

Drug Approval Opens the Door, but Commercial Execution Determines Who Wins

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At BIO Asia-Taiwan 2026, Handa Pharmaceuticals Director Toshiyo Chen explains why differentiated innovation alone is not enough, and how mastering patents, market access and global commercial strategy will define the next generation of specialty pharma winners.



The pharmaceutical industry's innovation equation is changing. Developing an entirely new molecule is no longer the only route to creating meaningful clinical value, particularly when smarter formulations can address toxicity, dosing, drug interactions and patient convenience while offering a potentially more efficient development pathway.

In an exclusive conversation with **BioSpectrum Asia** during **BIO Asia-Taiwan 2026**, **Toshiyo Chen, Director of Handa Pharmaceuticals Inc.**, discusses the company's transformation from high-barrier generics to a 505(b)(2)-led specialty pharmaceutical model. Chen explores why this could be a defining opportunity for Taiwan's pharmaceutical industry, the importance of mastering patents and global market access, and how Handa is building a resilient growth strategy around differentiated formulations, selective innovation and international commercialisation.

Handa has successfully transitioned from a generic-focused business to a more differentiated 505(b)(2)-driven model. What strategic factors drove this transformation, and how has it reshaped the company's growth trajectory?

Handa's R&D foundation was built on high-barrier First-to-File (FTF) generics. In our early days, we leveraged our speed advantages and patent litigation management to secure exclusive FTF positions and obtain 180 days of market exclusivity, establishing our initial cash flow.

However, as Indian pharmaceutical companies aggressively entered the market with vertically integrated scale and cost advantages, we realized that the pure generic competitive landscape had become uncontrollable. To pursue high barriers to entry, secure sustainable revenue sources, and meet the financial stability expectations of a publicly listed company, Handa initiated a strategic transformation in 2016 to focus primarily on 505(b)(2) differentiated new drugs.

This transformation has completely reshaped Handa's growth trajectory. Aiming to solve the pain point of revenue instability caused by intense competition in generics, we adopted a "dual-engine" strategy¹4utilizing existing generics to bring in

steady cash flow, while driving high-growth profitability with 505(b)(2) drugs. Focusing on 505(b)(2) development allows us to build upon the established safety and efficacy of known drugs and secure marketing approvals based primarily on pharmacokinetic (PK) data, effectively lowering the high risks and costs of clinical trials associated with traditional New Chemical Entities (NCEs).

Currently, 505(b)(2) products contribute over half of our revenue, demonstrating that Handa's transformation strategy has yielded significant results. Today, Handa has successfully transitioned into a lean and highly efficient Specialty Pharmaceutical company, armed with core intellectual property (IP) and global commercial negotiation capabilities. As we continuously stack our pipeline, we are establishing a biotech company with highly resilient revenue streams and a focus on sustained profitability, creating lasting value for both our employees and shareholders.

As healthcare systems increasingly seek cost-effective yet innovative therapies, how do you evaluate the commercial opportunities for specialty pharmaceutical companies originating from Taiwan in today's global market?

The ecosystems of major global markets are undergoing drastic divergence. The US market features highly diverse commercial and government insurance systems; while cost-containment rules like "try generics first" exist, premium differentiated drugs still find a customer base willing to pay higher prices. Conversely, Taiwan and mainland China face immense pricing pressures from global budgets and centralized volume-based procurement. Under such pressures to control healthcare costs, global medical systems no longer solely look for brand-new small-molecule drugs that cost billions to develop and command astronomical price tags. Instead, they demand cost-effective alternatives that retain high clinical value. This marks the golden age of the 505(b)(2) model.

For Taiwanese specialty pharma companies looking to go global, the key lies in "focusing on niches and mastering upstream core technologies," rather than following the majority of companies that sink resource-intensive investments into NCE development. Taiwan's strengths lie in high-caliber R&D talent and excellent manufacturing quality control, whereas its relative weaknesses include a small domestic market and a less mature capacity for clinical pharmacology and disease data analysis.

Therefore, Handa's solution is a unique organizational architecture that integrates Taiwan and US resources while partnering with service providers in other nations. Taiwanese companies must remain agile, focusing on in-house development, PK studies, complex formulations, and patents to control and deeply optimize the source of the supply chain. They can then leverage global out-licensing partners to push products into mainstream markets like the US. This is the most pragmatic, win-win path for Taiwan's Specialty Pharma to step onto the global stage.

