

Interview with Francesco De Santis, President, Italfarmaco

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Italfarmaco counts amongst the few players who really sustained the growth of the Italian pharmaceutical industry in the past 10 years.

Which specific values would you quote as keys to success that enabled the company not to fail like others and get where it is today, keeping growing organically yet remaining independent?

A number of success factors, that are inherent to Italfarmaco's identity, have allowed the company to maintain its growth in the past 10 years. First of all, it is a family company- therefore submitted to financial constraints, but on the other hand able to establish long-term plans without being affected by the market's ups and downs. In addition, Italfarmaco always remained committed to research and innovation. Even in the most challenging times, investments in this field have been maintained, and the facilities have continuously been upgraded. By chance -but also as part of its strategic goals- the organization managed to maintain its strategy in a consistent way. In times when bigger players started doubling their sales force in order to take advantage of the market's extremely high growth rates, Italfarmaco did not see any sustainable long-term advantage in following such a trend, and decided to keep its initial targets. Therefore, the company did not experience the same impressive growth in turnover as some of its counterparts, but on the other hand, it did not have to drastically downsize its sales force more recently. Italfarmaco proved to be highly flexible and responsive to change, by progressively developing in foreign markets and in several business lines.

What have been the main guidelines of the reshuffle and expansion of the group's structure, since you took the reins of Italfarmaco Holding?

Whereas Italfarmaco's main driver is research, the second one is surely international expansion. A consistent share of the revenues generated is reinvested to fulfill global ambitions and conquer new markets. Having first targeted Southern European countries as a priority, the group developed in Greece, France, Portugal, Spain and Switzerland. At the same time, subsidiaries have been opened in Russia and Chile, therefore opening doors to other regions. Italfarmaco always considers each domestic market as an integrated reality made of different segments- from generics to high-tech biotech drugs. Therefore, specific strategies have been developed for each business line, and it is generally easier to grow in new markets through specialization, by focusing on a few segments.

Looking at how such strategy converted into numbers, how do you assess 2008 in terms of growth and revenues?

Italfarmaco closed 2008 with a turnover of Euros 404 millions. The growth was mainly fuelled by the Italian, French and Spanish operations. Unfortunately, the generics business that mainly relies on the USA has been strongly affected by the Dollar's devaluation and registered negative results, with a 20% decrease of the sales in value- despite an unchanged performance in terms of volumes. For 2009, the group expects a global growth rate ranging between 8 and 9%. The first quarter of the year has been in line with such objective, with a 8.8 % growth, and a positive contribution of the generics business.

Now that a strong business model has been built and enabled to maintain a stable growth, on which main business lines will you focus to push the growth to the next level taking into account current challenging market dynamics?

The gynecology market already accounts among Italfarmaco's main targets and shall be further reinforced. In this field, the company is really driven by women health more than product themselves, and is adequately developing a series of compounds covering these needs, especially those linked to pregnancy. In addition, the hospital sector is becoming increasingly important. Italfarmaco is already a leader in Italy for thrombosis treatments, and expects to soon play a similar role on a global scale. Last but not least, building a strong CNS portfolio over the next five years is another key mid-term target. As it is increasingly hard to find new molecules in order to offset the expiration of important patents by launching new blockbusters, Italfarmaco is strongly betting on R&D of new drug delivery systems.

What do you expect from the new systems developed?

It is worth highlighting that according to its size, Italfarmaco perceives as “blockbusters” products generating revenues in the range of 100 million and therefore sees the development of new “blockbusters” as a more accessible reality than big laboratories. However, product lifecycle management is a crucial activity. For this reason, Italfarmaco is devoting 50% of its time and resources to develop new pharmaceutical formulations able to deliver incremental results to the patients. Amongst those, a topical formulation for vaginal atrophy linked to menopause is currently ready for registration and will be able to deliver 1/10 of the estrogen amounts available on the market. These types of enhanced delivery systems can be highly beneficial to the patients. Italfarmaco’s fully integrated structure enables to cover all the cycle, from R&D, to manufacturing of both chemicals and finished drugs.

How would you describe the investment policy that enables to ensure both the plants reliability and their technological cutting edge in the long term?

