

At the Forefront of Innovative Therapeutic Excellence Since 2006

Mr. Aldo Braca, the founder and CEO of BSP Pharmaceuticals speaks with IPI explains how BSP will consolidate and expand offering of the highest level of services and technology necessary to produce innovative drugs.

Q: BSP Pharmaceuticals has been at the forefront of the fight against cancer since 2006. Can you tell our readers the brief history of the company, how the company started and your growth so far?

A: BSP was created with the mission to become a valuable and trustable partner for innovators, engaged in the research of new effective therapies against cancer. Our original focus was on small molecules, mostly used in classic chemotherapy, but very soon, with the objective of supporting innovative therapies, we also found ourselves engaged in manufacturing biological large molecules as they were more promising innovative products for new generation of oncology therapies.

After successful results and receiving certification of our quality system, we were capable to meet requirements of the most demanding regulatory agencies, our growth has been driven by the increased demand of capacity for Oncology products (that was mainly planned as part of the intelligence work at the beginning of the project) and by the strategic decision to strongly support the development and evolution of ADCs and oncology biological derivatives.

Operating world class technology, paying attention to market demand and subsequently investing to expand available capacity which could be offered to partners, have been the most important hallmark of BSP.

Now the company has a consolidated role in supplying anticancer products and is a reference for the ADCs scientific

community and is ready to initiate a new step in its history by opening capacity for additional therapeutic areas.

Q: With all the different health issues your company could have explored, why did your company choose to go into the oncological research and development?

A: In 2006, when BSP Pharmaceuticals was incorporated, the Global Pharma Industry was experiencing a serious and extended shortage of oncology drugs, as well as a lack of products that could be available for patients worldwide. This issue arose mainly due to a general insufficiency of qualified manufacturing capacity suitable to cover the global increased demand of oncology therapies which was made worse when the European and American Agencies formalised regulatory actions against consolidated CMOs who were forced to temporary or permanently close production sites.

As a result of this emergency, Pharma Companies had to work hard to assess their outsourcing strategy and partnership selection processes. Companies started to look for reliable partners that could ensure the proper level of technology and flexibility to cover their needs in combination with consistent reliability to comply with the highest quality requirements, applied by worldwide Regulatory Agencies.

This scenario outlined a space with a high potential for developing a new project that could be specifically designed to satisfy a clear need and defined the space where our company wanted to enter.

Q: Your company focuses on essential elements of its supply chain safety, clinical and commercial production. With this in mind, how have you made a difference within the industry?

A: As a new player in the arena, BSP has been differentiating from the already consolidated CMOs by offering specialised, world class technology with a strong aptitude to look at innovative compounds, new class of products, new modalities and developing a range of capabilities designed to handle intricacies associated with the manufacturing of complex formulations.

Of course, the first point of differentiation is the initial decision to focus on a specific therapeutic area (Oncology), instead of opting for a wider basket of compounds and products. On one hand, this initially I looked like we were limiting our business opportunities, but on the other hand, this enabled us to clearly characterise the company and stand out as a specialist in the services we were offering.

The second point was the choice to apply the highest standard of technology and develop a full contained facility suitable to safely handle High Potent APIs, which is normally used to manufacture oncology drugs.

An additional point was the possibility to cover the entire life cycle of a product, from pre-clinical to clinical and commercial phase, combining development services and cGMP capability, with enough flexibility and capacity to quickly address forecast's variations and offering an end-to-end solution for pharma.





Last but not the least, it is our attitude to continuously upgrade and increase the level of services and capacity available for existing and new partners, while also supporting the rise in forecast and growing market demands.

Q: What major events have occurred in the industry and what has been its effects?

A: As the average age of the population in developed nations increases and the request for treatments of aged-related pathologies are becoming more and more relevant, the demand for innovative cures that could be beneficial for patients has been growing accordingly. Pharmaceutical and Biopharmaceutical sciences continue to find new applications, new modalities and new classes of compounds that can improve life expectancy and standards of living for people effected by chronic or degenerative diseases. We expect that this trend will continue to grow and BSP will be requested to consolidate and expand offering of the highest level of services and technology necessary to produce those innovative drugs.

Q: With ADCs being a relatively succinct form of Cancer Treatment (with only 56 companies producing them in 2019), can you tell our readers how your company's development stands out from the rest?

A: We have always been interested in ADCs, not simply as new classes of compounds that could be significantly beneficial in the fight against cancer, but more importantly as a new scientific approach to oncological diseases. By generating an immense number of new

ideas helping to treat cancer, we wanted to stay close to this scientific community with the objective of helping scientists to execute their ideas. With this in mind, we communicate and listen to the scientific community to learn and understand their needs and offer customised solutions to help them in promoting the progress of ADCs in the clinical and commercial environment.

In 2011 we developed and introduced the concept of "integration of services" and in 2013 we have been the first CDMO

to offer an integrated supply chain for ADCs. Manufacturing drug substance in conjugation suites and drug product in fill finish suites, all under the same roof and all combined with QC and development services.

We also designed our capacity with flexibility to handle small/mid-size batches suitable for initial clinical needs and bigger size for commercial requirements, with the possibility to scale up process to 6.5 Kg mAb with a significant improvement, compared to





what other CMOs can offer. Finally, we have high annual capacity for either DS and DP manufacturing.

We are currently engaged in a significant number of ADC programs in different clinical stage and producing 7 of the 11 ADCs approved for commercial use, applying several conjugation technologies and payloads, with high annual capacity for either DS and DP manufacturing and ongoing expansion that will be available in the next months.

In the last decade, BSP has become a reference point CMO for the ADCs'

community and wants to consolidate this role by continuing supporting the growth of this class of compounds.

Q: Innovation is one of the Company's key values: This brings forth the question of if or when you plan to expand into other areas? Which areas are you expanding into?

A: In 2017 BSP approved a new step in its strategic growth plan, which incorporated significant investments on the site, which will drive the future growth of the company.



The objective of this plan is to continue the process of integration of already available services initiated few years ago and expanding to other therapeutic areas.

Considering how Big Pharma and Small Biotech's are distinguishing their pipelines by prioritising their focus on oncology, immunology, immunotherapy and evaluating the growing number of biological compounds entering as NBE within the clinical and the commercial phase, we started the construction of a new site in our plant in Latina, Italy in 2018.

This plant will incorporate the same level of technology we already use on site but will be dedicated to the manufacturing of non-cytotoxic products and will host six filling lines with significant capacity for liquid and lyophilised formulations.

The original plan was scheduled to be completed by 2026, but with the crisis created by the worldwide COVID-19 emergency and the subsequent extraordinary need of qualified capacity for strategic products (like the ones BSP is already producing) BSP pushed the top Management to speed up the completion of the project, which is now expected to be finish by end of 2023.

With this new extension of capacity, the Company intends to consolidate its current role in producing Oncology drugs as well as expanding into additional therapeutic areas like Immunoncology and immunotherapy by keeping the original focus on innovative compounds.



Aldo Braca

Aldo is the Founder and CEO of BSP Pharmaceuticals and has several years' experience in the pharmaceutical business. Aldo has been President of Patheon Europe, a subsidiary of Patheon Inc., since 2010 and developed the company in Europe starting from 1999. Aldo's career includes 29 years with Bristol Myers Squibb European operations, where he held positions of increasing responsibility. He served Bristol Myers Squibb, as President – Worldwide Manufacturing Operations at Medicines Group.