Yuan-Hung Hsu – President, Megapro Biomedical

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18.08.2026

Tags: Taiwan, MegaPro, Biotech, Nanomedicine, Precision Medicine, Partnerships, Strategy

Dr Yuan-Hung Hsu, President of MegaPro Biomedical, discusses the Taiwanese company's evolution into a late-stage nanomedicine company, with two platforms targeting precision medicine. He highlights MPB 1523, a heavy-metal-free MRI contrast agent for liver cancer, and MPT 1734, a nanomicelle-based therapy for prostate cancer, while outlining MegaPro's partnership strategy, cell-tracking technology, and ambition to deliver innovative diagnostic and therapeutic solutions globally.

MegaPro describes itself as entering its “harvesting stage.” What does that mean in practice, and where does the company stand today?

MegaPro is a spin-off from the Industrial Technology Research Institute (ITRI)’s Nano Bio project. The Taiwanese government established Nano Bio around the year 2000 as part of its broader push into nanotechnology, with a specific focus on nanotechnology applications in diagnostics and treatment. My own background is in this area: after completing my PhD, I joined the project, where our team handled synthesis, formulation design, and pharmacokinetic and pharmacodynamics studies. After roughly a decade of work, our team decided to establish an independent company capable of taking these technologies through clinical trials.

After raising capital for our first clinical trial and licensing our core nanotechnology platform, along with the associated intellectual property, we built our own GMP manufacturing capability and

began clinical development in earnest. To date, we have advanced four candidates into the clinic, two of which have now reached late-stage development. This is precisely why we describe this as our harvesting period, and why we believe MegaPro represents a genuinely attractive opportunity for investment at this stage.

Could you explain your platform, its underlying pegylation technology, and its broader significance?

Our core platform is built around pegylated iron oxide nanoparticles. Iron oxide nanoparticles are not entirely new to the field; earlier iterations relied on dextran or similar polysaccharide-based coatings to stabilise the particles in aqueous solution, since the particles themselves are not stable in an aqueous phase without such coatings. Unfortunately, these polysaccharide-based formulations were associated with allergic reactions and hypersensitivity. Given our team's background in chemical engineering and materials science, we instead developed a formulation using polyethylene glycol, conjugated onto the particle surface to achieve aqueous stability, in place of dextran.

We pursued this technology because it was originally developed as an MRI contrast agent, and the majority of existing MRI contrast agents rely on gadolinium, a heavy metal that carries known safety concerns. Iron, by contrast, is naturally present in the body, which gives our platform a considerably stronger safety profile. Beyond safety and stability, the key feature of this technology is that when conjugated to specific cell types, the resulting particles can be taken up by those cells and subsequently visualised via MRI, allowing the platform to serve as a contrast agent across a range of cell-labelling applications. Our first application has been liver cancer diagnostics, since these particles are taken up by Kupffer cells, the liver's resident macrophages, allowing us to distinguish benign from malignant lesions. In summary, this is a safe MRI contrast agent built on PEGylated iron oxide nanoparticles, using polyethylene glycol rather than dextran to reduce hypersensitivity, and avoiding the heavy-metal safety concerns associated with gadolinium-based agents.

Following your recent Type C meeting with the FDA, how significant is the opportunity for MPB 1523, and what unmet need does a heavy-metal-free contrast agent address?

That Type C meeting focused specifically on CMC, chemistry, manufacturing and controls, matters and on our clinical protocol design, and we reached alignment with the FDA on both fronts, which is important in avoiding a clinical hold stemming from CMC issues. MPB 1523 is our diagnostic candidate for hepatocellular carcinoma, HCC, functioning as an MRI contrast agent. Currently, the only liver-specific contrast agent on the market, is gadolinium-based, and as I mentioned, gadolinium carries heavy-metal safety concerns. In particular, since gadolinium is cleared through the kidneys, it cannot be used in patients with renal impairment, as the compound cannot be adequately cleared from the body.

Our particle behaves differently: following injection, approximately 80 to 90 percent is taken up by the liver rather than cleared renally, meaning it can be used safely in patients with kidney failure, unlike gadolinium-based agents, which carry explicit warnings against use in this population. Our Phase II data has also shown strong contrast enhancement. Taken together, this positions MPB 1523 as the first non-heavy-metal, liver-specific MRI contrast agent, offering clear visualisation to distinguish benign from malignant lesions, while remaining safe for patients with impaired renal function. We believe this gives us a genuine opportunity to displace gadolinium-based liver-specific contrast agents in the market.

What is your commercialisation strategy for MPB 1523, and what role do partnerships play?

Since HCC prevalence is considerably higher across Asia, our market strategy is focused there first. For MPB 1523 specifically, we are in discussions with pharmaceutical companies across the region, including mainland China, Japan and Korea, with the aim of partnering on registrational studies and, eventually, market distribution. Mainland China will be our primary target for approval and listing, given its patient population and market size, which we believe represents the largest opportunity for this asset. That said, we do intend to pursue other markets as well, including the EU and the US, following our initial approval in mainland China.

This reflects the fact that liver cancer falls into two broad categories: primary HCC, and metastatic liver cancer originating from other primary tumours, including lung and colorectal cancer. Given that colorectal cancer with liver metastasis is comparatively more prevalent in Western markets, we are pursuing two distinct strategies: focusing on primary HCC in mainland China, and pursuing US and EU market development around liver metastases requiring diagnostic imaging from other primary cancers.

How does your nanomicelle platform improve on existing therapies, particularly with MPT 1734?

