Alberto Chiesi – President, Chiesi

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The president of Chiesi explains how innovation and a strong focus on quality have led to outstanding growth and have established the Italian family-run business as a significant pharma player around the world. He furthermore elaborates on Chiesi's strategy to maintain growth abroad and reviews the challenge of attracting and maintaining talent in Italy, identifying the need for a public research funding agency to retain Italian talent.

Mr Chiesi, 2014 was a definitive year – 8.4 percent organic growth; EUR 1.34 billion in revenue and being ranked as the 46th largest innovative pharma company globally. Now that we are in March, how have the results of 2015 been in comparison?

In 2015 we achieved a total turnover of EUR 1.467 billion (USD 1.627 billion), which represents an increase of 9.4 percent compared to the 2014 fiscal year. Approximately eighty percent of turnover is generated by our operations abroad, which makes us a truly italic-international company. This tremendous growth was achieved organically without the need for any acquisitions! Spread over our 26 affiliates around the world, we employ over 4,500 people, and collaborate with approximately fifty different distributors and marketers.

We made some significant progress in our respiratory segment as our prime product *Foster*, which generated EUR 500 million (USD 563.5 million) in sales in 2015, proved to be very effective against asthma and chronic obstructive pulmonary disease (COPD) enabling us to achieve and maintain 19

percent market share in Europe and become one of the leading players in this segment. Another significant success was the approval of our innovative dry powder inhaler for *Foster*, which we successfully launched in many European countries. Overall, the cumulative approvals for *Foster* was an achievement of utmost significance to us as it allowed us to further tailor and optimize our offering to doctors, thus helping the patients suffering from asthma and COPD.

In our therapeutic segment, we achieved approval for our new regenerative product *Holoclar*, which will stimulate the regeneration of the cornea, the transparent area forming the front of the eye, which will help patients to regain vital eyesight. This is the first stem cell-based product approved in Europe!

Are there any other product launches we can expect in the short to medium term?

We are working on the *Triple* combination for COPD treatment, putting together a formula that will even further improve the lives of patients; and we hope to be the first to reach European approval for this unique combination as well.

Since we last met you a decade ago, much has changed. The main hallmarks of your new strategy seem to be innovation and internationalization. How have you reconfigured the company to reflect this new reality?

The main driver of growth is innovation and internationalization, which we understood and realized to full success. We adapted our organizational structure accordingly in order to comply with these growth drivers. We classified all our affiliates in three groups—Europe, Emerging Countries and the US—and appointed one Regional Head to each, while maintaining strong management functions such as marketing, finance, compliance and centralized control. We did so in aspiration of the future of our company, which will be mainly outside of Italy.

Much of your growth derives from the US & emerging markets. How are you coping with the recent slowdown in these economies and where do you predict future growth?

Europe will undoubtedly remain the main market for Chiesi. However, our overseas developments will reduce the European contribution from approximately 60 percent to approximately 45 percent as our other divisions grow. The US is currently the market we’re most focused on, although our

current presence there is limited to special care and hospital products.

We have experienced the most growth in emerging economies such as Russia, Turkey, China, and Brazil. However promising emerging economies are though; development itself will pose a challenge these economies naturally evolve to drive an economic protectionist policy, usually raising local content requirements which forces us to manufacture abroad. The consequence is either delocalization of manufacturing capabilities or finding an agreement with domestic manufacturers in order to comply with government policies. Therefore, it is highly likely that we will expand our international manufacturing capabilities in the future in order to sustain our foothold in those economies.

Looking at the US market, which is a very challenging playground for many European pharmaceutical companies, how are you consolidating your position there? Are you considering organic or inorganic growth along the lines of Cornerstone Therapeutics?

A well-balanced mix of organic and inorganic growth will consolidate our position in the US market; we are currently considering some projects in our special care unit which would translate effectively to the US market. *Holoclar* will be one of our pathways to steadying our US presence, although it is a treatment and not a medicine, which means if we want to market it in the US we need to establish a biotechnology company to gain the ability to manufacture domestically and thus comply with the US regulatory framework. I identify significant potential for acquisitions in the US start-up scene, which we will review carefully and seize when the opportunity arises.

Italian firms have sometimes been characterized as isolated family fortresses in an era of pharma mega mergers. What role will partnerships play in your future growth objectives?

Strategic partnerships are of upmost significance in achieving international growth, as it is the gateway to rapidly access new markets, know-how and technology. Especially in the rare diseases segment, partnerships are needed to swiftly tap into know-how. These can either be with universities, or company spinoffs. I am confident that strategic partnerships will become mandatory for all Italian pharma companies that strive for growth.

