I-Shu Lee – Founder & CEO, Vitae Biomedical

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Dr. I-Shu Lee, founder and CEO of Vitae Biomedical, began his career as a postdoctoral researcher before making the uncommon leap from academic laboratory to entrepreneurship in 2019. Built around a proprietary urine-based protein detection technology for early cancer screening, Vitae Biomedical has already achieved commercial traction in Taiwan, partnering with approximately 600 clinics, and has begun expanding into Japan, Europe, and Southeast Asia.

You trained as a scientist and worked as a postdoctoral researcher before founding Vitae Biomedical in 2019. What was the moment that convinced you to take your science into a commercial venture?

During my postdoctoral work, my supervisor, Professor Chen, and I initiated a project to identify a new target for lung cancer therapeutics. Our original intention was to develop a new antibody-drug conjugate, which required us to first identify a viable target. In the course of that research, we identified a candidate protein that could be detected not only in the blood but also in the urine. That observation opened a different line of thinking entirely. I went to my supervisor and proposed that this was an opportunity to develop a new screening or detection tool – something that could reach patients far sooner than a therapeutic ADC, which requires enormous capital and many years of development. A detection tool, by contrast, could be developed and commercialised on a much shorter timeline.

The challenge was that in academia, the institutional appetite is firmly oriented toward treatment solutions. Funding for a diagnostics commercialisation pathway was not something I could pursue within that framework. So I made the decision to leave, find independent funding, and establish a company to bring the technology to market. If we had not acted at that moment, I believe we would have lost the opportunity entirely. That is what took me from scientist to chief executive.

Your technology uses urine as the diagnostic medium – a highly variable biological specimen, influenced by everything from hydration to diet to physical activity. How has your research and development approach addressed those challenges to deliver a clinically reliable result?

Our first step was to compare results from urine specimens directly against serum specimens, to confirm that the target protein exhibited the same trend across both sample types. Once that correlation was established, urine became the logical choice for our platform – not in spite of its complexity, but because the accessibility it offers is central to our mission. Blood collection requires clinical staff and an invasive draw; urine collection does not. If the goal is to make cancer screening genuinely convenient and widely adopted, urine is the right specimen.

As for managing the biological complexity of the urine environment, our approach is grounded in antibody-antigen specificity. Our target is a protein, and we use a primary antibody to capture it directly. A secondary antibody, also targeting that same protein, is conjugated to a small chemical compound that responds to light energy – altering its configuration in a measurable way. A reader then detects and quantifies that change, allowing us to calculate the precise concentration of the target protein in the specimen. Because the antibody binds exclusively to the target protein, the surrounding complexity of the urine environment is effectively bypassed. Specificity is built into the chemistry of the test itself.

Low-dose CT screening – LDCT – is the established benchmark for lung cancer detection, but it carries a well-documented challenge of high false-positive rates, which can lead to unnecessary and invasive follow-up procedures. Does your technology address that problem?

Our testing is not designed to compete with LDCT – it is designed to complement it and, critically, to make the overall screening pathway more efficient. We position our test at two distinct points in

that pathway. The first is upstream of LDCT, as a primary filter. Patients with no elevated biomarker levels may follow a physician-directed follow-up plan based on their overall risk profile, reserving LDCT capacity for those who present a genuinely elevated risk profile. This matters enormously in practice: at National Taiwan University Hospital, for example, the current waiting time for an LDCT appointment has reached six months. For a patient with active lung cancer, that delay is clinically unacceptable. Our test allows lower-risk individuals to be appropriately triaged without consuming scarce imaging resources.

The second application is downstream of LDCT, at the point where a nodule has been identified but its nature remains ambiguous. In those cases, physicians face a difficult decision: recommend a biopsy – an invasive procedure that many patients are reluctant to undergo – or monitor and risk missing a malignancy. Our test can serve as a second-opinion tool at precisely that juncture, helping clinicians determine with greater confidence whether a nodule warrants intervention. Both of these applications are already in clinical use in Taiwan, where we are actively working with partners to reduce LDCT overuse and improve biopsy decision-making accuracy.

