Interview: Dr. Massimo Di Martino – President & Managing Director, Abiogen Pharma, Italy



04.03.2016

Tags: Pharma, Pharmaceuticals, Italy, Abiogen, Massimo di Martino, Italian, Local Manufacturing, International Partnership, Domestic Manufacturing, Made in Italy, Interview, Insight, Executive, Exclusive, Free

The President and MD of Abiogen Pharma discusses his family company's recent milestones, the reasons for persisting with local manufacturing, and the benefits of international partnerships.

You created Abiogen back in 1997, following the acquisition of Istituto Gentili by MSD, in order to maintain your family's entrepreneurial tradition and build upon the legacy of your great-grandfather. When we last interviewed you back in 2009, you were busy bolstering the company's R&D capabilities and forging new partnerships. What would you say have been the main milestones and achievements over the intervening 7 years?

Since 2009, Abiogen has undergone transformative change to both the business model and our competitive positioning. We have registered an impressive growth trajectory both in capturing market share and in pure sales power. The manufacturing side of the business has developed especially well and I am proud to say that Abiogen has evolved into one of the top performance pharma companies in the country. Today we rank inside the top twenty players for volume and within the top 30 for value. This is a formidable achievement when you look back to where we've come from as a company. We have more than doubled our figures in the last fifteen years. Personally, I put theses successes down to a highly astute business strategy whereby we have focused in on a limited number of therapeutic areas from both a commercial and business

development perspective. One consequence is that some areas that we used to cater to last time we met have been phased out so that Abiogen can play specifically to its strengths.

The osteo-articular domain remains a core therapeutic area for us where we can demonstrate particular expertise and prowess. We have also been deepening our activities in the pain management sphere – encompassing acute and chronic, inflammatory and non-inflammatory type aliments – and this represents a key growth driver for the business. We have also been very busy devising new methodologies, working models and instruments for delivery and have been investing deeply in the professional development and up-skilling of our top and middle management cadres.

A key plank of your business model rests upon your maintenance of local manufacturing capabilities. This very much goes against the broader market tendencies of delocalization and yet you are managing to buck the trend. What's the rationale behind betting on an area that some other local players would appear to have given up on?

Right from the start, we considered in-house, in-country manufacturing to be a crucial part of our operations as we were keen to preside over the entire value chain. It was fundamental for us to possess ownership of each critical function: research and development, production, and commercialization of finished products. Because we remain fully in control of each of the links of that chain, we can then ensure the quality standard of the products that reach the end customer. This is essential because we have designated 'quality' as one of the key features of our competitive advantage and as a differentiating factor that marks us out from certain competitors. The manufacturing component of our operations is thus where a lot of the value creation is carried out.

Furthermore, Abiogen is proof that Italy can be competitive in pharmaceutical manufacturing. Back in 2010 we manufactured 18 million units, but last year I am proud to say that we surpassed the 35 million-unit mark. This year, our intention is to push the boundaries even further and hit 40 million units. Our success is down to a number of factors. Firstly we have been able to significantly raise the caliber of our manufacturing through our partnerships with multinationals and the knowledge and expertise that we have been able to capture during the course of our collaborations in developing new molecular formulations. The exposure to new ideas and technologies intrinsic to such ventures has enabled us to maintain our capacity for innovation and to raise our game in terms of optimizing the ways we conduct our manufacturing.

Secondly we have been able to think outside the box and use our production facilities to get the most out of our existing product portfolio. One area that we are becoming especially strong in is product 'repurposing'. We possess some pretty old, but tried and tested assets that can be greatly

improved upon through the development of fresh formulations, new indications and optimized delivery techniques. What we refer to as ‘innovation process’ has thus become an important driver of Abiogen’s revenues.

We understand that your production capabilities have now expanded to include third party manufacturing…

Absolutely. We are now manufacturing for Abiogen’s own portfolio, for our partners both inside Italy and abroad (where we have established license and distribution agreements) and also for third parties such as Sandoz, Teva and Mylan. In terms of the current split in volumes and workload 80 percent is produced for us and our partners and 20 percent for the third parties.

We have been very attentive to upgrading and updating our facilities when the possibility has arisen. Initially we had a single production line for liquid oral formulations but, over time, have expanded that to three. Lately we have been investing in incorporating sterile areas. We already have one fully functional zone within our production site, but are keen to create a completely new ‘island’ within our production plant so as to enable speedy FDA approval of our products when endeavoring to penetrate the US market. Our manufacturing facilities are not only accredited with European GMP certification, but also with equivalent awards covering Arabian Countries, Middle Eastern and North African countries, and even the South Korean market. Currently we are awaiting an inspection from the Russian federation as well. It’s certainly exciting times.

Tell us more about taking the “made in Italy brand” abroad. We understand your target is to increase the contribution of exports to overall company revenue from 3.5% today to 13.5% by 2020.

