Michel Spagnol – President and CEO, Novasep, France

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Michel Spagnol, chairman and CEO of Novasep, a robust French CDMO, shares his insights on the key global trends that are shaping today's CMDO sector – particularly the emerging significance of biopharmaceuticals and gene therapies. Spagnol goes on to elaborate on his strategy to revitalize Novasep's organizational structure and position the company as a reference partner of choice within the biologics space.

Looking at the global CDMO landscape, what would you identify as the most important trends currently in the sector?

Quite clearly, I would have to say the key trend in today's CDMO environment is the rise in biopharmaceutical demands. In fact, this has been an underlying growth over the past years, but it is certainly developing further at a faster pace than anyone had anticipated. Looking at the maturity curve of some of these products, the monoclonal antibodies have been increasing tremendously, antibody drug conjugates which have been gaining momentum recently, and of course, there are the gene therapies.

This is an area in which Novasep wagered on several years ago and it turned out to be the right bet. At the time we made this decision, gene therapies were still an uncertain playground as there were only a small handful of products that had actually gained FDA approval. However, we can see today that the market for these products is moving along quite nicely. Overall, biologics at large

are going to be the shapers of the industry moving forward, and I am glad to say our company took this path several years ago.

What are your assessments of the consolidation which seems to be happening within the CDMO space?

Looking at the CDMO sector overall, it is still relatively fragmented. Having worked in several companies before Novasep, I was surprised to continually be discovering clients we had that I had never heard about. CDMOs generally have a pool of preferred customers that hold high importance in the business operations – being big pharma. After the heavyweight players come a raft of biotech companies, which is really the sweet spot for Novasep. We have consciously decided to work with biotechs in particular, focusing on markets like the US.

Pharmaceutical companies are looking to simplify their outsourcing activities and work with few partners who can offer a wider range of services and this is especially true for biotechnology companies who typically work with one service provider for one product. Therefore, yes, we do expect to see further consolidation within the CDMO space. No one today can be the king of all areas alone – constantly investing to build new competencies from the ground up is impossible – so acquiring technologies or other assets is absolutely necessary for building capabilities.

As Novasep today, the company was really built up in past years through aggressive acquisition activity. For this reason, we have a pool of different technologies which is key for meeting our clients' needs in the business we are in.

What do you see as the critical skills needed by a CEO of a globally competitive CDMO in today's market?

Especially in today's environment, a CEO must be like a sponge – soaking up all the information they can from the market, customer, and macroeconomics. Having specific knowledge in just one area whether it be the technology or business strategy is no longer enough. Each company is unique, and a CEO must be able to understand the constraints they are working within to drive their organization forward in a sustainable way.

What is Novasep's current development model for achieving growth and profitability?

Novasep's *Rise 2* strategy means we are aiming to grow and quickly. The fundamentals for this growth were put in place during our *Back to Basics* strategy. I implemented *Back to Basics* when I arrived at Novasep as a way to break the company's conundrum of only growing through acquisitions. Novasep is a technically focused company created in 1995 with the idea that a technology used in petrochemicals can be adapted to pharmaceuticals. From the next 15 years, the company grew mainly by acquisitions through leveraged buyouts (LBO), trying to spread this technology as much as it could be. Novasep's last LBO was the tipping point in the company, and after the acquisition was not as successful as anticipated, Novasep went through a restructuring period in 2012.

When I joined Novasep in 2013, instead of continuing to restructure, I submitted to the shareholders the *Back to Basics* plan which was focused on market development rather than M&A growth. This involved simplifying our processes, clarifying our market offer, and focusing on organic growth. We have used this strategy quite successfully for the last four years.

By simplifying our offer and selling some assets, we were able to make key investments, 70 percent of which were in biopharmaceuticals focusing on gene therapy and monoclonal antibodies drug conjugate. In parallel, we invested in a large site in the south of France to purify omega3 for a pharmaceutical API and another site in Pompey to produce a key adjuvant for vaccines. The second phase of our turnaround strategy, *Rise 2,* is focused on the fulling of these capacities which we have invested in.

How did you identify the opportunity to enter the biologics area in France, where the sector is less mature than in other markets such the UK, with great players such as Cobra Biologics, and several more?

This was a mixture of analyzing market data, intuition, and a bit of luck! If a portfolio is balanced and risk is reduced, luck can be a product of design… Novasep does not enter the generic space, we primarily choose to work with biotechs who have mature late-stage products. Looking at our investment in gene therapy, at the time there were very few products approved by the FDA, but the market data was promising, and we were working with products which were at final stages in the pipeline.