At what stage is the business commercially, and what does the regulatory and approval pathway look like from here?

In Taiwan, we operate as a laboratory testing service rather than selling a diagnostic kit directly. Clinics and hospitals collect urine samples from patients, which are then transferred to our laboratory via logistics partners. We conduct the analysis, generate a structured report, and return it to the treating physician, who then calls the patient in for a follow-up consultation to discuss the results and advise on next steps. We currently provide clinical applications through a laboratory testing service model while actively advancing regulatory pathways to support future productisation and broader clinical adoption.

We are already commercial under this model. Approximately 600 small and mid-sized clinics across Taiwan are currently working with us. The large academic hospitals have tended to rely on LDCT as their primary screening tool and have shown less immediate interest, but the clinic segment – which historically lacked access to any comparable screening capability – has been highly receptive. Taiwan’s national health insurance system means that smaller clinics must increasingly develop self-pay service lines to sustain their operations, and our test fits naturally into that model.

Taiwan is your current base, but you are clearly looking further afield. What does the international expansion strategy look like?

We are currently advancing our expansion strategy across Japan, Europe, and Southeast Asia simultaneously, while adopting different market-entry approaches tailored to each region. In Southeast Asia, we are establishing demonstration sites, pursuing regulatory approvals, and developing clinical collaborations to gradually replicate the business model we have already validated in Taiwan. The case for Malaysia is straightforward: LDCT penetration is far lower than in Taiwan, where coverage is extensive. In markets where imaging infrastructure is limited, the need for an accessible, non-invasive first-line screening tool is considerably more acute.

In Japan, we are initially entering the market through a research-use-only (RUO) strategy to accumulate clinical and market experience before progressing toward regulatory approval and broader market adoption. In Europe, alongside our clinical validation discussions with partners in Lithuania, we are also evaluating potential market-entry opportunities with local collaborators. Expanding validation across different populations and geographic regions remains a key priority for us, as our existing clinical data has been generated primarily from Taiwanese cohorts. Successful cross-population validation will strengthen our ability to enter European and other international markets with greater confidence. Validating the technology across ethnically diverse cohorts is an essential step before we can credibly enter European and other international markets.

Diagnostics shape about 70% of clinical decisions but account for only 2-3% of healthcare spending. How do you position your test as a clinical necessity rather than a discretionary cost?

The answer lies in education, and I regard that as one of our core responsibilities as a company. The fundamental challenge with cancer screening is behavioural: people do not seek testing until they experience symptoms, and with lung cancer, symptomatic presentation is almost always late-stage presentation. Shifting that behaviour requires sustained public and clinical education around the value of regular, proactive screening.

In Taiwan, we have been building that case progressively. The government has been supportive of lung cancer screening as a public health priority, which creates a favourable policy environment. In the markets we are entering next – Malaysia, Indonesia, the Philippines – the health economics conversation is different, but the trajectory is encouraging. These are economies growing rapidly, with populations that are increasingly focused on health maintenance as disposable incomes rise.

That creates an opportunity to engage directly with governments and healthcare stakeholders in shaping future screening frameworks. However, we believe the value of our test comes from addressing gaps that already exist within the lung cancer screening pathway. It can support risk stratification and follow-up management, helping limited imaging resources such as LDCT to be used more efficiently for higher-risk populations.

In Taiwan, this approach complements an already established screening infrastructure. In emerging markets where screening pathways are still evolving, there is an opportunity to incorporate this design philosophy from the outset and build a more complete and efficient lung cancer screening ecosystem.

For patients in remote or geographically dispersed markets, logistics are a genuine barrier. Do you see a pathway to reaching those populations?

This is where our product development roadmap becomes relevant. Our current laboratory service model is our first commercial phase and our primary revenue engine. In parallel, we have developed a diagnostic kit format that, once approved, can be sold directly to hospitals for in-house use, eliminating the logistics requirement entirely. That is the second phase.

