Aldo Donati – CEO, IBSA USA



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Aldo Donati, CEO for Swiss firm IBSA in the USA, discusses the challenges for European mid-caps in expanding to the US market and his portfolio strategy for ensuring future successes for IBSA USA.

Can you begin by outlining your career trajectory and what first attracted you to the opportunity at IBSA USA?

I grew up in Florence Italy and attended the local university with the initial aim of pursuing a career in international diplomacy. While studying, I interned at Boehringer Ingelheim in Germany, which was my initial exposure to the pharmaceutical industry. In addition, my whole family is dedicated to the healthcare sector, we have physicians, pharmacists, pharma industry executives, etc. so my career in the international pharma industry is undoubtedly a mix of serendipity and genetic predisposition.

I professionally grew within the Bristol Myers Squibb organization working in their US Division, international business development and then in multiple Overseas assignments. After Bristol Myers Squibb, I joined King Pharmaceuticals international division, in Charlotte, NC.

As King began to move under Pfizer, I started my own company – Compass Pharmaceuticals – helping European businesses enter and/or navigate the US market. More recently, Fidia Farmaceutici asked me to help them establish their business in the US. A full-time project that I accepted with enthusiasm as the idea of helping an Italian company enter the US market was one

of my career ambitions. The experience was rewarding both professionally and personally and I guess it did not pass unnoticed as a couple of years ago I was asked to do the same for Institut Biochimique SA (IBSA). That was the beginning of the current collaboration which is also professionally very rewarding but best of all, I can do it with the same team that came together, and whom I enjoyed working with in prior projects.

As you have mentioned, historically, three of the key challenges for European mid-cap companies setting up shop in the US have been the market size, the level of investment needed, and the differences in management culture. Are these challenges still as strong today?

The US healthcare system is based on a complex system of private providers and insurance companies that is regulated both at the Federal and State level. The market is very large equally geographically and demographically making commercial operations and supply logistics quite challenging and expensive to manage. Finally, the environment is in continuous evolution compounding its complexity. That said, in the global economy we are operating in, the US market cannot be ignored and if successful, the financial rewards and growth opportunities can be extremely interesting for an expanding pharmaceutical company. While larger corporations have the critical mass and leverage to more easily navigate the market complexities, smaller and medium-sized companies such as IBSA need to rely on increased flexibility of their business model, fast decision-making processes and ability to think and adopt out of the box strategies.

Can you expand on the specific challenges that IBSA’s products are facing in the US market?

Levothyroxine (T4) formulations are used by 15 million people in the US, it is a very large and well-established market. Many patients – we believe about 20-40 percent of the patient population – have conditions, take concomitant medications or have dietary habits that make more difficult the absorption of traditional tablet formulations or react adversely to excipients and fillers typically found in tablets.

Our unique T4 liquid formulations, available in capsule and oral solutions forms, provide an optimal solution for many of these patients. However, awareness of our products’ benefits, access to reimbursement or cost-effective DTP access of our products remain a challenge for many of these

patients. These two challenges are the focus of our commercial efforts and activities in the market.

When we talked to your colleague Maleša Ulrico Sidjanski, IBSA's Head of Swiss Business Operations, he mentioned that the company has two focus markets: the US and China. How do you see the company's US operations developing so that more patients here can benefit from your products?

Our Tirosint product franchise is doing very well and growing at about 30 percent in terms of utilisation year on year in a widely genericized market, which shows a recognition of the value of the formulations by both patients and physicians. However, we are still very far from their most logical utilisation. Many of the European markets where our formulations are available have much higher adoption. So, we still have a lot of work to do.

Better communication and experience with our products will be key to achieving our goals. We need to convey to physicians the differentiating benefits of our T4 products compared to tablet levothyroxine formulations and support the clinical evaluations that can provide clinical validation. For the patients, we need to encourage them to discuss with physicians the conditions that they are in. If they do not feel well-controlled or comfortable on their current formulations, they should discuss what are the available alternatives.

In what part of its life cycle is Tirosint currently in? How far from its full potential in the US market is the product?

Right now, our utilisation is still small relative to the size of the US market. There are 20 million hypothyroid patients in the US, 14.5 million of which are treated with T4 products. Tirosint adoption is still small in relative terms. We have the potential to grow exponentially if we are successful in implementing our communication, awareness and access strategies.

Is IBSA considering bringing other products from its global portfolio to the US? Is there a particular category of products that could be a good match for the US market?

Besides endocrinology, IBSA is a leader in several therapeutic areas including sports medicine/orthopaedic, fertility, dermo-aesthetics, etc. It is our plan, to leverage the IBSA global pipeline to expand our US business. Before the end of this year, we are going to introduce a new

once-a-day diclofenac patch entering the orthopaedic/sports medicine area.

Another very interesting and high growth area for IBSA globally is dermo-aesthetics. Our colleagues in Europe have developed a very comprehensive dermo-aesthetic portfolio which includes an innovative Hyaluronic Acid-based Bio-Remodelling product called PROFHILO that has been extremely well received wherever it has been launched. We hope to bring soon that line to the US market.

Being able to leverage the business over three and possibly more business areas would allow us to have a much stronger foundation to support our investments, accelerate growth and achieve significant operational costs efficiencies.

The ‘Made in Switzerland’ stamp has a lot of appeal in many geographies. How does it differentiate you when battling for market share with generics that originate from geographies such as India and China?

IBSA production facilities in Switzerland for Tirosint capsules and oral solution, are state of the art and provide products with high levels of consistency and reliability; something that is very important especially in narrow therapeutic range formulations like levothyroxine, where small-batch variations and formulation inconsistencies can result in different outcomes of treatment.

Also, in this challenging time of COVID-19, it is an added level of reassurance, welcomed by both physicians and patients, that our products will be available, without disruption of supply, with the same level of quality and quantity.

What message would you like to share with your fellow North American and global executives about IBSA in the USA?

IBSA is a company that develops innovative products that are an improvement on existing formulations addressing unanswered therapeutic needs. It may sound simplistic, but we do better products than whatever else is available in the therapeutics areas we enter. We look forward to continuing to grow our presence and product availability in the US and be part of this exciting and challenging market.

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