Spiro Gavaris – President, US Generics, Lupin

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Spiro Gavaris, President of Lupin's US generics business, shares a candid assessment of the shifting dynamics shaping today's generic and biosimilar landscape. He outlines how Lupin is positioning itself for long-term leadership through focused investment in complex generics across inhalation technologies, injectables, and biosimilars, while navigating a market challenged by persistent price erosion, supply fragility, and policy uncertainty. Gavaris also offers his perspective on what is needed from regulators, payers, and policymakers to create a more sustainable environment for the essential generics sector. According to Gavaris, rewarding value-added generics and supporting reliable supply will ensure that essential medicines remain accessible to American patients.

You've had an extensive career journey within the generic space, leading business units for Hikma and Mallinckrodt before joining Lupin in 2022. Could you start by introducing your professional journey and what drew you to Lupin specifically?

My career has taken me across a wide spectrum of the pharmaceutical landscape, though the common thread has always been commercial effectiveness and strategic growth. I began in field sales at Bristol Myers Squibb while completing my MBA at NYU, which really sparked my interest in the strategic side of commercialisation. That led me to Campbell Alliance, a boutique consulting firm focused on optimising commercial performance. Working with around 20 different companies across speciality markets like infectious disease, IVIG, women's health, growth hormone, and early

biosimilar-like categories gave me deep exposure to how different organisations launch and grow products.

After nearly four years in consulting, I moved into generics by joining Hikma through its US subsidiary, West-Ward. At the time, it was a USD 100 million business, and I spent eight years helping expand it to roughly USD 1.2–1.3 billion across both oral solids and injectables. My roles spanned strategy, commercial leadership, and ultimately serving as President of US Injectables. I also helped stand up a branded platform within Hikma through the launch of a 505(b)(2) product, which added another dimension to my experience.

From there, I went on to lead Mallinckrodt's Speciality Generics division, overseeing a global business spanning APIs and finished dosage forms across five manufacturing sites. That role broadened my operational and leadership experience even further.

By the time I left Mallinckrodt, Lupin felt like the natural next step. The company had a significant generics base that aligned well with my background, strong aspirations in institutional markets and biosimilars, and an interest in developing 505(b)(2) and branded opportunities. There were areas where I had developed extensive hands-on experience. In conversations with our CEO, Vinita Gupta, it was clear that my diverse background in retail, institutional, biosimilars, branded strategy, and injectables aligned directly to Lupin's ambitions. It felt like a genuinely synergistic fit, and an opportunity for us to move forward together with a shared vision.

How would you describe the current scale and structure of Lupin's US operations, and the weight of the market in the context of the company's global footprint?

The US is an enormously important strategic market for Lupin. It is our largest business unit globally, representing roughly 36% of the company's total sales. Lupin first entered the US in 2003 through the acquisition and reintroduction of Suprax®, an antibacterial drug, and expanded into generics in 2005. Our local manufacturing presence began in 2015 with the acquisition of Gavis and its facility in Somerset, New Jersey. This year marks a decade of domestic production, and our commitment to US manufacturing has only grown. Lupin is currently the 3rd largest generics player in the US by prescriptions (TRx and Statista), with 49 products in the #1 position (IQVIA/NSP).

In addition to the Somerset site and corporate offices in Bridgewater, New Jersey, we have our US headquarters in Naples, Florida, where much of our global executive team is based. We also operate a dedicated inhalation R&D centre in Coral Springs, Florida, where many of our complex

inhalation products are developed. Adjacent to that site, we are now making a significant investment to build a new manufacturing facility focused on inhalation and other complex products.

Over the past three years, Lupin has experienced remarkable growth globally, driven primarily by exceptional performance in the US market. Our US business, which now accounts for more than 35% of global sales, has constantly been reinforcing its strategic importance within our company. Between FY23 – FY25, the US experienced a CAGR of more than 20%, and the current fiscal year is very much on track to improve that trend — Q2 FY26 registered a YOY growth of more than 40%.

