

## Staffan Schüberg - CEO, Esteve, Spain

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*Staffan Schüberg, CEO of Esteve, highlights the restructure of the company as it moves towards its new age of being a truly innovative pharmaceutical company on a global level. Furthermore, he highlights the international strategy and the role the US market will play in the future, as well as his aspirations as the company embarks on the exciting journey ahead.*

**Despite the company's strong and storied domestic presence, Esteve has experienced a downward trend over the last few years. What was the diagnosis of the situation when you first arrived?**

Esteve was very attractive to me from the outset. As an outsider, I was long aware of Esteve's strong position and reputation in its domestic market. However, what truly attracted me was the company's strong foundation in innovative R&D and its willingness to take a long-term view. These are foundational elements for any transformation, and we wholeheartedly believe that we can leverage these strengths to establish Esteve as an international player with a global mindset. This may sound subtle, but it represents a significant mindset change.

Overall, Esteve is a company with a strong industrial heritage ... from APIs to generics, classical pharma, R&D and OTC. My initial diagnosis of this situation was that we were too diversified for a mid-size pharmaceutical company. To avoid spreading ourselves too thin, we are now restructuring to enable a more focused strategy.

## **What is the new Esteve structure you are looking to build?**

We have an ambitious vision to become a global proprietary specialty pharma company. The company's core strengths in innovative drug discovery, development, and manufacturing give me tremendous confidence that we can achieve this vision. This transition will require us to think very strategically about our corporate structure, and we may need to streamline our current business to ensure that we don't continue to spread ourselves too thin: a) Manufacturing capabilities: global in nature, focused on high-end specialty products; b) Pipeline: very innovative, combination of internal discovery and public-private partnerships, focused primarily on neuroscience and gene therapy; c) Emerging BD focus: clear recognition that we need to accelerate our BD efforts in a variety of ways to complement/supplement our early-stage pipeline and to build the required commercial infrastructure; and d) Generics: although strong (e.g., geographic infrastructure, broad pipeline), it may not be aligned with our strategic vision.

Over the years, Esteve has established itself as a global contract manufacturing partner of choice. Our Chemical business has a global manufacturing presence and has a proven ability to exceed expectations of a global client base. We will continue to service the pharmaceutical industry within this field as a CDMO (Contract Development and Manufacturing Organization).

Therefore, we are now molding Esteve to what we view as its best fit within the global pharmaceutical ecosystem. This will be servicing high-end clients with APIs and specialty pharma and segregating out generics arm of the business. We still are strategizing on how to do this, for example, through a joint venture or attracting venture capital to increase the generics business size. In any case, this branch must be grown and act on a global level to be efficient, working on high volumes demanded by the global generics market.

## **You mentioned specialty pharma as the future of Esteve. In which areas are you looking to focus?**

If you look at our pipeline and the expertise of our overall R&D organization, you will see that we have a core strength in neuroscience and gene therapy. We have world-class experience here, and we see these areas as highly attractive from a long-term commercial perspective. Our deep knowledge allows us to recognize the emerging challenges and opportunities in these areas, ultimately giving us a strategic advantage.

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However, we recognize that a strong pipeline requires multiple shots on goal, and we now recognize the need to complement our state-of-the-art R&D engine with a state-of-the-art business development chassis that can lead to more shots. To do this, we are absolutely in the market for possible acquisitions and mergers with companies that represent a strong strategic fit for Esteve.

**In this sense, what is the perfect fit for Esteve?**

There are three main avenues we are looking for in potential partners. First, companies with mid- to late-stage pipelines that align with our core focus in neuroscience and gene therapy. Second, enterprises that have solid growth projections, but most importantly strong EBITDA. Finally, companies that can help us increase and strengthen our geographical coverage by expanding or complementing our current European footprint.

Clearly, we cannot overlook the US market, and we are very actively evaluating strategic partnerships and M&A opportunities that would allow us to establish a sustainable, profitable US presence.

**You talked about being spread too thin in the past. By pursuing so many new markets, doesn't this create a possibility of falling into the same trap again?**

Not at all. If the core engine is running efficiently, geographic expansion should not be problematic. In fact, one of the main challenges is that Esteve has always had a global R&D strategy without a global presence. This results in significant risk during the development phase with smaller returns in the end because the commercial opportunity is limited to certain regions. With a larger geographic footprint, we will be able to truly maximize the potential of our innovative pipeline.

**The US is a mega market for any pharmaceutical company. What are you doing to establish Esteve's presence there?**

The US conservatively represents more than half of the global market, so ignoring that region would be foolish. Every single successful global pharmaceutical company has a strong and

meaningful US presence. For Esteve to establish ourselves in the US, it all comes back to our pipeline. We see a tremendous fit between several of our development-stage therapies and the unmet needs in the US market. Rather than spreading ourselves too thin, I view a meaningful US presence as critical to capitalizing on our R&D investments and ultimately helping more patients.

Beyond the US, Esteve's long-term commitment to China has really impressed me. This market of 1.3 billion people is radically evolving, and I am convinced that China will eventually represent a larger opportunity than the US. In general, China places significant value on western, high-quality medicines; coupled with the never-before-seen US pricing pressures, I believe that China will emerge as the leading global market one day.

