

Interview: Matt Moran - Director, BioPharmaChem, Ireland



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With nearly €4 billion of capital investment in large molecule manufacturing underway, Ireland's strategy to become a premier destination for biologics FDI has proven to be successful, according to BioPharmaChem Ireland director Matt Moran. Yet, Ireland today is much more than a manufacturing hub, and is well on its way to being a true innovative center of excellence for the global pharmaceutical industry as a whole.

It's been nearly four years since you were last interviewed by PharmaBoardroom -what would you highlight as the most significant changes in the Irish pharma industry since then?

The primary change has been the explosion of investment within the biologics segment of the industry. We estimate that just short of €4 billion of capital investment projects are under way at present. These are being carried out by both companies with existing manufacturing facilities in Ireland such as Eli Lilly, Pfizer, BMS and MSD, as well as a wave of newer biotech companies establishing very significant facilities in Ireland for the first time, such as Regeneron and Alexion. All these companies are investing in biologics manufacturing capabilities here, while Eli Lilly is expanding their small molecule operations alongside their large molecule.

As the first of these new facilities have come online we have also seen a resurgence in export values, following a dip we had seen alongside several significant patent expiries from 2011 through 2014. In 2015, Ireland's total export value of pharmaceuticals was up to €51 billion and €64 billion if you include chemical products. These figures represent roughly half the value of all national goods exported from Ireland. With more of these new facilities slated to come online in the next two or three years, which will all be manufacturing relatively high value products, some orphan drugs, we expect to see a significant increase in Ireland's total pharmaceutical value. With that, we will see the balance of large versus small molecule production in Ireland shift towards larger molecules over the coming years.

Within the installed sector, which is still predominantly small molecule, we have seen significant changes take place driven by competitive pressures. As an association we ran a lot of activities to promote improvements in operating excellence, working with both Enterprise Ireland and a Toyota manufacturing facility in north Wales; we essentially arranged group visits and workshops to train the Irish pharma sector in the best practices from other industries like the automotive industry. This had a substantial impact and unit operating costs have fallen significantly for many facilities; in fact, one of Pfizer's Cork facilities was slated for closure, but they were able to improve efficiency to the point that that closure has been postponed. That said, Ireland will never be a low cost country, but we are efficient and excellent; in 30 years the FDA has issued only one warning to any facility in Ireland, and such a track record in compliance is representative of Irish pharma's commitment to quality.

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You've mentioned a few names already; could you give us a brief overview of the most significant investments that have recently been made?

Regeneron's new facility is noteworthy for a few reasons, first being that this drug substance plant is being built in what was formerly a Dell computer fabrication facility. Dell withdrew their operations from this facility in Limerick and relocated to eastern Europe, and Regeneron bought the site and effectively dropped their biotech facility into the shell of this former computer plant. It's also noteworthy because when finished this will be the largest large molecule drug substance manufacturing facility in Europe.

However, Regeneron will likely only hold this title for a short time as BMS will be building a massive USD 900 million, large molecule facility in Cruiserath over the next few years. Mallinckrodt and Alexion are also building large molecule facilities in Cruiserath, so we will be seeing the

development of a key cluster in that Dublin suburb.

Eli Lilly is also constructing their second large molecule facility at their Kinsale campus in Cork, and they also have a small molecule site there; it is interesting to see that they have actually transferred some of their talent in operations from the small into the large molecule facilities there. They are also making some exiting investments on the R&D side, and are in fact developing what will be their global center of excellence for continuous API manufacturing there in Kinsale. This is a very significant step for the industry, as companies have been looking at switching from batch type to continuous manufacturing processes for a number of years, and its exiting to see an industry leader like Eli Lilly deciding to take one of their first big steps in that direction here in Ireland.

Pfizer's Grange Castle facility is worthy of mention as it is also huge in scope, in both development and manufacturing, and is a major recipient of investment both in terms of continuous improvement and R&D funding. From an academic or innovation standpoint, it's also very interesting because Pfizer is working directly with Science Foundation Ireland on some more basic areas of research out at Grange Castle, and is of course one of the stronger participants in the various academic-industry research collaborations taking place in Ireland.

Irish policymakers and industry stakeholders have been working to transition Ireland from being a “manufacturing hub” to more of an “innovative center of excellence” for several years.” Has this been achieved, and to what extent?