With the generics sector evolving beyond traditional oral solids toward higher-value products, how is Lupin's portfolio offering and product strategy reflective of this increased focus on complex generics?

As I mentioned earlier, one of the big things that attracted me to Lupin is its commitment to innovation and to moving decisively into complex generics and differentiated dosage forms. The company has made real progress and expanded beyond traditional oral solids into complex inhalation therapies, biosimilars and sophisticated injectables.

In inhalation, for example, we were the first to bring a generic version of Spiriva® to market with a hand-inhaler device and we continue to be the only generic player in that space years later. We are also one of the market leaders in albuterol inhalers, and we have several additional complex inhalation programs advancing through development.

Our strategy also includes significant investment in vertically integrated biosimilars with multiple programs expected to reach approval over the next few years. On the injectable side, we have already launched complex products such as Victoza, Glucagon, and long-acting Risperidone thanks to our PrecisionSphere™ technology platform for extended-release formulations.

Looking ahead, roughly 70% of our R&D spending is now focused on complex generics, 505(b)(2) opportunities, and other high-barrier products. The goal is to continue entering markets early, differentiate meaningfully, and deliver affordability, access, and improved standards of care for patients across the US.

Are there any current plans for introducing Lupin's biosimilars offering to the US market?

In November, we gained approval for our first biosimilar, Armlupeg™, as a biosimilar to Neulasta® (pegfilgrastim).

We have a strong biosimilars portfolio, but it is currently commercialised outside the US. However, over the next 24 months, we anticipate multiple biosimilar launches coming to the market. All of this work will be supported by our dedicated biosimilars manufacturing facility in Pune, where we already produce a product supplied to Europe and other regulated markets. We have just received FDA approval of the facility, and with that, secured the biosimilar products currently under review should be well-positioned to enter the US shortly after.

Within Lupin's advancement of its complex generics pipeline in the US, what areas do you see as the biggest drivers of future growth?

As our US business continues to evolve, the biggest drivers of future growth will come from expanding beyond traditional retail oral solids into higher-complexity channels and technologies. Historically, Lupin operated primarily through the retail pharmacy and wholesaler networks. Over time, we have moved up the complexity curve with inhalation products, which are still largely flowing through those same channels, but now we are diversifying much further.

In the past year alone, we launched three products in the speciality pharmacy channel. That shift increases not only the complexity of what we develop, but also how we commercialise, distribute, and partner. Currently, we work with all the major speciality pharmacy players on such launches.

Looking ahead, we already have a base of injectable products on the market, and as that portfolio expands, we will further build out our institutional commercial capabilities. Many of these injectables will be biosimilars, which represent another major pillar of future growth.

So, the four areas that will drive our next five to ten years of growth are inhalation, institutional injectables, 505(b)(2) and other value-added injectables, and biosimilars. These pillars each build on our technical strengths and position us well for the next stage of Lupin's evolution.

The Association for Associable Medicines (AAM) paints a picture of the challenges faced by the US generic market, which include price erosion, ongoing shortages of medicines,

and the difficulty of ensuring insurance formulary placement. How do these market dynamics impact Lupin’s ability to operate in the market, and what strategies do you have in place to help navigate these challenges?

The reality of today’s generics market is that we do face these structural headwinds. For us, the key to navigating these pressures and continuing to operate sustainably is innovation across every layer of the business.

A significant portion of our portfolio sits in the highly commoditised segment, where pricing pressure is most intense, and cost inflation is a constant challenge. To keep these essential medicines available and affordable, we have to innovate within our own operations. That means driving greater efficiency across the supply chain, optimising processes, and an uncompromising commitment to quality so that we can continue supplying high-volume generics reliably at a very low cost.

At the same time, portfolio innovation is equally important. By expanding into more complex and value-added products, we can diversify our revenue base and support the wider business. A balanced portfolio that includes both high-volume commoditised products and higher-margin complex generics ensures we have the financial strength needed to invest in large-scale operations and maintain our long-term commitments to the market.

