

Interview: Giuseppe Cassisi CEO, Doppel, Italy



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Doppel has been selected as the nucleus for significant investments in the CDMO industry by PE firm Trilantic Capital Partners, according to recently hired CEO Giuseppe Cassisi, who shares the organization's plans to invest in both greenfield facilities and M&A in the coming years.

Italy's pharmaceutical exports are growing faster than any other country; how has this trend been reflected in terms of pharmaceutical outsourcing?

Pharmaceutical manufacturing is very important to Italy as a country and, according to a recent survey performed by the CDMO Association, Italy is in fact the leading country within Europe for pharmaceutical outsourcing. Germany comes in second place with France in third position. As such, Italy plays a critical role within the European pharmaceutical manufacturing industry. This leading position is the result of a strong base of expertise and culture around pharmaceutical manufacturing that has developed over several decades and today the base of pharmaceutical manufacturing capital is very high; the average plant in Italy is more sophisticated than in many other European countries and there are a number of truly state-of-the-art facilities in the country. While Italy's position and leadership in this regard has not always been well known; those working in the pharmaceutical industry today are generally aware that Italy is a center of excellence for pharmaceutical manufacturing.

Doppel has played a critical role in developing the industry's culture, as for many years it was the leading Italian-owned CDMO in the country. In fact, our President Mr. Paolo Lanfranchi actually founded the CDMO group within Farindustria and served as president for the first two terms. Indirectly, Doppel contributes significantly to Italy's pharmaceutical exports via our clients, as nearly 40 percent of our EUR 90 (USD 102.6) million revenues are generated by brands that are eventually sold outside of Italy. Moreover, Doppel has a presence via our clients in markets not just across all of Europe, but worldwide in countries like Russia, China, South Korea and Brazil. For the time being we are not present in the US, but three projects are underway to get FDA approval for certain production lines; we expect to have our first pre-approval inspection in Q1 of 2017 pertaining

to an orphan drug that will be manufactured at our Rozzano site.

Last year, 21 years after the company was founded, a new investor joined Doppel's ownership by acquiring 90 percent of the company's equity. What are some of the new directions Doppel will be taking under the new ownership?

Doppel is very glad that Trilantic Capital Partners, who now hold 90 percent of Doppel's equity, has more than just financial objectives for their investment in Doppel, but rather a clear industrial vision for what Doppel can achieve with their support. Trilantic very much considers Doppel to be a strong base in the CDMO industry that can be built upon through organic growth, investment in greenfield facilities, and the acquisition of other businesses in the CDMO industry. For a private equity fund, they have expressed a willingness to be involved with Doppel for a significant period of time, at least five to seven years, so we will have the time and support to execute substantial investment plans and expansion strategies with the goal of growing in terms of size and presence across diverse geographic regions. So far the transition has been very smooth, as has been the adjustment of expectations for Doppel's future, yet we have only just begun to lay our expansion plans for the coming years.

Sitting on the cusp of what will certainly be a period of significant transformation, what are some of the key aspects of Doppel's corporate identity that it will be important to hold on to and strengthen?

When you exclude the multinationals, Doppel is one of the largest CDMOs in Italy, yet Doppel has avoided losing touch with clients needs as it has grown. Today, the company is widely considered to have an impeccable reputation and be an extremely reliable partner. From the beginning, Doppel has always worked with the utmost respect for quality, safety and ethical concerns, and today five of the top ten "big-pharma" companies are amongst our base of 100 clients, along with some of the leading multinational generics players. Certainly, our entire team is extremely proud to be part of this high reputable organization that works with some of the most advanced and sophisticated companies in the global pharmaceutical industry.

Today, this team consists of 470 employees in total with roughly 30 working in our R&D department. Doppel considers itself to be a CDMO, with significant emphasis on the "D", and as such our 30 R&D personnel are essential to our ability to deliver the best service possible to our clients. Given our team's significant expertise in developing new products and formulations within our areas of capability, Doppel knows how to develop a product for our clients with a reasonable price and timeline, and then can produce the product for years on end with the highest degree of reliability.

What are the main investments that Doppel is considering making?

Our first priority will be to begin construction of a new facility with certain capabilities that we feel will be necessary if we are to become a "first tier" CDMO at the global level. Specifically, we would like to invest in the injectable field, specifically in capabilities relevant for small to medium volume biotech products; vial fill and finish technology, pre-filled syringes, and lyophilization. This area is a priority for us as we see the global pharmaceutical market trending away from large volume small-molecule drugs with large patient populations and towards biotech drugs with small target populations and thus low-volumes, but high prices. As such we are aiming to develop the capabilities to produce and participate in the development of such products. Of course, timelines are also a consideration and it will take some time to build a facility and begin generating substantial revenues, so it is in Doppel's interest to begin the work as quickly as possible.

In terms of significant investments, the second priority will be identifying potential targets for acquisition that fit well with Doppel's existing business and vision. While Doppel is proud to be a

part of Italy's exemplary pharmaceutical manufacturing community, we will consider acquisitions in any country with a well-developed and capable manufacturing industry, including the US, Canada, UK, Germany, France and elsewhere. Our sites in Italy will continue to play an essential role within our organization and certainly the wealth of bio-pharmaceutical manufacturing experience we have access to in Italy will be an asset to be leveraged as we grow, but at present our aim is to internationalize our business not only in terms of our client base but also our operations. Timing wise, if we find the right acquisition target with the right fit for our organization, we will be willing and able to move forward with such a transaction relatively quickly and it is certainly possible that Doppel will end up integrating an acquired business contemporaneously with the construction of our new greenfield facility.

Finally, it's important to recognize that significant organic growth possibilities still exist for Doppel. We have available capacity, can certainly expand the capacity of our current facilities if needed, and are always discussing new potential projects with clients. In fact, in some cases Doppel may be willing to make some capital investments to enable us to take on certain projects for our clients. As such, while we may be making conspicuous investments in new facilities over the coming few years, Doppel will certainly remain committed to growing and strengthening our existing business lines organically.

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