Interview: James Lennertz – Group VP and GM (EUMEA), Biomarin, Ireland



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16.12.2016

Tags: Ireland, Biomarin, Biotech, Rare Diseases, Strategy

James Lennertz, Group VP and GM EUMEA for BioMarin, discusses the key highlights of the past few years for BioMarin, their unique positioning as a company offering innovative therapies for ultra-rare diseases, the main challenge he sees for BioMarin's international operations, and his priorities for the next few years.

James, as Group VP and GM EUMEA for BioMarin, you have a very broad remit. Can you give us an overview of your responsibilities?

2016 and beyond will see a number of very exciting milestones for the company. Firstly, the group is celebrating our 20th anniversary in 2017 after two decades of fantastic growth. The European organisation was founded in 2005 and our first product, Naglazyme, recently celebrated its tenth anniversary of being on the market, so it was doubly exciting for us here in Ireland.

Our Dublin office actually houses our Global Commercial Operations, which includes marketing, sales, customer service, legal and compliance functions – essentially, the infrastructure supporting our business in the European Union, Middle East and North Africa (EUMEA), which I oversee. The EUMEA region represents the 43 countries BioMarin operates in, including all 28 Eurozone countries, Russia, CIS countries, and territories and across the Middle East.

As you know, BioMarin is a highly innovative company developing therapies for unmet medical needs within the ultra-rare disease space – diseases that, for the most part, have fewer than 3,000

patients globally, so you can imagine that there is a huge amount of complexity involved in bringing these products to market.

What are your key priorities at the moment?

My core objective is to facilitate patient access to the innovative medicines that we provide. Currently, this would primarily be for the mucopolysaccharidosis (MPS) business through our products, Naglazyme® and Vimizim®, which would be BioMarin's main priorities at the moment. Both are enzyme replacement therapies for rare diseases.

Vimizim® has been our most successful product launch to date, reaching $225 million in sales in 2014. This year, sales are expected in the range of $340 to $360 million. We are also working to expand the number of markets in which Vimizim® is available. This year alone, we have added six new markets, so I would say progress has been steady and promising.

In the past year, we have also launched Kuvan® in Europe. We recently acquired the rights to market the therapy from Merck Serono, having marketed it in the United States for almost a decade. That has been another nice opportunity for us.

As an innovative biotech company, R&D is naturally critical really important to us. At any given point in time, BioMarin would usually have about five new products in the pipeline, so we are always preparing to launch products for the next year. Right now, we have two new drug applications (NDAs) in submission, for which we are working our way through the regulatory processes in Europe and the US.

Early on in BioMarin's development, we had a number of partnerships with other companies, with Genzyme being the most notable, but that was primarily before we had the commercial presence we do now. Most of the science behind our products now is in-house, or we have licensed the science very early in the development process.

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Given that BioMarin operates in the ultra-rare disease space, what implications does that have in terms of BioMarin's market access and commercialization strategy?

The ultra-rare disease space in which BioMarin operates is unique because our treatment areas are so specialized. In most countries, there would typically only be a dozen or so centers that cater to our patient populations. This means that we do not require the large salesforces that other pharma companies might need. BioMarin is also unique in another sense: our products primarily only have

one indication.

Given that the EUMEA region is chiefly run through single-payer systems, our work is fundamentally about building constructive engagement with the government in the countries that we are present in. Everything we do around access would be government-focused. As a clear illustration, basically all the EUMEA governments now undertake health technology assessments (HTAs) as part of their pricing and reimbursement processes. We take that extremely seriously. We ensure that we engage in dialogue with the government bodies as early as possible, while we are still in the development phase. This gives us welcome input and direction in terms of what they expect to see from us throughout the process.

Outside of the market access piece, BioMarin also works hand-in-hand with national healthcare systems and the governments to fill in gaps within the healthcare infrastructure, for instance, delays in diagnosis. In some markets, there may not even be laboratories available to do the genetic testing to assess whether the patients are appropriate candidates for treatment. We therefore come in to support the local healthcare systems and provide solutions in terms of diagnosis where we can.

We also engage extensively with key opinion leaders (KOLs) as well as patient associations. Ultimately, we want to work in the most positive way we can in order to engage with all the stakeholders, from the government to academic to research to patient groups, to make sure that patients get access to our innovative treatments.

What would you say is the biggest challenge for BioMarin's international operations?

