early-stage development efficiently, and weâ??ve learned â?? particularly from our first PD-L1 programme â?? that engaging partners early brings far more than capital. It brings clarity. When you have multiple candidates, early feedback helps ensure alignment with clinical needs and market priorities, allowing programmes to advance with greater focus and purpose.

One of our core advantages is execution speed. In multi-regional clinical trials, weâ??re often able to generate 30-40% of the data in China, complementing contributions from the US, Europe, and beyond. These efficiencies translate into meaningful savings in time and cost while still supporting global regulatory submissions.

Culturally, I place a great deal of value on collaboration, both externally and within our organisation. Weâ??ve built a culture at 3D Medicines that is flexible, pragmatic, and entrepreneurial. I believe true innovation cannot be imposed from the top down; it has to be nurtured from within. Just this morning, I told one of our researchers: if you create something valuable, Iâ??ll reward you, maybe even with a car. That mindset, empowering individuals to take ownership, is at the core of how we operate and grow.

What would you most like the global biopharma audience to understand about 3D Medicines today?

3D Medicines is entering a pivotal new chapter. Weâ??ve already demonstrated our ability to execute clinical development effectively and efficiently within China, and weâ??re now leveraging that foundation to scale globally through differentiated technology platforms.

Our focus is anchored in two core areas: radioligand drug conjugates (RDCs) and a proprietary mRNA-LNP platform. Both hold the potential to reshape treatment paradigms, particularly in oncology. As we continue to advance these programmes, weâ??re actively seeking global partners, not merely to out-license assets, but to co-develop them in a way that draws on complementary strengths and creates sustainable value. We approach partnerships with flexibility and a clear emphasis on collaboration. Our goal is to work alongside those who share our commitment to scientific rigour, efficiency, and patient impact, and who recognise the opportunity to build something enduring together.

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