Jennifer Cannon, SVP Global Head Mammalian Biologics – Lonza

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Lonza's global head of Mammalian Biologics, Jennifer Cannon, talks about disruption in the CDMO industry, explains how the Swiss giant is reimagining new models based on risk-sharing, and goes through the effects of the pandemic on both the company and the industry, including supply chain disruption, demand for new capabilities as the industry invests in new molecules and reduced time to market.

Jennifer, you have a research background and, prior to joining Lonza in 2021, worked in the biopharma industry for more than 18 years. Can you briefly introduce your career and current role at Lonza?

I have been with Lonza for just over a year. I moved from the United States, where I was based in California, to Basel, Switzerland. I have a background in research, pharmacology and biochemistry, and did my postdoc in the industry, at Genentech. I was very interested in the development of pharmaceuticals and the services and products that support the development of new therapeutics.

From there, I continued in research as an application scientist in mass spectrometry and slowly moved over into the business, looking at launching new products, new services and emerging technologies around proteomics and protein analysis tools for a division of Thermo Fisher for about nine years. It was a split between products and services, and I had an applications science team, taking P&L responsibilities which required me to bring many different products and services to

market.

During that time, I was fascinated with contract manufacturing and how new technologies and tools are leveraged to deliver a broad range of capabilities to small and large pharmaceutical companies that do not have that capacity or expertise in their own manufacturing and development networks.

After that, I went to Ajinomoto and became interested in services and products in the biologic space; microbial, mammalian, drug substance and drug product manufacturing. Then I had the opportunity to step into the client's shoes, taking on a role at AbbVie where I helped run their internal contract manufacturing network. That was a great experience to learn how pharmaceutical companies face challenges from a supply chain and development perspective. I also learnt how customers balance and optimize the manufacture of their products in development and prepare for launch, and how they manage external supply versus building capabilities and capacity within their own networks.

Finally, in 2021, I took a role with Lonza to serve as Executive Vice President and Global Head of the company's Mammalian Biologics business unit. Since Lonza is the leader in this space, I believe that it is a great opportunity to make use of my background and share my expertise with the team.

The business unit you oversee is part of Lonza's largest division, Biologics, which represents almost half of their total revenue. Can you explain how Mammalian Biologics is structured and the role it plays for Lonza?

Biologics, led by Jean-Christophe Hyvert, is the largest division within Lonza. At the beginning of 2021, we structured ourselves into different drug substances or drug product formats, as well as different modalities and molecules. We have one of the most complete and flexible CDMO portfolios in the biologics industry, consisting of mammalian and microbial expression systems as well as capabilities for bioconjugation and mRNA manufacturing. During the pandemic, we rapidly brought our mRNA manufacturing services to the market. Within conjugation, we have expertise to really take monoclonal antibodies and conjugate them to cytotoxic or specific drug linkers.

The business unit I am responsible for, mammalian biologics drug substances, has historically been the growth driver of Lonza and continues to be from a licensing, manufacturing and services perspective. My team is responsible for program management, supply chain specific to mammalian biologics, commercial development, technical sales operations, and supports seven mammalian manufacturing sites around the world: Singapore, China, Spain, Switzerland, San Francisco/Bay

Area (US), Portsmouth (US), and the United Kingdom. The seven sites serve customers throughout their product lifecycle, from preclinical development, through trials, to launch and market supply. We are currently supporting about 250 molecules within the network.

Can you provide an approximate split of the lifecycle stage of the molecules supported by the unit you manage?

At the moment it is a pretty even split, although we are looking to grow our IND (Investigational New Drug Application) space. The split is about 25-30 percent in IND, another 30 percent in clinical trials phase I and II, and a third in phase III and commercial, but that is just because of clinical attrition. We have the highest number of commercial molecules on the market, which suggests that Lonza is the partner of choice for those looking to outsource, whether they are small biotechs or large pharma companies. As of today, we have about 50 large molecules launched.

You explained that Lonza operates seven mammalian manufacturing sites around the world. Can you talk about the Porriño, Spain plant and how it fits into the network?

The Porriño, Spain site has been part of the Lonza network for a long time. There, we have a multi-product production facility with four 10,000L bioreactors and a purification train to support clinical and commercial supply. The expertise within that team is world class.

We use the Porriño site as a centre of excellence, bringing new employees or operators from the entire network for training. MSAT teams come to Porriño to learn how to introduce a new products into a facility. We also use the site as a launch site. The team offer all of this, in addition to their day-to-day work, which is commercial manufacturing for three or four large pharma companies.

After visiting the Porriño site, I was very impressed with the technical capabilities and how they recruit from Spanish universities. Spain has really strengthened its technical pool of knowledge. Working with the human resources team, I have learned that the country has invested heavily over the last decade in strengthening its sciences curriculum. Spain’s effort has benefited many companies that operate sites in the country, including Lonza. We use it as a pool of talent, moving experts around our network, and take it in consideration when looking to future investments.