What is the importance of being a home-grown Italian company? Does it mean anything to your performance as a company?

Italy is traditionally known for its excellent manufacturing capabilities and its brilliant talent pool with great ideas! However, the latter is artificially limited as funding the development of these ideas is challenging in Italy. Consequently, only a little talent remains in Italy as the majority emigrates to the US or other European nations, seeking organizations that have the ability to fund their ideas. Despite the brain drain we're witnessing, Italy has served as an excellent starting platform for Chiesi for 80 years, which is proven by our successful development ever since.

Many industry stakeholders witness and report a brain-drain in Italy. What is Chiesi's position towards attracting talent and maintaining it within its operations?

As explained earlier, our ambition is to grow as a research-based company. Over the years we have continuously invested significantly in research and development (R&D), and are currently working on over forty projects at different stages. As you suggested, we need new talent and maintain that in order to sustain our R&D efforts. While we're focusing on attracting talent in Italy, preferably in Parma, we additionally went beyond usual methods to retain talent; we go where the talent is. Three years ago, for instance, we acquired a small research company operating in Sweden and Denmark and succeeded in maintaining all its staff and integrating it into Chiesi's operations, thus benefiting from the synergies created.

In order to find a domestic solution we need support from our government. We need a governmental agency which controls and distributes budget to fund public and private research, thus incentivizing Italian talent to stay in Italy, carry out their ideas domestically therefore creating a win-win situation for all stakeholders. The current government is already reviewing the possible establishment of such an agency and I genuinely hope that this will be realized in the short-term future.

How challenging is market access in Italy?

Nowadays all our development projects are European based rather than Italian only, therefore the first institution we approach for market access is EMA. The Italian agency is significant for mature products already existing in the market, and of course for getting on the reimbursement list. Europe is dominated by a multitude of attitudes towards market access and pricing, and naturally,

the first countries to seek access into are the pharma hubs such as Germany, UK and the Scandinavian nations.

In the Italian and Spanish markets alike, we face the challenge of a decentralized national healthcare service. Market access is decided on a regional level which complicates market access and naturally lessens market attraction. I hope our current government will reconstruct this system soon, not only for the benefit of markets access, but more importantly for the Italian patients that are subject to unequal healthcare access depending on their region.

Italy has no pharma giant, however, has delivered numerous mid-sized champions such as Chiesi over the years. Given the current market conditions, is there room to see another Chiesi grow?

With the right innovative products and market access, any company has the potential to rise in Italy. That said, I don't believe that our specific business model is easily replicated. Besides being research-based, we strive towards globalization while maintaining a medium size. This paradoxical message is easily explained: we want to further focus on our here key segments—respiratory, neonatology and rare diseases—and maintain a top positioning in these segments on a global scale. To achieve the former, we have to focus our investments in those research areas and strive for maximizing quality rather than quantity. The idea is to be global whilst remaining as flexible and quality focused as a medium-sized company.

You've witnessed many eras of the pharma industry: the period of industrialization, the rise of the blockbusters and the trend towards internationalization. What do you identify as the new era of pharma?

E-Healthcare will possibly herald a new era in the pharmaceutical industry. Applications could very well enhance compliance and information transfer. In the respiratory segment for instance, electronic devices could significantly enhance information transfer in between patient and doctor, thus improving the therapeutic effect on the patient. E-devices could gather substantial information from patients that could possibly improve healthcare as a whole. That said, the challenge in this innovative technology is the question of ethical handling of the data. Clear rules and regulations have to be put in place ensuring this data is not misused in any way, and a solution to this challenge will not be easily found.

Looking to the future, where do you think Chiesi will be in five years' time?

In five years' time, we will have doubled our presence in the US market, will still be an important player in Europe and—if the political situation permits—will have further secured our presence in our emerging markets. We will possibly have expanded in other emerging markets that are currently opening up as well; Iran, for instance, could be a very interesting possibility.

With this development I expect our turnover to reach EUR two billion (USD 2.26 billion) within five years!

How do you ensure the brand Chiesi is carried abroad in the right way?

Corporate branding is one of the key reasons why we prefer establishing wholly-owned affiliates over collaborating with distributors. Affiliates ensure that our brand, our values and our products are portrayed and nurtured in the right way. Using distributors can work, however almost certainly our brand will not be represented as well as through one of our affiliates.

Could you give a final message to our readers?

In 2015, Chiesi celebrated 80 years of operations, with the third generation of the family controlling the business. Our mission is to be recognized as a research-focused international group, able to develop and commercialize innovative pharmaceutical solutions to improve the quality of human life. Our goal is to combine commitment and integrity, always operating in a socially and environmentally responsible way.

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