

## Sterile Pharmaceutical Products for Hospitals



**Fred Defesche**  
Chief Executive Officer  
Beloteca, Inc.

**CEOCFO:** *Mr. Defesche, your site indicates Beloteca is focused on the development of pharmaceutical products, emphasizing sterile pharmaceutical products. What are sterile pharmaceutical products?*

**Mr. Defesche:** Sterile pharmaceutical products are essentially hospital based products. These are products that typically come in glass vials or prefilled syringes as opposed to the more typical products that most people are familiar with, which would be tablets and capsules. Our typical products are the smaller generic products that do not have much competition. Additionally, we are also performing some product reformulations. This is where the product was originally designed many years ago but with changes in how the product is used and advances in medicine; these products are not in the ideal presentation based on how they are used.

**CEOCFO:** *What is an example?*

**Mr. Defesche:** For example, products where a new indication for the product exists where the usage profile could be different from the original indication. This could include where a product was previously in a vial and needed to be reconstituted, which means to be mixed with another liquid to be diluted to a usable concentration that can be given to the patient. In these instances, we are reformulating the product in that more diluted form to make it easier for the hospital to use and thereby reduce medication errors. Another example is where the amount that a patient receives as a dose has changed and the presentations on the market do not work for the new doses. For example, if a patient many years ago were required to have 40 milligrams, but today the optimal dose is 100 milligrams. The currently marketed products were designed around the 40 milligrams and in order to achieve a 100 milligram dose you would have to buy three 40 mg containers. In this case we would develop the 100 milligram dose to make it easier to dispense the proper dose.

**CEOCFO:** *Have hospitals been looking for better products or do they not think much about it and you will need both to introduce yourself and to educate them as to why they should be thinking about improvements?*

**Mr. Defesche:** These kinds of changes have been performed on some products over the years. The ability to penetrate the market with these products does require a bit of education but, hospitals are very cost conscious these days, especially with the pressure from the insurance companies to reduce the cost of treatment. This pressure to reduce costs both for the drugs and labor are the primary drivers that make these types of changes easier to introduce. The difficulty in getting market penetration for these products is reduced with the fact that we are focusing on modifications of product that are already on the market. We enable the hospitals to save money by needing to buy one container instead of three or instead of having to buy a vial and a diluent; they can just buy the product and they do not have to use the labor to prepare the product into the final form. These changes do not change the practice of medicine and are simply cost cutting measures for hospitals. With insurance companies reducing their reimbursement rates this is the easiest way for hospitals to reduce their expenses.

**CEOCFO:** *Where do you fall in the regulatory spectrum?*

**Mr. Defesche:** The work that we do internally with the new lab that we just opened up is non-GMP development work. This work is in support of developing our products from a formulation and analytical perspective and does not involve anything where the FDA would come to inspect our facility. For FDA regulated activities, we use a variety of contract manufacturers. From the compliance perspective, it is the people that we are outsourcing our work to that have systems to comply with FDA requirements and would be inspected by the FDA. Within the FDA, all the products that we develop fall under the jurisdiction of the drug division of the FDA as opposed to the devices or biologics divisions.

**CEOCFO: *Would you tell us about your new lab?***

**Mr. Defesche:** Previously, we would always use contract development facilities. When you are starting to go through the development of a product, there are many twists and turns that could occur. When you are using contract labs, that usually slows your development down because the labs want to get a change order in place to reflect the new costs that you are going to incur for the additional work, or if you are just wanting to do some quick feasibility of some projects, if you are using a contract lab, you need to get quotes put in place before they will start doing the work. With us having a small formulation and analytical lab, we are able to quickly evaluate some molecules, do some preliminary testing, and then we can actually complete the whole development internally. This gives us control over the personnel to be able to optimize the work and adjust with the requirements of each specific product.

**CEOCFO: *You hired Dorla Mirejovsky, Ph.D. as chief scientific officer not too long back. Will you need to add additional staff because the lab is on premise?***

**Mr. Defesche:** Dorla Mirejovsky, Ph.D. is our chief scientific officer. I worked with her previously when I was at Spectrum Pharmaceuticals. Yes, we have hired someone to manage the lab. The lab that we have is a smaller lab, so we anticipate bringing on a couple of entry or medium level scientists to work there over the coming months.