Oncology and central nervous system (CNS) Neurology disorders remain highly competitive therapeutic areas with significant unmet needs. Where do you see the greatest opportunities for innovative formulations and differentiated products to improve patient outcomes?

In the oncology and neurology fields, many blockbuster drugs currently on the market deliver significant efficacy but suffer from widespread clinical pain points, such as high toxicity/side effects, volatile bioavailability, severe food-drug interactions, and administration inconveniences for specific patient populations. We firmly believe that solving these unmet medical needs can bring substantial benefits to patients. Even without changing the Active Pharmaceutical Ingredient (API), we can create immense commercial and clinical value, which is precisely the core value proposition of 505(b)(2) products. We see substantial opportunities in steering the development of differentiated products toward enhancing patient safety, convenience, and compliance.

Handa's technological strategy is hyper-focused on:

- **In the Neurology Field:** For multiple sclerosis, we precisely target the needs of pediatric patients and individuals with dysphagia (difficulty swallowing), significantly boosting compliance and reducing the burden on caregivers.
- **In the Oncology Field:** Exposure-response simulation of 2,000 virtual patients with advanced renal cell carcinoma (RCC) over 180 days compared the current standard 60 mg cabozantinib dosing scenario with a continuous 34.5 mg of Handa's alternate-salt scenario. Because Handa's alternate-salt scenario reduced high-exposure outliers in the simulation, the model predicted fewer patients crossing toxicity thresholds that trigger dose holds or reductions. When fewer patients reach those high-exposure levels, the model predicted lower hazard ratios for key exposure-driven toxicities. The model also predicted fewer dose modifications which may support improved treatment continuity.

We do not pursue dozens of projects simultaneously; instead, we are highly selective in choosing our development targets. Handa's R&D culture centers on "extreme focus"—moving from doing one generic exceptionally well at a time in our early days to developing an optimal number of new drugs concurrently today. We insist on concentrating our resources on high-barrier niche technologies and formulation platforms that are difficult to replicate, focusing heavily on raw material origins and

manufacturing process controls to establish comprehensive technological barriers.

With products now commercialized across North America and China, what key lessons has Handa learned from navigating diverse regulatory, market access, and commercial environments?

After successfully integrating US and Taiwanese resources and expanding into international markets, our greatest multinational commercial insight is this: obtaining a drug approval is merely an entry ticket; what determines life or death is market access, patent litigation management, and the dynamic balancing of revenue curves.

In the US market, we face global-tier patent defense battles. One of Handa's core competitive strengths is that we do not fear the patent walls of originator companies, and we possess top-tier capabilities and experience in managing patent litigation. At the same time, because we are a TPEX-listed company in Taiwan, the capital market and investors demand high revenue stability and predictability. The business cannot withstand revenue gaps or wild financial fluctuations caused by prolonged litigation periods. To navigate the external pressures inherent to both the biotech industry and public listings, we have accumulated rich, firsthand battle experience.

- **Experience in Resolving Patent Litigation:** Handa possesses deep transnational legal warfare and risk management experience from its global expansion. Facing high-standard US patent defenses, Handa has successfully reached patent settlements with originators multiple times, successfully paving the way for early launches of our 505(b)(2) drugs. This proves Handa's mature capability in patent litigation handling and commercial negotiation, effectively ensuring stable corporate operations and protecting shareholder interests.
- **Acquiring Assets to Diversify Revenue Streams:** In addition to in-house product development, during periods of pipeline adjustments or potential revenue gaps, we have rapidly executed external asset evaluations and decisively in-licensed products. For example, our complete asset acquisition of Phyrago was precisely timed to reinforce our immediate revenue curve. By bringing in a mature pipeline with clear clinical advantages, we effectively addressed a critical restriction where certain chronic myeloid leukemia patients could not take their medication concurrently with PPIs and H2RAs.
- **Selling Products in the US and Canadian Markets and Out-licensing Internationally:** Currently, Handa has multiple products actively selling in the US and Canadian markets, generating consistent cash flow and profits for the company. We have also successfully out-licensed several products to partners in Taiwan and China, accumulating extensive experience in identifying ideal commercial partners and navigating business negotiations. Moving forward, we will deploy this experience to continuously open up global markets and elevate the commercial value of our R&D achievements.

Tempered by these practical experiences, Handa now boasts a proven track record of independently completing product development, resolving patent litigation, and launching products. We have also demonstrated the capability to in-license external assets to fortify corporate revenues. Through this dual-track strategy of combining in-house development with strategic asset acquisition, the company aims to build stable revenue streams through product stacking, mapping out a highly resilient growth blueprint for investors over the next 3 to 5 years.

