Guy Jean Savoir – CEO, Carnot Laboratories

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Guy Jean Savoir, CEO of family-run Mexican pharma Carnot Laboratories explains the company's USD 150 million investment in a new facility, its plans to focus manufacturing efforts on vaccines and contribute to reestablishing the country as a vaccine production hub, and Carnot's continued focus on expanding its markets in Brazil, Colombia, and Peru. Savoir also reflects on the Mexican government's approach to the pharmaceutical industry and the need for greater transparency despite the positive effects of the private sector's increased participation.

What is Carnot’s current manufacturing strategy and how does it play into broader national goals around biopharma manufacturing?

We have two main strategies leveraging our manufacturing infrastructure. The first is focused on vaccination. To give you some background, Mexico was a prominent vaccine manufacturer until the late 1980s/early 1990s. However, due to systemic issues and government intervention, Mexico lost its significant vaccine manufacturing capabilities. Today, aside from the influenza vaccine, which is produced with Sanofi, all vaccines are imported.

These imported vaccines primarily come from one of the five major multinational vaccine manufacturers. This results in only one or two vaccines being available, which leads to two major issues. First, there is the risk of availability. Vaccines are allocated by country and time, so if you are not prompt, you might miss out. Secondly, limited suppliers mean less pricing pressure.

Other countries have successfully built their own vaccine industries—Brazil, China, Australia, Russia, and Japan are great examples. These countries have become competitive and successful vaccination hubs. Our first strategy is to establish modern, biotechnological vaccine manufacturing.

I understand you are on the verge of investing around USD 150 million in a new manufacturing facility. Was this decision planned well in advance of the recent fluctuations in interest rates?

The decision to invest in our new manufacturing facility has been part of our long-term strategic planning for several years now. It is not a reaction to short-term market conditions. Rather, this investment is driven by the significant growth and success we have experienced in both Mexico and Latin America, which has created a pressing need for increased production capacity. The new facility is being constructed exclusively to meet this growing demand for our products, both those currently on the market and those in our immediate pipeline. So, rather than being a speculative gamble, it is a strategic move to ensure that we can sustain our current growth trajectory and continue meeting the needs of our expanding customer base.

Can you shed some light on the financing aspect of this significant investment? Did you encounter any challenges with securing funding, particularly in terms of involvement from Mexican banks?

Fortunately, financing our new manufacturing facility was not a problem for us. We received ample support from private banks, and we did not face any significant hurdles in securing the necessary funding. While we did consider the broader Latin American context, particularly given our regional presence, financing our project here in Mexico proceeded smoothly without any major issues.

Will your facility be used for contract manufacturing, or are you looking at other models?

We will have the capacity for contract manufacturing, but our main focus is on licensing in technologies, tech transfer, and local manufacturing to supply the regional market. While we could engage in pure contract manufacturing, our primary aim is to license vaccines from tier partners and ensure regional supply through local production.

Do you have any preference for the technologies you will potentially adopt?

Currently, we are working with viral vector vaccines, which we believe is a robust platform for the future. It has demonstrated safety, efficacy, and adaptability to various needs. However, we are also exploring other technologies, such as mRNA, to ensure our strategy is future-proof.

How are the four different pillars of your portfolio performing, and which therapeutic area is currently the most important for your business in Mexico? What is the driving force behind this?

Gastroenterology (GI) is our leading area. We have two key drivers in gastroenterology. First, Libertrim Alfa, a patented product for irritable bowel syndrome (IBS), has gained significant market share. It is well-received by physicians and patients due to its quick onset of action and effective resolution of IBS symptoms. Second, we have Ki-Cab, a novel therapy and the first of its kind. Ki-Cab is a potassium receptor competitor, representing the new generation of treatments for acid reflux disease, including Helicobacter pylori, heartburn, and acidity. This is a substantial market, and Ki-Cab offers significant benefits over the best proton pump inhibitors available, making it a strong performer in the market.