My biggest concern is to make sure we work effectively to communicate the value of the treatments that we bring to patients. There is always the risk that the single payer, or the government, will look at the cost of treatment for an individual patient, and deem it too expensive to fund. What they need to understand is that our focus is on highly unmet medical needs and ultra-rare diseases. Orphan diseases are defined by patient populations of fewer than 200,000 patients globally; the subset in which we work, ultra-orphan diseases, typically have fewer than 3,000. This means that the overall cost burden to any individual payer system is really small. For most governments, it would be less than two percent of overall healthcare expenditures. If we are not careful, however, we could end up being lumped into larger disease categories and our patients being overlooked.

The communication of this message can be complicated but it is something we are constantly working on. We want our products to be either first-in-class or best-in-class – this needs to be

effectively and continuously communicated. In our HTA submissions, for instance, we work to ensure that we communicate the value of our products and really differentiate ourselves, through our commitment to unmet medical needs.

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Within the 43 markets that you oversee, where would the growth drivers be?

The primary markets are naturally the larger European markets: France, Germany and the UK; these would usually be the first markets we launch products in. That said, most of the markets in Europe are reasonably well-harmonized. The payer reimbursement systems are different but having the harmonization in regulatory and licensing is itself a huge advantage. European markets are also much more attuned to collecting and monitoring long-term outcome patient data. They want patients to be enrolled in registries and to see assessments on their individual recovery progress to make sure they are responding to treatments as hoped. There is a lot of effort expended in ensuring that patients see the right outcomes, which is very positive.

Again, BioMarin is rather unique in that we will enter smaller markets that may only have two to three patients. These may be difficult markets to enter – and the complexity of entering a market with just a few patients may in fact be on par with entering a large market! But ultimately patients want to be treated regardless of their location, and we take that very serious. Often there is simply no alternative to the products that we market, so we need to be present in all markets regardless of size.

Ireland is a good exampleof a small, but important market. With a population of just 4.7 million, it is a relatively smaller market but Naglazyme® is available and treating patients successfully. We are also in discussion with the reimbursement authority to expand access to Kuvan®, and to allow access to Vimizim®. There have been some challenges in terms of recognizing the importance of patients that need the ultra-rare treatments. That recognition is not fully built within the Irish system at the moment but we are in the midst of fairly positive conversations with the government, and we are very optimistic.

Speaking of which, can you outline BioMarin’s Irish operations?

We established our manufacturing operations in Cork in 2011, which is our second manufacturing facility globally. For the past few years, we have focused on transferring technology from our U.S. San Rafael campus over to the Cork facility. There has been a lot of expansion; the site now has around 300 full-time and 60 part-time employees. The Irish government has done a fantastic job at

promoting foreign direct investment (FDI), as I am sure you have been repeatedly told! We actually took over an incubator technology site that had been developed precisely for such an investment, which was one of the main attractions that brought BioMarin to Ireland in the first place.

In the five years I have been here alone, I have seen the pharma and biopharma industry develop very nicely. Ireland has really done a fantastic job in attracting people to the life sciences industry and I must commend them.

Given that spate of recent investment as you highlighted, has BioMarin faced any difficulty recruiting the staff that it needs?

As a company, our staff are motivated because of the unique areas that we work in. Talk to any of our employees and they are very proud to be working in areas of such rare disease and high unmet medical need. That is a big attraction. If we look at employee surveys, a big theme is that people are on a mission and they believe in this. That is a big attraction.

You have been with BioMarin for nearly seven years now, after spending time at Roche and Quintiles. What do you find most exciting about your current position?

I like the diversity of countries that we are dealing with; the different populations and cultures make my work really exciting and that was one of the main attractions that drew me to the job. The fact that we are working to fulfill such rare unmet medical needs, too, means that BioMarin is such a dynamic environment to work in. Not only is our work extremely meaningful, it is also a lot of fun and we truly believe in the value behind what we are doing every day. This really makes a difference.

As I have gotten to know the company better and better in the past seven years, I have realized that people are genuinely proud to be here. We want to cultivate and preserve a uniquely BioMarin culture; having an environment in which people thrive is really important to us, and to me personally.

Looking forward, what would you want to accomplish in the next three to five years?

In that time, I would like BioMarin to have launched at least two more products in EUMEA. Our turnover in 2016 is expected to be USD 1.1bn to USD 1.15 billion. Organic growth has been really good for BioMarin, so I want to see that continue, and to have our R&D pipeline remain robust. Bringing innovative medicines to the market for serious unmet medical needs – that is what we stand for, and I want to see us continue to do that.

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