The audits conducted on a regular basis by regulatory agencies worldwide expect laboratories to have each one of their production sites inspected regularly in the case of Italfarmaco, such quality pre-requisite applies to its three FDA-approved sites in Europe and one in Brasil.

As Italfarmaco always had a strong international footprint can we expect to see significant changes in its production strategy by relocating part of the production or constructing plants in countries that are more cost-competitive?

The Milano plant is not the most cost effective but its technological excellence makes it a pillar of Italfarmaco that we do not plan to relocate. On the contrary, the Camaçari Plant in Bahia Estate can enjoy Brazil’s favorable tax regime, and a perfect environment to conduct consistent production activities. Overall, the company is more likely to invest in more tax-effective countries when the time comes to open new facilities, instead of relocating the existing production.

Looking at the Italian environment for R&D and manufacturing activities, which assets make Italy as a strategic hub, and where is there still room for improvement to push innovation forward?

In my opinion any law designed to attract FDI in a country shall follow a long term vision and set guidelines for at least 10 years. It has been the case in all the major European countries- Ireland has been the first, followed by Spain that established tax incentives for research, then France where the biotech segment has been strongly stimulated recently. Unfortunately, Italy is not following this trend yet. The government seems aware of the importance of research as a key

driver towards a knowledge-based economy, but consistent laws or long terms tax credits have not been established in this sense.

In this regard, do you perceive the highly decentralized management of the Italian healthcare system more as a challenge or an opportunity for companies conducting research and commercial activities in the country?

Regionalization does not imply any specific challenge in terms of research activities, and can even offer opportunities to small laboratories able to benefit from regional and local funds. However, when it comes to commercialization, the highly decentralized system is clearly an obstacle to the homogeneity of market access throughout the territory. Getting drugs approved in each region requires a high level of flexibility. Surely this is why Italfarmaco has also been growing beyond the Italian borders.

How is the distribution between Italian and overseas turnover expected to evolve over the coming years and in which markets do you see more remaining unexploited potential?

International sales shall grow faster than domestic ones, therefore taking the company towards more international exposure. Indeed, even if the Italian market remained stable in the past five years, Italfarmaco has been able to increase its market share in the country, and now has to strengthen its position overseas. Beyond reinforcing existing foreign affiliates, the group will grow organically in new countries. Amongst the opportunities recently identified, the Turkish market comes as a priority, as well as the Russian one- which offers a challenging environment, yet an extremely high potential to further reinforce the group's existing activities. Overall, international expansion will follow an opportunistic approach without pre-set rules. Organic growth shall account for an increase of 7 to 9% of the existing business over the next five years; but in addition, Italfarmaco will keep looking for in-licensing opportunities in order to complement its strong in-house portfolio and increase its volume by 3 to 4 %.

When it comes to develop new in and out-licensing partnerships overseas, what makes Italfarmaco the partner of choice?

For laboratories looking to hand in their products to a strong European hospital sales force, there are very few alternatives besides Italfarmaco. In addition, we offer an extremely complete oncology line to potential licensees. Thus, Italfarmaco is a partner of choice for both in and out licensing agreements. But it is worth mentioning that the group is looking to establish such collaborations with highly specialized local players. For this reason, when it comes to attract these kind of focused partners, the company's everyday work and results delivered speak for themselves. Performance is

Italfarmaco's best way to increase its visibility, much more than any forum or conference.

Taking into account that Italfarmaco has a clear drive to further reinforce its international leadership, in a context when not so many Italian players managed to reach very high levels of global visibility, what are your personal ambitions for the group over the next five years?

One has to take into account that the late introduction of the patent law in Italy has always left the country a few years behind its European counterparts in terms of research and development. But Italian entrepreneurs can achieve international success. Some local pharmaceutical players proved that the country is catching up on the rest of Europe, and Italfarmaco counts amongst those to a smaller extent. In this context, the group is willing to grow by 10 to 12% over the next five years. Two research projects shall be soon brought to the market, the API strategy might be re-shaped, and presence in Turkey, Russia and South America will probably be well-established by then. All these achievements will contribute to further consolidate the company's excellent track record in a global environment.

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