What we are also seeing industry-wide is that sustained price compression can reach a point where some manufacturers simply cannot supply products profitably, leading to withdrawals and, ultimately, shortages. This directly affects patient access. One of Lupin’s core strengths is our responsiveness in these moments. We work closely with agencies overseeing drug shortages, continuously monitor market shifts, and maintain a highly agile supply chain so we can scale up when needed. Our goal is to ensure stable, reliable access to any product in our portfolio for patients throughout the US.

In your view, what changes are needed within the US healthcare system and policy framework to support a more balanced environment between affordability and innovation?

Simply put, one of the most important changes needed is a clearer understanding at both the policy level and in the broader public conversation of the fundamental differences between generic and branded pharmaceuticals.

There is a consistent push to lower healthcare and drug costs, which is understandable. But when broad, uniform downward pressure on pricing is applied to the commoditised end of the market where most generics sit, it can destabilise supply. These products require significant capital investment to manufacture, maintain, and distribute, yet they generate minimal margins. Many are already barely sustainable to produce. When pricing is pushed even lower without discrimination, the ecosystem becomes fragile, and manufacturers may be forced to rationalise products.

We are seeing the consequences of this play out today. When just a few manufacturers exit a category, it triggers drug shortages that create far more cost, operational disruption, and patient risk than the marginal savings such price pressure was intended to achieve.

It is important to remember that roughly 90% of all prescriptions filled in the US are generics, yet they account for only about 8–10% of total drug spend. In other words, the system is applying aggressive cost controls to the segment that is already the most affordable and has the least room to absorb them. The actual savings available are relatively small, but the potential disruption is enormous if these essential medicines become unsustainable to produce.

If I could get one point across, it would be that we need greater clarity and nuance across the healthcare ecosystem about these dynamics. Cost-containment strategies must be applied thoughtfully and selectively. Otherwise, we risk undermining the stability of the generic market, and doing so, jeopardising patient access to the essential, affordable medicines that the entire system depends on.

As reliable supply has become a core differentiator in the generics market, Lupin recently announced plans for a state-of-the-art pharmaceutical manufacturing facility in Coral Springs, Florida. Could you elaborate on the strategic rationale for the new facility?

Lupin already has a strong manufacturing presence in the US with its facility in Somerset, NJ. With our plans to expand manufacturing in Coral Springs, FL, we’re demonstrating our commitment to aiding in reducing America’s dependence on foreign suppliers and building a resilient foundation for the future.

When we think about our investments in the US, the new Coral Springs facility is really the next step in a broader strategic progression. As our portfolio continues to shift toward higher-complexity products, we need to build the right talent and technical capabilities here in the US. This goes not

only for R&D and development, but also for commercial manufacturing.

Onshoring is an essential part of that strategy. Developing and manufacturing these complex products in the US strengthens supply chain reliability, positions us closer to our customers, and ensures we can maintain a consistent, high-quality supply. It also allows us to continue building a deep talent base locally by investing in US jobs, skills, and advanced manufacturing expertise.

The decision also made sense from a geographic and organisational standpoint. With our US headquarters in Florida and a dedicated inhalation R&D centre already established in Coral Springs, expanding that footprint into a co-located manufacturing facility was a natural extension. It allows us to pair development and production seamlessly, especially for the complex inhalation products that represent one of our key growth engines.

What will this new manufacturing facility represent in terms of Lupin’s continued commitment to American patients?

We believe that the closer we are to patients, the better. Bringing more of our manufacturing to the US is a deliberate commitment to strengthening supply reliability, supporting access, and ensuring that American patients receive consistent, high-quality medicines.

As the third-largest generic supplier by volume in the US, we recognise the responsibility that comes with that position. We work closely with federal agencies and other stakeholders to ensure we can continue meeting patient needs with a steady supply and ongoing innovation. Building advanced manufacturing capabilities in Coral Springs is a major part of that effort, especially as we bring more complex technologies onshore.

We are also looking beyond traditional medical benefits. The technologies we are investing in include next-generation inhalation platforms that incorporate environmentally friendly, low-impact propellants. So, this facility will not only support patient access but also position the US as a hub for more sustainable pharmaceutical innovation.