Overall, France is a bit late in this area and the industry is doing the best it can to correct the situation. Although several of our investments are in Belgium, the French administration is pushing to develop this area and in fact, Emmanuel Macron visited our biologic site in Pompey for

purification. Nevertheless, the government must continue putting effort into supporting biotechnology companies and CDMOs like Novasep. The manufacturing chain solutions are not fully developed yet in France, but this is a development we are hoping to come over, with time.

How are you balancing Novasep's robust range of service offerings that cover several differentiated markets?

The range of services Novasep currently offers span from very high-tech processes in biologics and gene therapies, and on the other extreme, we sell equipment to purify sugar. Initially, the sense behind this is that the technology behind purification, whether it be for sugar or viruses, is fundamentally based on the same principle. Obviously, we must choose where we will focus our growth and investments and Novasep has chosen to follow the biologics route. Looking forward in the long term, perhaps in five years or so, we will likely simplify our offering to focus on the driving area of Novasep. As a French company with a majority of assets in Europe, our only way to be differentiated is through innovation and therefore we must select carefully where we chose to invest in for our future development.

How does Novasep build added-value in a space where manufacturing volumes cannot use scales of economy to boost profitability?

Absolutely, the question today is how can a production factor of 10 or 100 be reached in the manufacturing of biopharmaceuticals? This will never be on volume but rather on efficiency, capture, and continuous or single-use processes. In fact, we have entered into a collaboration agreement recently with Sartorius Stedim Biotech (SSB), a leading supplier for the biopharmaceutical industry, in the area of chromatography and single-use bioprocessing. Novasep also recently developed BioSC®, a groundbreaking low-pressure continuous chromatography solution for the purification of monoclonal antibodies and other biologics. The BioSC® platform and SSB's single-use technology will form the basis for the development of innovative chromatography systems. These processes will provide the most attractive alternative to batch and continuous resin-based chromatography – namely higher productivity, smaller-scale operations, and increased robustness.

What is Novasep’s international positioning and strategy of building its presence overseas?

As a French company, a majority of our investments, capabilities, and employees are based out of France. However, we export 95 percent of what we produce overall. Novasep has five production sites in France, a large facility in Germany, and a site in Belgium which has the biggest growth potential for the group currently. It is in Belgium where we have invested the most in gene therapy for both API and finished products. Astounding, we have doubled the number of employees at the site within a year and a half, which has been a huge driver for our biopharma activity. Lastly, we also have production facilities in China and the US.

Our presence in Shanghai is well positioned to tackle our food and equipment activity in the southeast Asian markets. On the other side of the world in the US, we started with a small development lab to build a relationship and trust with our clients there, eventually shifting the majority of manufacturing to Europe once the product has matured.

For our CDMO and pharmaceutical business, our priorities are primarily on the US, European, and mature Asian markets – namely South Korea and Japan. Within our equipment business side, we mainly deal with emerging markets, specifically India, which is closely linked to the manufacturing of biosimilars.

How is Novasep valued internationally as a French-born business?

No matter where you are in the world, clients place the most value on service. I have always believed a company is only as good as its last delivery. We strive to always meet our delivery obligations on time and in full, which makes the clients we collaborate with very happy. The expectation of meeting safety, quality, and timelines is paramount to Novasep’s offering as a French player.

Ten years ago, quality was not necessarily a differentiator to the extent it is today. Data integrity has become a very stringent topic in the current environment. As a French company, Novasep delivers on the reputation of the French to consistently comply with the regulations in place and stay up to date with industry standards and requirements.

Looking forward, what objectives would you like to achieve within the short to mid-term future?

I aim to deliver on the promise I have made to Novasep's shareholders on doubling the company's profitability within the next five years as part of the *Rise 2* strategic plan. At the same time, I want to bring Novasep into the position of a 'humanized' company. Corporate social responsibility and employee centricity are valued as a core principles of Novasep. We want to ensure that all our stakeholders are satisfied and fulfilled as part of the team. I want to give employees a purpose by working in a company that is bringing a real impact on the world and patients.

What concluding words would you like to share on behalf of Novasep and France?

The French ecosystem is a strong one and we have very innovative companies here. It is undeniable that France has had a long history of excellence in science. The landscape is evolving and I am confident that France will play an important role in the development of biologics and gene therapy moving forward. As Novasep, we have made a solid commitment to facilitating this effort. Regardless of where our assets are, we are a French company and we will always keep this at our core. We hope to continue creating long term relationships with our current clients and creating a new network as we further advance our capabilities and positioning within the biopharmaceutical sector.

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