**“Beloteca opens lab to bring sterile pharmaceutical products development in-house.”- Fred Defesche**

**CEOCFO: *How do you decide where to focus first?***

**Mr. Defesche:** Our team’s experience lies in the generic injectable side. That is where we have initially focused our product selection. However, we remain opportunistic with the products we develop and will not limit ourselves to only injectable products. We acknowledge that we are smaller company and for the big products that are fairly straight forward to do, it is very difficult for us to compete with the likes of Teva, Mylan and Fresenius. We focus on products where there are definite barriers to entry and those barriers can be a wide variety of things such as lack of available drug substance, complex formulations, limited batch size, and unique presentations. Essentially the kinds of products that create headache for the bigger companies where would not pursue these products and would simply develop another product that does not have these headaches. Our selection of products with niche markets sizes in the 10 to 20 million dollar range also reduces competition from the larger companies.

**CEOCFO: *Do you have a strategy in place about how you will be reaching the hospitals? Will you be going directly? Would you be inclined to work with distributors?***

**Mr. Defesche:** That is exactly what we are doing. We are developing the products and taking them all the way to FDA approval. For the sales, we are entering into sales and licensing arrangements for our products with sales and marketing organizations who would sell these products for us. We focus on what we do well, which is developing products and getting FDA approval. Similarly, we will partner with companies who do the sales and marketing very well.

**CEOCFO: *Do you have products now or are you still in development?***

**Mr. Defesche:** We are in the early stages of development. We expect to do our first FDA submission late next year and our scope is to develop about four to five projects a year. Starting next year, we should have roughly two to three FDA submissions and then we should have one going every quarter thereafter.

**CEOCFO: *What have you learned from past experiences that has helped you so far and that you feel will help you as you move along?***

**Mr. Defesche:** This is my second startup company. With the first company that I founded, I learned the benefits of controlling things in-house, maintaining the ownership of the intellectual property that you develop, and not giving away an opportunity for a short term in-flux of cash, but sticking it out for the long haul. I also realized the value of putting a good experienced team around you because you cannot do everything yourself. Especially as a smaller company, you have to rely on your team to be able to succeed effectively.

**CEOCFO: *Will you be seeking any funding or partnerships as you move forward or can Beloteca handle it on its own?***

**Mr. Defesche:** Right now we have done a small friends and family raise for finances, which we anticipate should take us through the first five products. We initially focused on friends and family who have benefited nicely with some previous investments they have done with me. We anticipate opening up a new round of funding in March or April 2016. This second round should be our last as it will take us to profitability and self-sufficiency.

**CEOCFO: *Has a similar concept been tried?***

**Mr. Defesche:** There are many small generic companies that do similar things. Where I think we are unique is that we really focus on the difficult products that have a little more complexity and will take more due diligence to work through some of the issues. We realize that some of the products we are developing, other people are working on as well. I think our experienced team will enable us to be successful and we may get lucky with a few of our products and be the only generic on the market. With generics, it is a numbers game where you develop five products and one of them is awful, two to three are average and then you have the one really good one. Therefore, we have to develop many interesting products to be successful.

**CEOCFO: *What gives you the confidence to tackle the products that others will not or do not think are worthwhile? How do you know that you are in the right direction?***

**Mr. Defesche:** You are never sure whether or not you are headed in the right direction until it is too late. Our confidence in our success comes from our team. The experience that our team has in developing difficult products lets us believe we will be successful. If you develop enough difficult products, you know you are going to be successful with several of them. You may have some failures and some may not make it to the market, but you have other ones that will succeed. The team that we have has tackled various significant challenges in products in their careers, so we are able to use our experience to work through tough challenges. My mindset is if when you are developing a product and there are no issues that arise, that is where I start worrying that we did selected a product that was too easy and therefore competitive. If we have all sorts of challenges that we did not expect to see, those are the types of projects that we get excited about because we have to work through those, but it also means that other people are going to have to work through those same issues.

**CEOCFO: *Why look at Beloteca today?***

**Mr. Defesche:** Beloteca today is a small company but we have very big goals to be able to focus on products where the current need is not being met either in the presentation of products or where generics are not available today. We plan to fill these needs.

**CEOCFO: *Will the products be under the Beloteca name so that a hospital may say they are using two or three products from Beloteca so why not look at the rest of them, or would each product stand-alone?***

**Mr. Defesche:** We will be using sales and marketing organizations that will sell our products under their respective names. Eventually, once we have a basket of similar products, then we may introduce the Beloteca label however that is several years out. Our current plan is to sell our products under the names of the sales and marketing companies that are selling the products.

**CEOCFO: *Final thoughts?***

**Mr. Defesche:** With a small group of people, you really can be successful in starting up a pharmaceutical company and it does not always take a big venture capital fund to be able to push things through and make it happen. When you get a dedicated team together, you can make some amazing things happen. I believe we have that team. Taking advantage of the responsiveness and quick action you can have with a small organization is a positive that will enable us to succeed. We have the ability to have the leaders of the company get together very quickly and make decisions will enable us to be extremely responsive to the challenges we face and that is a huge advantage.

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