Taiwan continues to gain recognition as a biotechnology and pharmaceutical innovation hub. What additional measures could further strengthen the ecosystem and support the global expansion ambitions of Taiwanese pharmaceutical companies?

Taiwan's biotech sector does not lack capital, and the social environment is relatively forgiving toward enterprises. However, to nurture genuinely globally competitive Specialty Pharma companies, we must bridge massive gaps in "innovative talent," "clinical pharmacology capabilities," and "practical experience in international patent and regulatory affairs." While Taiwan boasts exceptionally outstanding talent in manufacturing quality (CMC/QC), it lacks the strategic ability to translate clinical insights into foundational product formulation designs.

More critically, the US is the world's largest pharmaceutical market and the primary battleground for Taiwanese biotech companies looking to go global. Taiwan still lacks professionals who are well-versed in international (primarily US) patent mapping, FDA regulations, and drug approval review practices. Only by knowing how to find breakthroughs within the cracks of international patents can we successfully convert strong R&D technologies into tangible commercial value.

Furthermore, the recent AI and semiconductor booms have created a powerful siphon effect on capital and top-tier talent, further exacerbating the shortage of talent in biotechnology. While capital and top talent will eventually return to value-driven fundamental industries like healthcare—much like what happened after the dot-com bubble—Taiwan must accelerate industry-academia collaboration at this stage.

Handa has already begun platform-based industry-academia collaborations with professors from top universities like National Taiwan University (NTU) and National Cheng Kung University (NCKU). Starting with modest initial funding, the focus is on cultivating hard-to-replicate formulation platform technologies and accumulating talent. We must offer globally competitive compensation and a dedicated nurturing environment to draw back multinational talent who understand US FDA regulations and possess clinical pharmacology and disease data analysis capabilities. Only when companies return to the fundamentals—using solid execution and profitability to rebuild market trust—can we attract the next generation of truly passionate talent into this industry.

Looking ahead, what will define Handa Pharmaceuticals' next phase of growth over the coming five years, and where do you see the company's greatest opportunities for value creation?

Over the next five years, Handa's strategic goal is crystal clear: we do not want to be just a company that launches successful products; we want to build Handa into an indispensable, highly predictable Specialty Pharmaceutical Company in the global supply chain. Our next phase of growth will be propelled by three core strategies:

First is the consecutive and successful development and launch of our product pipeline. We will continuously advance the NDA submissions and market launches of 505(b)(2) new drugs such as HND-039, HND-027, HND-044, and HND-045. Combined with externally acquired assets like Phyrago, we aim to ensure that Handa introduces new products every single year, maintaining stable revenue momentum. Throughout this process, Handa will fully capitalize on the rich practical experience accumulated from our international commercial history—such as successfully overcoming patent litigation to bring products to market and acquiring external assets to enrich our pipeline—thereby creating substantial value for the company.

Second is the sustained investment in technological platforms and the deepening of our global market layout. In addition to ramping up R&D investments in our proprietary formulation platforms and strategically purchasing core technologies with intellectual property protection—which is precisely why we established our Innovation Center—we will accelerate the monetization of Handa's international business capabilities. Currently, Handa has several products generating active sales in the US and Canadian markets and has successfully established a business model of out-licensing products to partners in Taiwan and China. Moving forward, we will leverage this experience to expand further into other regional markets. Simultaneously, targeting China—the world's second-largest pharmaceutical market—Handa is actively evaluating diverse cooperative architectures to further deepen our presence there.

Third is capital governance and the maximization of our core platform value. Handa has always adhered to a prudent capital philosophy of "fundamentals first." Our greatest value creation in the future lies in continuously optimizing this R&D, patent, and regulatory platform that consistently yields high technical barriers and precisely penetrates international markets. Furthermore, looking at the long-term evolution of our supply chain, while we currently utilize global partners to support an asset-light operation, Handa remains open to establishing our own manufacturing lines in the long run. Once our product pipeline reaches a sufficient scale and displays clear commonalities and manufacturing synergies, self-owned production lines will help further elevate our manufacturing autonomy. Through sustained profitability, we will build long-term confidence among investors, ensuring that Handa's innovative formulation technologies continue to deliver genuine benefits to patients on the global stage.

Standard Safe Harbor Statement

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