When you look at your GI portfolio and other areas, are you aiming for market share first, or are you focused on achieving a certain level of reimbursement? What criteria guide your portfolio selection?

Our portfolio selection is based on several factors. These include the relevance to physicians and patients, addressing unmet needs, the clinical benefits we can offer, market size, the therapeutic area, the payback period, and the net present value of the project. For us, two crucial aspects stand out. First, we seek to provide a clinical benefit over existing market options. Second, we aim to secure some level of exclusivity for our products. Although we often launch products with generic active pharmaceutical ingredients (APIs), we are not purely in the generic market. We focus on products that offer clinical benefits to both physicians and patients, adding value to the market.

It is challenging to categorize companies, but would you describe yourselves as a branded generic company or a generic company?

We consider ourselves an innovative company. The last purely generic product we launched was probably around 15 years ago. Most, if not all, of our products have some degree of differentiation. Approximately 70 to 80 percent of our growth is based on patented products.

How has the pharmaceutical industry been treated by the government in terms of delays on tenders and lack of clarity, and what has been your experience with this?

We are pleased with our current performance, ranking as the second fastest-growing pharma company in Mexico. However, our experience with the government's approach to the pharmaceutical industry has been a mixed bag. While there have been delays in tenders and a lack of clarity in certain processes, particularly regarding public procurement, we have also seen positive aspects, notably in the realm of private sector participation.

The involvement of private entities has proven extremely beneficial for companies like ours, contributing to growth and market stability. However, despite these successes, there remains a widespread sentiment within the industry for greater transparency and organization in government dealings, especially concerning the purchase of pharmaceutical products for public use. A more structured and transparent system is not only desirable but necessary to ensure equitable access to medication for the entire population, particularly those reliant on the public sector for healthcare services.

Achieving such improvements will not only enhance efficiency but also bolster trust and collaboration between the pharmaceutical industry and the government, ultimately benefiting both providers and consumers of healthcare services. Mexico's healthcare system is split evenly between public and private sectors in terms of value but heavily favours the public sector in terms of the number of units.

How far has Mexico advanced in terms of biosimilars?

Interestingly, the first biosimilar was developed in Mexico by Probiomed. We do not lack infrastructure in this country, but there have been significant institutional barriers to the entry of biosimilars into the market.

One major issue was the lack of specific guidelines for the approval process of biosimilars. This regulatory ambiguity created a situation where subjective requirements could be imposed, leading to high costs for products to meet regulatory standards. This was a significant hurdle.

Additionally, Mexico's proximity to the US means we must respect intellectual property (IP) to maintain good relations. Unfortunately, the abuse of IP protection mechanisms has extended exclusivity beyond the patent life, which prevents the entry of second-entry biotechnological products. This issue, known as linkage, has been applied in such a way that even expired patents continue to block new entries.

While we respect IP and generate our own, the misuse of IP laws can stifle innovation. IP should incentivise innovation by providing exclusivity, but if it never becomes public, it prevents incremental innovation on previous innovations. This, in turn, blocks access to new developments.

What factors have contributed to Carnot's rapid growth?

Carnot's remarkable growth can be attributed to several key factors, primarily stemming from our extensive investment in R&D over the years. This investment has enabled us to develop and launch high-performing products that address significant medical needs and offer tangible benefits to patients. For instance, our success in the central nervous system (CNS) segment, where we introduced products targeting depression, anxiety and migraine, has been particularly noteworthy. These products have been well-received due to their efficacy and compliance. Adherence to established guidelines ensures that our products meet rigorous standards of quality and effectiveness. Overall, our focus on innovation, coupled with our commitment to meeting patient needs, has been instrumental in driving our growth within the healthcare sector in Mexico.

Could you outline your Latin American strategy, particularly in terms of market expansion and acquisition opportunities?