That has not been fully achieved yet, but much of that journey is now behind us. Our first goal in this regard was to advocate for development plus manufacturing investments, or “D+M”, and looking at the current installed sector and the investments now underway, it seems that idea has fully taken root; it's impossible to build a large scale biologics facility without significant resources being invested in product and process development onsite.

From the other side, Irish academia has developed significant and globally relevant research infrastructure and capabilities in the life sciences, and for the most part research agendas are well aligned with industry priorities. Through organizations such as the Synthesis and Solid State Pharmaceutical Center (SSPC) and National Institute for Bioprocessing Research and Training (NIBRT), Irish academics now collaborate closely with life science innovators on a wide range of research topics, with a significant portion of funding coming from the private sector. Moreover, these collaborations have helped to create an academic environment that is now helping to provide students and graduates with the skills needed to drive the further development of the industry.

Finally, the pharma industry itself has driven the development of a strong and vibrant array of service providers, including a sophisticated engineering sector and an array of experienced and skilled consultants and contractors.

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What are the next steps for Ireland to take along the path towards the drug discovery end of the development cycle?

The ultimate goal has long been to move back down the development cycle towards the moment of drug discovery, which we will do eventually.

There are several areas however that we have identified where there is a significant opportunity for Ireland in the short to medium term. First, it is a priority to expanding and maintaining the innovative edge of our sector on the manufacturing side, and at present we see this mostly in the biotech space with the new state-of-the-art facilities coming online, as well as the research and technology development taking place around NIBRT and companies like APC. However, we also think it is very important to sustain and enhance the small molecule segment of the industry because we see the future of the sector in both small and large molecules. This is where we are glad to see investments such as that Eli Lilly is currently making in continuous manufacturing for APIs at their Kinsale site.

Second, given Ireland's robust technology and medical technology industries alongside the pharmaceutical industry, as a community we have felt that significant opportunities lie in the convergence of these sectors. This is particularly true when you look at how innovative therapeutics today are being administered to patients often via devices, and the increasing pace at which such devices feature e-health or telemedicine type features. We recently hosted an event in collaboration with the Irish Medical Device Association (IMDA) focusing on opportunities in this area, and such convergence areas have been identified as research priorities by Irish academic institutions as well.

We also see a potential role for Ireland in the area of advanced therapeutics. Ireland already has a licensed stem cell manufacturing center in Galway at the Regenerative Medicine Institute, and while its very early days yet perhaps Ireland will be able to take a stronger leadership position in this area.

While pursuing such areas of opportunity, it is essential that as an industry we maintain the existing manufacturing base because this is where the industry's value creation and employment

really lie. We understand that in many cases products that are developed and manufactured here will move to lower cost manufacturing locations when their patents expire, but that being said we do have a substantial generic manufacturing base with Teva, Mylan and Allergan all running large generics manufacturing operations here. To retain some of these older products, it is essential that Irish facilities continue to enhance our efficiency and operating excellence to ensure we remain competitive in terms of price. Moreover, we continue to attract new investments and with them, new products.

To wrap up, what are the main competitive factors Ireland needs to further advance and sustain its ability to attract such large scale investments, as well as more investments in the R&D space?

Our primary competitive advantage is still our best in class tax incentive package. It features highly competitive corporate tax rates, along with strong R&D tax credits and a new “Knowledge Development Box,” reducing the tax burden on income generated from patents developed in Ireland. This has been core to Ireland’s strategy for many years, and will continue to be. At the same time, as an evolved cluster, Ireland has significant expertise and experience in areas like regulatory compliance, supply chain management, and other key functions that gives us a strong advantage.

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Ireland’s biggest advantage perhaps lies in the availability and sustainable supply of skilled professionals to the industry. Talent recruitment is a major challenge for the industry globally and as a small and interconnected country Ireland has been able to take the steps needed to ensure a strong and sustainable supply of skilled workers to the pharmaceutical industry. NIBRT has played a key role in that regard, alongside our universities and other academic institutions who offer degree programs that are well aligned with industry needs, and have ensured graduate students and PhD candidates have strong exposure to the pharmaceutical industry, and are thus well prepared to be engaged by the sector.

In the coming years, it is essential that we are always aware of the offerings of other countries we are competing with for investments, and continue to focus on talent and education to ensure that our offering continues to be the most comprehensive package. Moreover, it’s essential that the industry, led by the IDA, continues to ensure that the overall offering is well known and promoted internationally, and that our reputation as the best-in-class destination for pharmaceutical FDI

investment remains secure.

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