

Interview with Padraig Somers, General Manager, Helsinn Birex

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Mr. Somers, can you please introduce us to the Helsinn Group and its unique in-licensing model?

Helsinn is a Swiss-based, private company owned by the Braglia family. The Braglias have been in the pharmaceutical business since the late 1930's. The current company, incorporated as Helsinn, is about 35 years old, operates from Lugano in Switzerland, and has approximately 500 employees worldwide. 160 of these employees are based here in Ireland. The company also has 40 people in the US, and the remainder of our staff is split between our HQ in Lugano and our API facility in Biasca.

Our business model aims to in-license products that are partly developed—typically drugs that are at Phase II and have worldwide distribution rights, or else rights for distribution over large territories such as the US, Europe or Japan—and bring them to commercialization. Our commercial strategy is to sell our finished products through exclusive distributors, who typically will market the drugs under their own name.

Our portfolio is a mixture of branded patented and off-patent medicines. Across the board, our strategy is to offer great products that are effective and meet the highest standards of quality. We have a particular interest in cancer-supportive care products, as we feel that this is an area where we have a significant amount of expertise.

We have partnerships with many of the major pharmaceutical companies, such as Merck and Eisai, but also with many mid-sized companies. One of our unique competencies as a company is identifying the right partner in a specific market, based on their portfolio and how they share our

vision.

Incorporated in Ireland, Helsinn Birex Pharmaceuticals is the drug product supply and development center for solid dose products for the entire Helsinn group. All of the commercial drug products sold by Helsinn to our network of distributors and exclusive partners worldwide are managed by the team based at this facility. We serve over 70 countries from Ireland.

How successful has the Group's strategy been in today's environment?

It has held up well, despite the fact that governments are struggling to fund healthcare in many countries.

Our revenues have continued to grow year-on-year and we are very proud of the fact that we are an independent group that is not reliant on external financing. Helsinn has been carefully managed since its inception, so that the burden of debt has never been a risk to our operations.

Our philosophy limits what we can do in terms of up-scaling the business, but it allows the company to grow organically through reinvestment in product development. Our decisions are driven by technology, capability and volume. Because we have four contrasting yet complementary areas of competency across our four operating facilities, our decision making process is very much a team effort, involving representatives from each of our operations.

It is good to be a relatively small company that 'punches above its weight' in a global business sector. We have a turnover of roughly €300m per year, which I believe is quite impressive considering the size of our organization.

In 2009, Helsinn invested €13m in an R&D Center of Excellence in Ireland. Brian Lenihan T.D., the former Minister for Finance, commented at the opening ceremony, "This investment is a further endorsement of Ireland as a prime location for highly innovative companies carrying out key strategic activities." Can you elaborate on why Helsinn chose Ireland for this commitment?

Historically, Helsinn separated its drug product supply activities from its R&D activities, because sometimes mixing the two doesn't offer the most optimal solution due to competing priorities. However, over time, as we fulfilled our mandate here in Ireland—which had evolved from local manufacturing to managing the overall supply chain, as well as assuming other activities such as Regulatory Affairs and Pharmacovigilance processes—the Group's perception of our capabilities evolved also. We have been able to fully realize the potential of the workforce here to be creative and help solve problems in development as well as supply. We also had excellent support from the

Government R&D tax credits scheme as well as IDA, who had abundant experience in helping other companies to shift R&D capabilities to Ireland .

R&D can be quite risky, as one does not know what the outcome will be—particularly given the nature of our business model, wherein we acquire rights to new medicines before they have been approved. The group needed to ensure a secure of supply of development products across our operations, and we needed an agile supply chain in case something unforeseeable happened during development. It was our objective to achieve this agility by bringing these activities in-house to support two very significant projects in our pipeline in 2009 that justified the investment in new capabilities here in Ireland.

Our board of directors is quite happy with how things have developed here thus far, and have great confidence in the competencies of our staff and in the ability of the Irish operation to work as part of the Group team and respond to new challenges. We are now preparing to make an NDA submission in the US and EU for the first of the pipeline products I mentioned, which is a very important milestone for the company and Helsinn Group!

What is the best management approach to take, when one carries this kind of responsibility within an organization?

First and foremost, you need to ensure you have good people who are aligned to our goals , and we certainly do. We try to develop people’s capabilities and competencies while broadening their understanding of the business we are involved in. We believe that customer service is our leading performance indicator both for product supply and our development activities. We are always focused on ensuring that we work hard to bring satisfaction to our customers, and that ethic permeates throughout the company.

There is also a strong emphasis on quality and compliance, as well as encouraging and facilitating communication across all of our teams so that we take a unified approach to new challenges.

What are the key challenges for your organization today?

Our primary challenge is to serve the demands of our customers. That is our mandate. Our duty is to provide customers with a high level of service and help them to find solutions to problems of supply, service or cost containment.

Recognizing the pressures on our partners in terms of price, Helsinn also faces a challenge in keeping costs down. The Helsinn pricing model incorporates our partner’s pricing constraints, and

obliges us to remain competitive against our competitors. We routinely benchmark our costs against CMOs, so that we know where we stand in the broader scheme of things.

Key areas of competitive advantage in which we also look to excel are compliance and quality.

If cost is an issue, why not move this operation to India?

Talent, creativity, team working skills and knowhow are some of the definitive benefits of operating in Ireland which are difficult to replicate. We also have to take into account the clustering effect—the broad access to support services, pharmaceutical skills and talent we see in a concentrated pharma hub like Ireland.

Are you fit at this site for the future of the company?

From what we know today we are, but future-proofing requires ongoing evaluation and planning. I believe one of the things we do well at Helsinn is strategic planning: each year we create an rolling ten year plan for the group. We are always very financially focused, and maintain a balance between our revenues and our ambitions. Helsinn Birex strives to be aligned with these ambitions and relevant to realizing them. It is worth noting that Ireland continues to attract innovative life science companies to set up operations here thanks to its attractive taxation environment and availability of high quality staff and support services which is relevant to Helsinn's future success also.

Do you have a final message for our readers?

I have worked in Ireland for 30 years and witnessed a lot of change in the sector. Multinational companies have gradually moved more and more value-added activities to this market. We have an excellent skill set in the country, and a world-class compliance record that is becoming an increasingly important competitive advantage.

The industry is still evolving to adapt to the new challenges we face on a global level. If Ireland will continue to be flexible, and open to adapting to the new reality we will continue to be competitive and we will continue to be successful.

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