The third, and in many ways the most strategically significant, is a point-of-care device currently in development. This device will use the same urine-based platform but will deliver a result within three to five minutes, directly at the clinic or in a community setting. It is designed for scalability – and ultimately for personal or home use. In markets with vast geographies and underdeveloped logistics infrastructure, a compact, rapid-result device that requires no laboratory support could significantly reduce dependence on logistics networks and central laboratories. We are actively advancing the underlying technologies and product development efforts to further improve accessibility and ease of use.

Taiwan’s identity as a global leader in semiconductor and ICT development is well established. How does that ecosystem shape your device development?

It is directly relevant to the point-of-care device. The device comprises two components: a reader and a testing chip. We are currently advancing our platform through multiple sensing technologies. In the near term, we are leveraging Surface Acoustic Wave (SAW) technology to accelerate the commercialisation of point-of-care applications. Over the longer term, we are developing a

proprietary sensing platform built around Molecularly Imprinted Polymer (MIP) technology, combined with semiconductor components such as Field-Effect Transistors (FETs), enabling biological signals to be converted directly into measurable electrical outputs. The common foundation across these approaches is the deep integration of biological detection capabilities with semiconductor technologies. That signal is then transmitted to the reader, which processes and displays the result. The convergence of our biological platform with semiconductor manufacturing capability is not incidental – it is central to what makes the device feasible. Being based in Taiwan, with access to world-class semiconductor expertise and supply chains, is a genuine structural advantage for us in developing this kind of integrated biosensor technology.

You took an unconventional financing path for a biotech company. How would you characterise the funding ecosystem in Taiwan, and what has your experience been in building the company financially?

Our path has indeed been atypical. We began, as most early-stage companies do, with funding from family and friends, and then secured angel investment. What distinguished our trajectory is that we chose to generate revenue early, through the laboratory service model, rather than remaining purely in a development and fundraising cycle. That decision gave us something most early-stage biotechs cannot offer investors: a visible financial track record. It allowed us to approach banks for structured financing to scale the service business, rather than being solely dependent on equity rounds.

The consequence is that our funding journey has been more gradual and operationally grounded than a typical venture-backed biotech. Over the past two to three years, as our commercial traction has become more evident, we have seen a meaningful increase in inbound interest from angel investors and venture capital funds. The momentum has been building, and we are now preparing for the next significant step.

What does that next step look like – are you considering an IPO or a strategic acquisition?

Our strong preference is an IPO rather than a trade sale or merger. We are targeting a listing on the Taiwan stock exchange within the next one to two years, and we have already begun the preparatory work in earnest – including engaging PwC as our corporate accounting firm to ensure

our financial reporting meets the standards required of a publicly listed company. We are also continuing to strengthen our team and organisational capabilities to build the operational and management infrastructure required of a publicly listed company. The groundwork is being laid this year.

If I return to Taiwan in five years, where do you want Vitae Biomedical to be?

Five years from now, I would like Vitae Biomedical to be operating as a genuinely global company – not defined by Taiwan or a handful of regional markets. We have already planted seeds in Europe through our Lithuania partnership, and the US and European markets are clear long-term targets. China I view as a later-stage opportunity. On the product side, I want us to have expanded well beyond lung cancer into multiple cancer types – developing distinct pipelines for the clinical problems that are most difficult to solve with existing tools. I also want our device platform to be fully AI-integrated. As users are able to continuously monitor their health status through point-of-care testing, the longitudinal data generated becomes extraordinarily valuable. AI-driven analysis of that information could meaningfully support personalised health management and lifestyle decision-making. There is a great deal to build in five years – but that is precisely what makes it exciting.

You made the transition from scientist to chief executive. What is your philosophy for navigating that shift, and what does a successful marriage of science and business look like to you?

I would not claim to have it fully resolved – but the most important principle I have learnt is that, when operating as a chief executive, I cannot rely solely on the mindset of a scientist. The laboratory and the boardroom run on fundamentally different logics. In the laboratory, creativity and iteration are virtues: you can pursue an idea at midnight, run an experiment on a hypothesis, and pivot freely. In a company, the governing priorities are system stability and consistent quality. Processes must be repeatable and reliable, and decisions must account for people, resources, and organisational consequences in ways that laboratory thinking does not prepare you for.

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