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Although our footprint in China is currently limited to manufacturing, we have strong fundamentals to build partnerships there in the future. In summary, our focus is squarely on Europe and the US in the near-term, but we will be keeping a very close eye on China.

### **How important are partnerships for the company's R&D strategy?**

The company has an impressive track record in successful partnerships, and it is one of our great strengths and part of our DNA. And really, being a mid-cap pharmaceutical company has allowed us to remain relatively nimble, and this agility has allowed us to gain long-term partnerships with household names such as Novartis, Lilly and Mundipharma amongst others.

If Esteve is to continue to grow, we must focus on smaller opportunities that Big Pharma may overlook ... and we will place tremendous value - and care - on these types of products. We are a partner of choice because we will be committed.

### **How significant is it to be based in Barcelona?**

We are fortunate to be located here, and we are profiting from a flourishing and innovative ecosystem. For example, we are working hand-in-hand with a local university to develop a gene replacement therapy for Sanfilippo A syndrome, a rare and fatal pediatric disease with no approved treatments. In this case, we can provide drug development expertise and horsepower, and we also have the ability to effectively bring this therapy to the patient community. This is just one example

of our many collaborations in a thriving Barcelona research ecosystem.

### **What more can be done to see Barcelona become another of Europe's biotech hubs?**

I actually think that the Spanish government is taking some important steps forward, but they must continuously review their processes, and put in place tax incentives for long-term investments and R&D. Furthermore, enacting simple concepts will go a long way, such as ensuring universities have the freedom to work with non-government organization as well as private enterprises.

### **How is Esteve adapting to the new age of biologics, especially in the manufacturing ecosystem?**

Right now, we are not active in biologic manufacturing. We are focused on NCE (New Chemical Entities) small molecules, and we have a global presence in this market. Nevertheless, we are bringing innovation to this sector; for example, spray drying, a technology that allows insoluble chemical entities to be easily absorbed by the body. This is just one example, but we believe that small molecules can still offer the innovation that clients require.

Saying that, within biologics we are looking at ways to get our foot in the door. For a CDMO, it is best to do this through a guaranteed partnership as it is a high investment entry point and working with partners will create sustainability as contracts are already ensured. In fact, we have a 15 percent share in a Chinese biologics manufacture. This will allow us to gain an insight into what we must do to manufacture biologics, so in the future we can bring these technologies and processes to Esteve.

### **What will be the cornerstone of the company as you embark on establishing the "New Esteve"?**

In very basic terms, we are staying true to Esteve's historical mission of helping patients. The pharma market has changed dramatically over the years, and our challenge is to adapt our approach to ensure long-term profitability. And we will do so by leveraging our foundation of innovation.

We are now setting off on Esteve's "profitable journey," meaning that we are focused less on topline growth with low margins and more on bottom-line growth with greater profit. This will then allow our R&D program to receive the necessary investment to grow our portfolio.

### **What are your priorities for 2019?**

Our number one priority is to find a new home for the generics business. This will allow us to streamline our focus on innovative API manufacturing, R&D, and a proprietary portfolio. In parallel, we will be aggressively evaluating external opportunities that can complement our existing pipeline and commercial footprint.

### **And your long-term vision?**

Our success will hinge on our ability to successfully develop and launch products from our own pipeline into the US. This footprint, within the US and European markets, must be a profitable business that is focused on aligning our innovative therapies and APIs to patient unmet needs.

### **What are some of your own products you envision being launched?**

Our most advanced asset is a unique co-crystal form of tramadol and celecoxib for the treatment of moderate-to-severe acute pain. We believe that this product is very well-positioned to meet a significant unmet need exacerbated by the US opioid epidemic. Our plan is to file the NDA with the US FDA in early-2019.

As I mentioned earlier, we are also extremely excited about the potential for our Sanfilippo A gene therapy program. Sanfilippo A is a very rare lysosomal storage disorder (LSD) that is estimated to affect less than 1 in 70,000 births. Children with Sanfilippo A are born without an enzyme required to build connective tissue. Children are born without any symptoms, and there is no way to screen for this disorder. As a result, it often goes undiagnosed for several years ... although the disease is causing progressive damage. The condition typically manifests in neurological and physical symptoms such as the inability to eat, walk, and speak. Children continue to regress, and their lifespan is significantly shortened.

At Esteve, we believe we can change this. Our Sanfilippo A gene therapy is designed to replace the defective gene, and we see a very hopeful future for patients and families living with Sanfilippo A. Our therapy is in early clinical studies right now, and we are optimistic that we can continue to advance this program in the near future. Luckily for the Sanfilippo A community, Esteve is one of several companies pursuing a treatment, and we believe that our unique approach can provide meaningful benefits.

**Esteve is a family-owned company. What benefits does this bring and what attracted you to such a position?**

Being a family company is what really drew my attention. Generally, family-owned enterprises are able to think more in the long-term than traditional publicly-owned pharmaceutical companies, despite decisions sometimes taking longer to make. Additionally, family-owned companies tend to be more willing to ride out market complications or drug development setbacks because they take a long-term view. This ownership structure is a unique asset for Esteve that will benefit us during our journey toward becoming a truly innovative global player.

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