To what extent did COVID change the needs of Lonza's clients and the way you look at supply chain management?

COVID had a two-fold effect for the company. We had many pharmaceutical and biotech companies looking to develop COVID-related treatments and vaccines. There were many different therapeutics coming to our door with large volume requests and short timelines. At the same time, the world and the industry had to deal with the impact of the pandemic on our own workforces.

The situation forced us to look at how our systems and processes were able to deal with such high demand. We had to be careful with our planning to not overorder raw materials, while at the same time ensuring that materials showed up in a safe and secure manner so that our customers could avoid delays. We transformed the way we worked, choosing to implement a more robust automated system for supply chain management.

From our customers point of view, they are aware of their supply chain and where their risks may lie. Of course, the larger the company, the more eyes on its supply chain; smaller companies rely on Lonza to provide a secure supply chain.

Due to the innovative nature of the industry, we often encounter clients with unique R&D approaches that require highly specialised products and materials that come from different sources around the world. Our role is to help them reduce costs and increase quality, which is why our teams will come up with solutions regarding particular materials or ingredients. For instance, our quality teams may have tested a salt or resin that performs similarly and offer another source that can provide a safer supply. Many of our smaller clients come with an R&D mindset, which is great, but Lonza is commercially minded and, after decades of experience, can help them build a plan to reach commercialisation.

Where is the industry on the road to supply chain stabilisation?

Across the industry, the significant demand for COVID-related products and services meant that many non-COVID clinical trials had to be delayed, but they are now coming back. Fortunately, our suppliers have built additional capacity and are able to respond to that high demand for materials.

Our expectation is that the market will be in the process of stabilising during 2022 and 2023. Lonza has crafted a supply chain taskforce, which meets every week, that looks at every SKU and materials that may be at risk.

What other trends affecting the CDMO industry do you believe our audience should know about? What does it mean to be a flexible CDMO in 2022?

Customers, depending on their size and the product they want to bring to the market, have, over the last six to seven years, looked for innovative models to work with CDMOs so they can bring a product to the clinic and market faster.

In the case of a possible blockbuster product, they would have to build whole new facilities, investing hundreds of millions. However, the last stages of drug development, up to commercialization, carry plenty of uncertainty and not all companies can or are willing to take such a big risk. If a product does not succeed in clinical trials, the customer might end up with underutilised plants which is why some choose to outsource 100 percent of supply. Somewhere in the middle we can find creative options, hybrid models where they outsource part of their supply to CDMOs. Lonza has pioneered that joint-venture model that allows partners to have flexible capacity.

Moreover, the number and types of molecules has exponentially grown. Ten years ago, we saw the standard monoclonal antibodies experience a boom but, if we look at today’s pipelines, we see that the number of modalities and molecules has grown as the industry looks for more efficacy and targeted therapies. Bioconjugation is a rapidly growing space, so are gene therapies.

Personalised medicine means specific targets based on a particular molecular profile of a patient population; it means that historical therapies such as anti-TNF monoclonal antibody might not be the most efficacious molecule for many patients. Companies are tailoring their therapies to specific disease indications and signalling pathways, which means that Lonza and other CDMOs must be able to develop and produce those different types of molecules.

Fewer companies are going to want to build big facilities for multi products like that. So, if CDMOs have that capacity, and they build infrastructure within their network to support many molecules out of one asset, they will be able to offer a more cost-effective solution. From the perspective of supply chains, project management and operations, if a company only needs a few batches, it will be better to outsource them to a CDMO.

This is true from a technical perspective, too. Lonza is developing that expertise so it can manage and produce specific antibodies, complex proteins, recombinant proteins and bioconjugate molecules. Generally, pharmaceutical and biopharmaceutical companies want to focus more on

their R&D and less on figuring out the nuances of manufacturing unique molecules.

Is there another topic we have not touched upon that you would like to mention?

We have spent quite some time talking about initial IND filings and bringing a product to clinical trials, but where we also see a need in the market is at the end of the R&D journey. The move from phase II to phase III is the toughest hurdle, the one with the highest failure rate. We have a number of biologics clients that are in a challenging situation because of COVID, facing much longer lead times on materials. There is a limited capacity in the market; it is can be tough to find phase III capacity. They know that planning far in advance is key, but they have not had their phase II read out. They must make a huge financial commitment without any guarantee that their molecule is moving to phase III.

Lonza is looking at creative models to support customers to help them have the best of both worlds. The objective is to help them secure that capacity, ordering material that in the case of a poor readout can be repurposed for other molecules, helping to mitigate their finan

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