Our primary strategy revolves around consolidating our current market positions in key regions, with a particular emphasis on Brazil, Colombia, and Peru. These markets offer significant growth potential, and we aim to capitalize on our research and development efforts by introducing innovative products tailored to their specific needs. While organic growth remains our priority, we are also open to inorganic growth opportunities, including acquisitions of products and facilities in these markets, aligning closely with our therapeutic focus. In some cases, such as Peru, we have

initiated subsidiaries with our own portfolio, while in others, we have pursued acquisitions to establish a foothold and leverage existing regulatory support. This targeted approach allows us to strategically expand our presence and enhance our market share across Latin America.

Considering the complexities of the Brazilian market, particularly its vast size and inherent challenges, how do you navigate the landscape while maintaining your market share and growth trajectory?

Brazil indeed presents unique challenges due to its substantial size and complexity, constituting around 40 percent of the entire Latin American market. We approach this market with patience, discipline, and focus, which have been key factors in our success thus far. By strategically investing in commercial activities and prioritizing products with significant potential, we have managed to maintain our foothold while adhering to a prudent growth strategy. Despite the difficulties, Brazil offers unparalleled opportunities due to its sheer population size, where even moderate success surpasses achievements in other markets. While some mid-sized laboratories may witness a shift in local market importance over time, we remain committed to our long-term vision and anticipate continued growth and relevance in Brazil over the coming years.

Looking at Carnot’s future growth trajectory, do you envision it remaining heavily focused on the Mexican market?

Our long-term plan involves gradually reducing Mexico’s weight in our overall portfolio. However, despite our efforts to expand internationally, Mexico continues to be a significant contributor to our company’s overall value. In terms of units, we are currently split approximately 50-50 between Mexico and the rest of Latin America. However, our strategy is geared towards expansion, so we anticipate Mexico’s proportion to decrease over time as we grow our presence in other markets.

As a family-owned company with a longstanding presence in the pharmaceutical industry, what guiding principles shape Carnot Laboratories’ decision-making processes and strategic direction?

Our family holds a deep commitment to our work and adheres to guiding principles that underpin our strategies and decisions. Firstly, we prioritize making a tangible difference in the lives of

patients and physicians by providing exceptional clinical support. This commitment guides our product selection and development efforts.

Furthermore, we operate under three fundamental pillars. Firstly, innovation is paramount to us. We firmly believe in investing in cutting-edge R&D to bring superior products to market, ensuring accessibility for patients. Secondly, we place immense emphasis on quality. It is not merely a concept but a tangible commitment to surpass regulatory requirements across all aspects of our operations, from manufacturing facilities to commercialized products. We hold ourselves to the highest standards, and if any product fails to meet our stringent criteria for risk-benefit profiles, we opt to discontinue its commercialization.

Our perspective is profoundly long-term, driven by a relentless pursuit of excellence. Lastly, internationalization stems from our foundation of innovation and quality, enabling us to expand our reach into different markets and offer our innovative solutions on a global scale. These principles serve as our compass, guiding every decision we make and ensuring that our commitment to excellence remains unwavering.

Latin America has shown remarkable growth as indicated by IQVIA statistics. With such growth, it is no surprise that private equity firms are keenly interested in companies like yours. Have you considered how ownership might evolve, especially considering the need for expansion and the finite nature of capital?

We have been in contact with reputable private equity firms interested in healthcare. While we are not averse to equity partnerships, it is essential to recognize the high cost of such capital. Currently, we are able to finance our growth internally, so equity partnerships would only be considered if our own means became insufficient, which has not been the case thus far.

Is there anything else you would like to emphasize for our audience, especially regarding the intersection of finance and biopharma?

While we are proud of our ability to bring innovations to market, it is worth noting that not all innovations need to be our own. We see ourselves as potential partners for companies worldwide that lack the capacity to introduce their products in Latin America. Our expertise in navigating regulatory processes and our established commercial presence make us a valuable ally for bringing innovative products successfully to this region. Whether it be managing regulatory requirements or

executing effective marketing strategies, we have the experience and capability to ensure the success of innovative products in Latin America, a market where such expertise is invaluable.

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