The current policy environment in the US is increasingly emphasising domestic manufacturing and reduced dependence on overseas suppliers. To what extent do you see these policy shifts impacting the generics sector?

If tariffs were to be applied to generic pharmaceuticals, it would create real disruption across the supply chain.. The reality is that in highly commoditised markets, manufacturers cannot universally pass those added costs through. That means some companies would be forced to exit certain products or categories altogether.

The challenge is that many essential medicines in the US are supported by only a small number of viable manufacturers. If even one of those players exits because tariffs make the economics untenable, the remaining companies would suddenly need to absorb upwards of a third of the market volume. In a regulated industry where capacity expansion requires capital investment, regulatory approval, and time, that simply is not feasible. The result would be supply disruptions and real risks to patient access.

The encouraging piece is that policymakers appear to recognise these dynamics, and there has been thoughtful discussion about whether generics should be exempt. Given the fragility and essential importance of this segment of the market, my hope is that those considerations will lead to a decision not to apply tariffs to generics. But if tariffs were imposed, the generics sector would face a material challenge that would almost certainly create pockets of supply instability for US patients.

Looking forward, Lupin's annual report specifies that the company aims to launch 100+ new products in the US by FY2030. What key priorities are you putting in place to reach this goal?

While it is an ambitious goal it is absolutely feasible. Over the past three years, we have consistently launched close to 20 products annually, and that momentum is backed by significant investment. In the last five years alone, Lupin has invested roughly USD 1 billion across R&D and capital projects to expand our capabilities and is looking to maintain a similar, or even bigger, level of investment in the next 5 years due to the strategic importance of the US market. Continuing to build on that foundation positions us well to deliver the scale of launches we are targeting.

Our focus is not only on the number of products but also on increasing complexity. We are prioritising areas where we can meaningfully differentiate, whether through advanced formulations, inhalation technologies, injectables, or biosimilars. Another major driver is our strength in patent challenges. Lupin has a strong track record of being first-to-file and successfully navigating IP pathways to enable earlier generic entry. That work from our IP and R&D teams is critical because breaking through patent barriers allows us to bring lower-cost alternatives to

patients sooner.

What final message would you like to deliver to American stakeholders on the importance of creating a more favourable environment to support the generic and biosimilar sector?

While we talk about onshoring, pricing pressures, and the realities of commoditised markets, another critical challenge that deserves more attention is the adoption and utilisation of products at the time of launch. As the sector moves from traditional oral solids to biologics and long-acting injectables, the investment required to develop the next generation of generics continues to rise. At the same time, patent litigation has become more complex and costly, with strategies evolving from a handful of patents to portfolios of 10, 15, or even 20 patents that companies must navigate to gain entry.

After overcoming those hurdles, manufacturers often face another barrier of payer blocks tied to PBM rebating practices. Generic entry too often becomes a negotiating tool for PBMs to extract deeper rebates from the branded product rather than an opportunity to support generics that meaningfully lower costs. As a result, we see markets with high value and high rebate potential where generic penetration remains only 20–40%. This dynamic makes it difficult for manufacturers to justify the significant investments required to develop complex generics and biosimilars.

A key part of the solution lies with Medicare and Medicaid. These programs need to take a more pro-generic stance in their formulary decision-making. Creating stronger incentives for generic and biosimilar adoption will ultimately deliver far greater system-wide savings than relying on rebates from branded drugs.

We are seeing some positive movement, particularly in biosimilars, where regulatory pathways are becoming clearer and interchangeability is improving. Lowering barriers to entry, whether through streamlined study requirements or more supportive substitution policies, broadens the range of products that are economically viable to develop. Combined with reducing payer-side obstacles, this will encourage more manufacturers to invest in bringing lower-cost alternatives to market.

This is reflected in our own portfolio, which continues to expand as the policy environment improves. If the government continues to advance reforms in the right direction, it will strengthen the incentives needed to drive greater adoption, bring more biosimilars and generics to market, and ultimately increase affordability and access for patients across the US.

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