There are many unmet medical needs out in other geographies that even some of our popular, older assets could well respond to. Some would constitute new chemical entities in other markets outside of Italy so it makes sense to leverage this potential and make full use of our product portfolio. We are intending to really ramp up or export volumes in the coming months and years. Recently we have been busy preparing the groundwork and acquiring the requisite certification for the overseas regulatory authorities in the markets that we wish to target. We were able to secure authorization from the notoriously stringent South Korean regulator in only 9 months, which is quite a feat and testament to our high baseline on quality.

This is actually an area where Italy performs pretty well as seen from the fact that the country is the second biggest exporter of medicine in Europe. Why do you think that is?

I think it’s a natural consequence of the dramatic strictures imposed upon the Italian pharma industry in the early 2000s when both indigenous players and the in-country affiliates of the multinationals alike were subjected to a whole array of measures from price cuts to the claw-back to restricted market access. This actually obliged the Italian pharma industry to restructure prior to the global financial crisis and ironically ended up serving us well. Italian manufacturers were compelled to invest a lot in upgrading their facilities and in securing authorizations to penetrate new markets as it was necessary to look for revenues outside of the home country as a way to stabilize revenues and diversify risk. Meanwhile the delocalization of the 90s seems to have been thrown into doubt and many of the manufacturing jobs are being repatriated back across a wide variety of industries and sectors. From Abiogen’s own perspective, we can compete well against any Central or East European outfit on both cost and quality for third party manufacturing contract. Obviously no European facility can compete outright on price with the Asian basket of countries such as India and China, but there are still many advantages to be leveraged from manufacturing closer to home and Italian producers, with their well-earned reputation for quality, can exploit this reality.

How important is partnership-building as an enabler to your expansion into new markets abroad?

Abiogen has always exercised a very open door towards partnership building. Although we believe that our assets are solid, we are not yet convinced that our assets are innovative and exclusive enough to start opening affiliates abroad. Therefore, licensing-out is the most obvious mechanism for enabling us to reach out into new markets and to expand the footprint of our products. Licensing-in, on the other hand, brings us great opportunities to renew our portfolio and upgrade our manufacturing processes and know-how.

For licensing-in, the value of our brand reputation comes to the fore. Our strong track record and enduring capacity for innovation render us a partner of choice and result in the repeated renewal of our license agreements. For the licensing-out, we are making an effort to select young, dynamic and high performance SMEs that will consider our product important and collaborate from a level of equality rather than opting for supersize-entities where the relationship will be much more impersonal and the priority affording to our product weakened due to the sheer number of production lines that will be in operation. In short, our strategy is to seek out genuine partners with whom we can grow together, as opposed to opting for ventures where our power of negotiation is vastly reduced and the relationship rather asymmetrical

Abiogen has made R&D the core of its value-offering for over 50 years. How do you go about securing market access for your products under the prevailing economic climate in Italy?

Right now, we're at a certain juncture in the history of Italian healthcare policy where governance of public health is undergoing profound changes. New pathways are being explored to make the entire system more sustainable again. On top of the immense pressures that are putting the system under strain from a financing perspective, Italians also have to grapple with the additional difficulties of needing to secure access from regional systems that are not necessarily aligned with the national healthcare plan. This prolongs the time taken to reach market unnecessary and has resulted in some significant shifts in the market structure. Over the past 10 years, for example, multinational innovators have seen their profits being eroded by genericists in areas like chronic impairments as their patents expire while waiting for secure reimbursement authorization. As a reaction, most of the big pharma companies have been reducing the investments on those sorts of product lines, i.e. closing down some dedicated sales forces, and instead focusing their energies on a more limited number of high-price, high-impact innovations. At Abiogen, we have to find our own space and expand our presence by adjusting to the trends. When the average price of products in our portfolio lies below 4 euros, we really need to be chasing maximization of volume while never sacrificing our propensity for innovation.

What are your main priorities looking forwards?

As always, we will remain highly attentive to maintaining and improving the Abiogen brand. The number of Italian pharma manufacturers has decreased over time as the market has undergone consolidation and the 13 or so entities that remain are strong performers each with their own brand recognition so we need to do whatever it takes to ensure that we continue to be looked upon as a partner of choice. Our reputation is our foremost asset and we must never lose sight of that fact. Nor must we forget that brand reputation takes years to acquire, but can be lost in an instant. Maturing the Abiogen brand therefore counts as one of my upmost priorities.

We will also be pressing ahead with plans to diversify our offering by expanding into new geographies and establishing footholds in new markets. Right now a full 92 percent of our revenue comes from the home market and we seek to broaden the contribution derived from overseas.

Finally we will seek to retain our innovative edge and tread new paths. Right now, for example, Abiogen and the wider group finds itself at the forefront of new understanding surrounding vitamin D deficiency, the hormonal regulation of different mechanisms and the interrelationships with

pathologies even beyond osteoporosis. We plan to be busy shedding light on this rapidly developing field, to raise awareness amongst the medical community and come up with appropriate therapies, as our main strategic driver is to maintain the worldwide leadership in the cholecalciferol area.

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