Our nanomicelle platform is equally important to us, and we hold proprietary patents covering the encapsulation of hydrophobic compounds. Hydrophobic compounds cannot generally be injected directly into the body, which typically necessitates surfactants, many of which themselves carry hypersensitivity risks. Our approach instead uses a highly biocompatible excipient to resolve the hydrophobicity problem directly. We believe our platform represents one of the strongest hydrophobic drug delivery systems available, comparing favourably to alternatives such as liposomal or PEGylated systems. Because of its unique structure, the hydrophobic core of our nanomicelle can encapsulate the drug entirely, substantially improving solubility, whereas liposomal systems can only encapsulate hydrophobic drugs within their bilayer, giving our platform a considerably higher drug-loading capacity.

Our first candidate built on this platform, MPT 1734, is a second-generation taxane, based on cabazitaxel. Our nanomicelle formulation significantly improves its solubility. The existing marketed formulation relies on the excipient Tween 80, which carries hypersensitivity risk and requires steroid pre-treatment, and is also associated with severe bone marrow suppression, including significant neutropenia. Our Phase I data showed that our formulation does not require steroid pre-treatment and significantly reduces neutropenia. Our initial market strategy focuses on prostate cancer, though our Phase I data also indicated strong potency in head and neck cancer, which we see as our next indication, while our immediate focus remains prostate cancer.

We met with the FDA last year to discuss our development strategy going forward, and the FDA agreed to a Phase II/III trial design, along with allowing a 505(b)(2) NDA pathway supported by a bioequivalence study, which meaningfully reduces cost. We have now completed that consultation and are focused on CMC work to scale up manufacturing of the listed product. We plan to file the IND for our bioequivalence study by the end of this year, initiate that study next year, and expect it to take approximately one year to complete. Based on this timeline, we intend to file the NDA for MPT 1734 in 2028, alongside our NDA filing for MPB 1523, our liver lesion diagnostic candidate, which we also plan to submit in 2028. Both represent our late-stage clinical candidates.

Are you in discussions with partners for commercialisation, or do you intend to bring these products to market independently?

Our partnership strategy is indication-dependent. We do not intend to distribute these products ourselves. Our plan is to complete registrational studies and remain open to partnership discussions depending on the stage of development, whether through self-registration followed by a distribution partnership, or through direct licensing. We intend to handle self-registration ourselves through the initial study and registration process, but we remain fully open to licensing discussions with partners, including after Phase III, depending on how the clinical strategy evolves.

Could you say a few words about your RegenTrace platform and how you see it fitting into the broader cell therapy landscape? Is this an active area of focus currently?

We approach cell therapy through the lens of our nanoparticle platform, since MegaPro is not a pure cell therapy company but fundamentally a nanomedicine company. We use our MRI contrast agent technology to address what we describe as the “black box” problem in cell therapy: many physicians have told us that, following cell injection, they simply do not know where the cells go, how they distribute, whether they persist, or what happens to them afterward. We set out to integrate our technology directly into cell therapy to solve exactly this problem.

Around three to five years ago, our CEO, Dr. Jesse Wong, presented this work at a conference, which led to a collaboration with Stanford University. Together, we used our particles to label stem cells and cartilage for tracking purposes, and demonstrated that our particles enable real-time in vivo tracking via MRI. Critically, compared with existing iron oxide agents, which typically allow tracking for only one to two weeks, our particles remain detectable via MRI for up to four weeks. This four-week traceability window is significant, as it can serve as a surrogate biomarker for predicting therapeutic outcomes: if the signal disappears too quickly following injection, there is no opportunity to track the cells over a meaningful period. Our particle allows physicians to monitor cell behaviour in the body over a considerably longer window, giving them far more information to guide decisions such as re-dosing timing, or understanding why a given patient is not responding to treatment. We refer to this, in effect, as making cell therapy visible rather than invisible after injection. This candidate is, in essence, also an MRI contrast application, integrating directly with our core imaging technology.

Across diagnostics, therapeutics and cell therapy, what is MegaPro’s top strategic priority today?

We are genuinely developing both platforms in parallel, since each now has a late-stage candidate demonstrating feasibility for market application. On the diagnostic side, that is MPB 1523; on the therapeutic side, our nanomicelle platform addresses existing hypersensitivity issues, such as those caused by Tween 80, in established drugs. Diagnostics and therapeutics are being developed in parallel as we scale the company, and looking ahead, we see real potential in integrating both platforms, combining diagnostics with treatment in a manner consistent with precision medicine. Our cell-tracking work is itself a form of precision medicine, since it allows diagnosis, real-time tracking, and prediction of therapeutic outcome within a single approach. We hope MegaPro will become a genuine player in precision medicine going forward.

How have investors responded to MegaPro's recent clinical milestones, and how do you assess the Taiwanese capital market's reception to biotech?

We would expect our stock price to rise following entry into late-stage development, and we hope that progressing into Phase III, alongside initiating our bioequivalence study, will drive further appreciation and make the company more attractive to investors. At present, however, our valuation does not reflect this, and we consider ourselves undervalued. That said, we believe this is part of a broader trend across Taiwan's biotech sector. Demonstrating our ability to initiate these later-stage studies should meaningfully improve our valuation going forward.

What message would you like international investors and potential partners to take away about MegaPro, and what types of partnerships are you seeking?

MegaPro's technology has been built by a genuinely experienced team, and I believe our platform rests on a strong scientific foundation. We bring substantial preclinical and translational research experience, which I think differentiates MegaPro from many other biotech start-ups. Having validated our platform through Phase I and Phase II clinical data, we believe this makes for an attractive proposition, whether for licensing or direct investment, and we remain fully open to discussing co-development as well as direct licensing arrangements, depending on what best suits a given partner.

My message to investors and potential partners would simply be that we believe we are currently undervalued as a company, with two late-stage platforms behind our lead assets, which we believe makes this a genuinely attractive opportunity for investment.

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