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NO 'SYNERGIES TO THE BONE'

GBT maintains a local focus to grow regional footprint

By Marie Powers, News Editor

SAN FRANCISCO – Growing a regional specialty pharma from the ground up is an ambitious goal, especially in Latin America, which has almost no publicly traded pure pharma players and only a handful of companies whose territories extend beyond the borders of a single country. Still, that was the aspiration of Grupo Biotoscana SL (GBT), which traveled last week to pitch its story to investors at the 34th J.P. Morgan Healthcare Conference (JPM).

As a privately held venture, GBT was spared exile to JPM's slender Latin American track, held on the 32nd floor of the Westin St. Francis, which included five publicly traded life science companies focused on consumer health, over-the-counter drugs, diagnostics or animal health. GBT presented during JPM's private company track in a much tinier space but with a much larger audience.

GBT was "born of an idea" five years ago, recounted CEO Mariano Garcia-Valiño, through the backing of private equity firms Advent International and Essex Woodlands. Garcia-Valiño, a former president-Latin America at Bausch + Lomb who also had tenure with big pharma and venture firms, and Advent, which has a major presence in the region, found themselves discussing opportunities to create the "right place" for growth in Latin America.

In general, pharmaceutical utilization in Latin America enjoys a growth rate at least twice that of the rest of the world, and the specialty pharma market is growing at the same clip, according to Garcia-Valiño. "If you combine the two, you have something with the potential for high growth," he observed.

However, few companies in the region were focused on specialty pharma and even fewer were seeking to grow outside their home markets, leaving potential investors with a dearth of opportunities to establish a footprint across Latin America. A specialty pharma with a regional presence would provide global investors not only with a more balanced risk portfolio across multiple countries but also with the ability to attract small biotechs for partnerships and big biopharmas for licensing deals.

Seeking to create a company whose business model encompassed a blend of licensing, internal development and M&A, "we looked at whether we could actually buy something like this and start growing," Garcia-Valiño told *BioWorld Today*. "We didn't find it."

Instead, he added, "We basically said, 'This is a puzzle. Let's buy the pieces and then put the puzzle together.'"

Those pieces started to come together in 2011 with Bogota, Colombia-based Biotoscana, the leading specialty player in the Andean region, which had longstanding partnerships with global pharmas such as Actelion Pharmaceuticals Ltd., of Allschwil, Switzerland, and CSL Behring, of King of Prussia, Pa. Garcia-Valiño and the management team expanded the company's operations into Ecuador, Peru, Chile and Argentina and added several licensees to expand the portfolio.

In 2014, "we found a company in Brazil that looked exactly the same," Garcia-Valiño said. Headquartered in Sao Paulo, United Medical was the country's leading specialty player and had existing relationships with Gilead Sciences Inc., of Foster City, Calif., and Celgene Corp., of Summit, N.J. United Medical's owners were so impressed with GBT's business model that they became investors.

Last year, "we found a company in Argentina, which was the other leg of the stool that we were missing," Garcia-Valiño said. LKM was the premier oncology player in the region, with a state-of-the-art pipeline that included high-end branded generics. The company also boasted cross-Latin America certified manufacturing facilities and exports to 10 countries.

With the three units now combined, "we think we have a company that can still be developed but has a great shape," Garcia-Valiño observed.

'WE WILL PROBABLY NEVER BE AN R&D POWERHOUSE'

About 70 percent of GBT's revenues come from licenses and the remainder from proprietary products, but the split is likely to move closer to 50/50 within a few years. Over its five-year history, the company has grown at a pace of approximately 25 percent annually, measured in U.S. dollars. Measured in the local currency, which is subject to greater fluctuation, the growth rate is roughly 40 percent, according to Garcia-Valiño.

Relationships with partners have actually strengthened.

Gilead, which originally had one product license with United Medical, for Ambisome – a liposomal rendering of the antifungal drug amphotericin B – added agreements with GBT covering Sovaldi (sofosbuvir) and Truvada (emtricitabine/tenofovir disoproxil fumarate), even though the big biotech has its own operation in Brazil. Actelion increased its licensing lineup from one product to four, and Celgene added a second license to the portfolio.

"We take this humbly but proudly as a measure that we're doing something good for them," Garcia-Valiño said.

Going forward, GBT is in a position to accelerate growth, with sufficient capital for additional acquisitions and the market clout to secure new licenses. The company focuses on assets in oncology, hematology, HIV and other specialty indications that are high cost and highly complex, require high touch and have limited availability in the region.

GBT is currently negotiating some 40 deals. "We're not going to get all of them, of course," Garcia-Valiño admitted. "We're going to get maybe six or seven, but we're well positioned to get the right six or seven for the company."

GBT came to JPM – its second visit to the conference – to "start to show in the right places" and begin to tell its story on a bigger stage. Although its equity partners represent "a great combination" of owners, "at one point they'll want an exit," Garcia-Valiño acknowledged. "We're nowhere near that. We still have enough capital to grow for some time, and our debt is very low at this point so we could probably get more debt if we wanted. But at one point we will need public funds."

That transition may come as GBT expands its proprietary pipeline. The company is "working backwards, little by little," Garcia-Valiño said, starting with the formulation, registration and manufacturing of branded generics and a few biosimilars. The company is beginning to collaborate on development-stage assets, beginning with phase III compounds.

"We're a small company from Latin America," he pointed out. "We don't really have the critical mass that would allow us to deploy millions of dollars in clinical data. We believe that we will probably never be an R&D powerhouse – that's just not the nature of the region – but we can collaborate more. We can go further upstream."

Recognizing the importance of respecting differences across the region, each unit is operated locally. In all, GBT has 16 operating sites in 10 countries and an exclusive distributor in Venezuela. Nearly half of its 650 employees are in Argentina, and although sales and marketing professionals represent the largest percentage, by job classification, the company has 39 full-time regulatory specialists just to manage the array of laws and procedures across the region.

"Once you have a dossier that works for one country, there are minor things that you have to adapt for the others, but not because you have a process in Brazil that you would be able to fast-track in Argentina or Colombia," Garcia-Valiño explained. "We're the first truly Latin American company because we really manage each of the countries individually. We are not one of those companies that take synergies to the bone."